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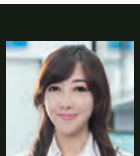
the business of Bio & Health Sciences
ASIA EDITION

Volume 20 | Issue 3 | March 2025

MITIGATING PATENT CLIFF FALLOUT

Trump's Executive Order Impinges WHO Ops - **28**



"Biotech sector in Taiwan moves fast, making it easier to pivot and innovate"
- Vivian Ling, CEO & Chief R&D Officer, Caliway Biopharmaceuticals, Taiwan - **30**

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Acknowledgement/ Feedback

Thank you BioSpectrum Asia for publishing Advarra's article on clinical trial management in the February 2025 edition.

- Lisa, USA

Thank you for including comments by Parexel in BioSpectrum Asia's cover story on AI-driven drug discovery.

- Emma, UK

We saw the wonderful interview with Docquity published in BioSpectrum's February 2025 edition! Thank you so much for the generous feature.

- Theresa, Singapore

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Letter from Publisher

Ravindra Boratkar
Publisher &
Managing Editor,
MD, MM Activ Sci-Tech
Communications Pvt. Ltd.

Dear Readers,

The pharmaceutical industry is predicted to lose over $236 billion in revenue by 2030 as a result of the looming "patent cliff," which will result in the loss of exclusivity for 190 drugs, including 69 blockbusters. According to a Deloitte estimate, this amounts to roughly 46 per cent of sales at risk, for the top 10 pharmaceutical companies over the next 10 years. A survey by Dimension Market Research estimates that the monoclonal antibodies (mAbs) market is worth $279.8 billion and will grow to $804 billion by 2033.

The industry is up against several challenges as the patents on many of these valuable drugs are about to expire. Our team has looked at 11 blockbuster mAbs whose patents are set to expire between 2025 and 2030 for the lead story. These expirations will significantly disrupt the market and the revenue streams of some of the largest pharmaceutical companies. They are looking at a number of tactics, such as partnerships, mergers and acquisitions, and patent thickets, to lessen the revenue loss due to patent expiry of these blockbuster drugs.

Given that the US is the World Health Organization's (WHO) greatest donor, providing approximately 18 per cent of its budget, the announcement of the US's exit from the organisation raises serious concerns. The WHO is now suddenly hit with a significant financial shortfall as a result of this decision. In an article, our correspondent discusses how the organisation and its member states plan to quickly solve this 'spanner in the works' and how it could change the global leadership scene in health governance.

Antibody-Drug Conjugates (ADCs) have emerged as a major therapeutic approach creating new opportunities for a range of cancer treatments. The development of ADCs has advanced significantly in the biopharmaceutical sector in the last five years, while eight of the 14 ADCs have obtained regulatory approval. We have experts analysing how ADCs have the potential to transform targeted medicine and give patients new hope with further development and wise funding.

2025 marks the 10th anniversary of the International Day of Women and Girls in Science (IDWGS) (observed on February 11) and the 30th anniversary of the Beijing Declaration and Platform for Action, two significant milestones in the global effort to promote gender equality and women's empowerment. Recognising the importance of gender inclusivity, Viet Nam has taken major policy steps to empower female researchers and entrepreneurs. By investing in education, policy reforms, and celebrating the achievements of women scientists, an expert in an article says that Viet Nam is setting a global example for inclusive development.

International Women's Day (IWD) (celebrated on March 8) has been around for over a hundred years, as have many of the issues still impacting women's advancement. Since 1911, IWD belongs to all who care about women's equality. Focusing on the need to Accelerate Action (theme for IWD 2025) emphasises the importance of taking swift and decisive steps to achieve gender equality. Talking about the status of women in the Australian life sciences space, an industry veteran calls for action for better health, booming businesses and a stronger economy.

I am sure you will find this edition a great read.

Thanks & Regards,

Ravindra Boratkar
Publisher & Managing Editor

COVER 20

Mitigating PATENT CLIFF Fallout

Monoclonal antibodies (mAbs) represent a $279.8 billion market, projected to reach $804 billion by 2033, according to a report from Dimension Market Research. With patents for many of these valuable drugs set to expire in the coming years, the industry faces significant challenges. In this story, we examine 11 blockbuster mAbs whose patents will expire between 2025 and 2030. These expirations, affecting some of pharma's biggest players, will have a major impact on the market and their revenue streams.

Alice Zeng,
Senior Consultant,
Clarivate

US vs WHO

Speaking With

ADCs

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Women's Day

REGULARS

GRAPPLING WITH CORRUPTION & SLIPPING QUALITY

Dr Milind Kokje
Chief Editor
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Healthcare, medical and pharmaceutical sectors are in deep doldrums in China due to the slipping quality of generic drugs. The other issue is related to corruption in healthcare systems and the actions initiated by authorities to stop it. Interestingly, both issues have come to the fore due to public outrage which is rare to be seen in China. Anything that affects the pharma sector in China always has a greater impact due to its huge pharma market size which is second after the US with nearly $240 billion in sales in 2023.

China launched a centralised drug procurement programme in the last six years, whereby drugs are included in the state-run healthcare insurance and the prices are negotiated on a national level. No doubt, this system brought down the cost of drugs, in some cases even by half as domestically produced generics replaced off-patent drugs of prominent pharma companies which were imported. However, doubts about the efficacy of those drugs have been expressed since then. In the recent round of purchases, the prices of some drugs were reduced by even 70 per cent.

But the issue came to the fore decisively when around mid-January, 20 prominent medical professionals from Shanghai openly complained about the efficacy of drugs despite increasing the dosage, calling it a serious safety risk. An example that was cited was serious as even anesthesia was not found to be working to its desired effect with cases reported of patients waking up during surgeries.

Foreign companies are now talking about discrimination against them in the purchasing process. Foreign brands bid for supplying some off-patent drugs, but none of them were selected with health authorities opting for local generics. But now the same generics have come under doubt and scrutiny. Patients are allowed to buy foreign medicines online, but they are not covered under health insurance. Doctors and companies are opining that the procurement system should not look at the low price alone as safety, efficacy and clinical results are also important.

While facing the issue of quality and efficacy for home-produced generics, another issue that has rocked the healthcare sector is corruption. As a part of its ongoing anti-corruption campaign in the healthcare sector, China's State Administration for Market Regulation (SAMR) has issued compliance guidelines for Pharmaceutical Corporations on the Prevention of Commercial Bribery to guide the companies on the management of anti-corruption risk. Through the guidelines, the primary responsibility for managing anti-corruption risk is put on corporations.

Recent reports said that over 350 prominent figures in China's healthcare sector, including senior health officials, hospital directors, top academics, and pharmaceutical company executives, were punished in the previous year's anti-corruption campaign. National Supervisory Commission (NSC), China's top anti-corruption organisation, thoroughly investigated cases in which healthcare professionals exploited medical services and misused insurance funds. Strong actions against unethical practices in the industry like kickbacks and bribes were also taken.

The NSC had submitted in December, a report to China's top legislative body, standing committee of the National People's Congress, showing clearly how the problem was widespread. In all 52,000 medical corruption cases were filed in the country and 40,000 people were punished while 2634 referred for prosecution last year. The administration has intensified its efforts against corruption in the healthcare field for the last two years, due to public outrage over unethical practices in the sector.

While the anti-corruption actions and campaigns are on, the efficacy of the generic drugs is being tested. Its results and subsequent actions, if any, by the authorities will be known in due course. One positive highlight is that the serious issues impacting the industries and patients have come to the fore and are highlighted. BS

Korea announces Top 10 Promising Biotechnologies of 2025

The Ministry of Science and ICT and the Korea Research Institute of Bioscience and Biotechnology have announced the "Top 10 Promising Biotechnologies of 2025", presenting a vision for the future of life sciences. The Promising Biotechnologies are expected to be realised technologically or industrially within the next 5 to 10 years and are anticipated to have significant technological and industrial ripple effects beyond the field of advanced biotechnology. This year's Top 10 Promising Biotechnologies include the human immunome, multi-cancer early detection, RNA structurome, AI-designed gene editors, Anti-ageing antibodies, Molecular glue, motile living biobots, Digital artificial organs, Healthcare digital twin and bio foundation models. Additionally, the government plans to analyse recent bio R&D initiatives to identify gaps related to promising technologies and develop new national projects to nurture these fields. With the anticipated launch of the National Bio Committee, a collaborative effort between the public and private sectors to advance bio research, the government aims to strengthen end-to-end support for biotechnologies, from systematic development to commercialisation.

Australia releases National Framework for Genomics in Cancer Control

The Australian government has released Cancer Australia's National Framework for Genomics in Cancer Control, marking a significant step toward improved cancer outcomes through personalised cancer care. It has the potential to deliver vital insights into the way gene mutations drive cancer behaviour. The role of genomics in cancer prevention, screening, diagnosis and treatment is expanding rapidly, with broad implications for patient care. The Framework will guide health professionals, researchers, health services, and policymakers in safely and effectively incorporating genomics into cancer care. Cancer Australia's vision is to make genomics a standard part of clinical practice, ensuring high-quality, culturally safe cancer care is accessible for all Australians. The Framework sets out specific goals for the future of genomics-informed cancer care and lays out actions for implementation across the cancer care continuum and the broader health system. A National Framework for Genomics in Cancer Control was identified as a priority action under the Australian Cancer Plan. The Framework provides a policy basis for equitable access to genomic medicine for all Australians affected by cancer.

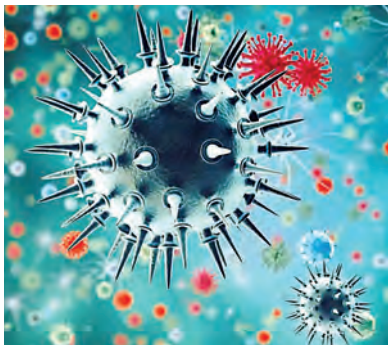
India and Indonesia ink MoU in the field of traditional medicine

The Prime Minister of India, Narendra Modi and the President of Indonesia, Prabowo Subianto witnessed the Exchange of Memorandum of Understanding (MoU) between India and Indonesia. One of the MoU exchanged between India and Indonesia is in the Field of Traditional Medicine Quality Assurance between Pharmacopoeia Commission for Indian Medicine & Homeopathy, Ministry of Ayush and Indonesian Food and Drug Authority. This collaboration is intended to play a crucial role in ensuring the safety, efficacy, and quality of traditional medicines, setting the stage for a more integrated and scientifically-regulated approach to this valuable healthcare system. This strategic partnership focuses on fostering collaboration in traditional medicine quality assurance, with both parties committing to various forms of cooperation. Key provisions of the MoU include exchange of information and expertise

on regulatory provisions for traditional medicine; capacity-building initiatives such as seminars, workshops, and training programmes aimed at enhancing professional knowledge and skills; technical visits to facilitate familiarisation with the regulatory processes of both countries.

Singapore to establish Communicable Diseases Agency

The Ministry of Health (MOH) in Singapore will establish a new Statutory Board, the Communicable Diseases Agency (CDA), on April 1, 2025. CDA will consolidate public health functions for the detection, prevention and control of infectious diseases, previously distributed under MOH headquarters, the Health Promotion Board, and National Centre for Infectious Diseases (NCID). It will focus on preventing disease spread through public education, vaccination policies, and infection prevention and control measures;



leading and coordinating public health preparedness efforts, working with various stakeholders to build sectoral readiness against infectious disease crises, and to safeguard national interests such as vaccine and therapeutics development and access. CDA will also strengthen surveillance capabilities, including exploring the use of new modalities of surveillance to supplement traditional surveillance approaches, and explore data analytics and artificial intelligence to enhance its ability to make sense of large volumes of data. The formation of CDA will allow the government to quickly respond to disease outbreaks as one concerted public health effort, and play a pivotal role in safeguarding Singapore from infectious disease threats.

New Zealand announces Public Health Surveillance Strategy

New Zealand's first Public Health Surveillance Strategy has been announced by the Ministry of Health (MoH) on how to gather and coordinate public health information to better protect New Zealanders against threats to their health and wellbeing. The collection and effective use of public health information has advanced substantially in recent years and is already being used across the health system to improve services for New Zealanders in many areas. Opportunities for further strengthening public health surveillance include using better population specific data to ensure informed and well-targeted health policy decisions; and improved surveillance of public health threats beyond communicable diseases, such as antibiotic prescription rates, housing and water quality. Much of this data is already available, but greater coordination can better generate insights to inform health policy and services.

UAE introduces National Licensing Platform for health professionals

The Ministry of Health and Prevention (MoHAP) in the United Arab Emirates (UAE) has launched a National Licensing Platform, an innovative initiative aimed at standardising the licensing of health professionals. The unified platform, launched in collaboration and integration with all health authorities in the country, features an entrepreneurial, innovative, and integrated business model developed in collaboration with its strategic partners. It offers all licensing services for health professionals, reducing effort and time for users while improving their experience. From standardising to streamlining licensing procedures and requirements, the platform shortens the time needed to obtain licenses. This initiative is part of the Ministry's ongoing efforts to comprehensively develop the regulation of the health sector, enhancing its competitiveness, flexibility, and effectiveness. The national platform targets medical professionals, qualified specialised personnel in the healthcare sector, including doctors, nurses, health technicians, pharmacists, allied medical field specialists, and technical staff.

Adani injects Rs 6000 Cr to build super-specialty hospitals and medical colleges in India

Gautam Adani, Chairman of the Adani Group, has announced the launch of Adani Health City (AHC) integrated health campuses, to be implemented through the Group's not-for-profit healthcare arm. The Adani family will fully meet the cost of bringing affordable, world-class medical care and medical education to people from all strata of society pan India. The family will donate upwards of Rs 6,000 crore to build the first two of these integrated health campuses in Ahmedabad and Mumbai. Gautam Adani has plans for more such integrated Adani Health Cities across India. Each of these integrated AHC campuses will comprise 1,000-bed multi-super-specialty hospitals, medical colleges with an annual intake of 150 undergraduates, 80+ residents and 40+ fellows, step-down and transitional care facilities, and cutting-edge research facilities. The Adani Group has engaged USA's Mayo Clinic Global Consulting (Mayo Clinic) to provide strategic advice on organisational objectives and clinical practices at these establishments

Bain Capital to acquire Mitsubishi Tanabe Pharma for $3.3 B

Bain Capital, a leading global private investment firm, has signed a definitive agreement to acquire Mitsubishi Tanabe Pharma Corporation (MTPC) in a carve-out transaction from Mitsubishi Chemical Group Corporation. The investment is being led by Bain Capital's Private Equity teams in Asia and North America together with the firm's Life Sciences team and values the business at approximately 510 billion JPY ($3.3 billion). As an independent company, Tanabe Pharma will continue to build on its legacy of medical innovation while developing new opportunities for growth through business development, licensing activities, enhanced R&D productivity, commercialisation and strategic acquisitions. Bain Capital's global Healthcare platform has deep experience supporting the growth and innovation of global pharmaceutical companies including Aiolos Bio (now part of GSK), Avistone Pharmaceuticals, Cardurion Pharmaceuticals, Cerevel Therapeutics (now part of AbbVie), Kailera Therapeutics, Stada, Tenacia Biotechnology, and Timberlyne Therapeutics.

GHIT announces $12.7 M worth investment for developing diagnostics and drugs for malaria, NTDs

The Global Health Innovative Technology (GHIT) Fund, headquartered in Japan, has announced a total investment of approximately JPY 2 billion ($12.7 million) in eight projects for the development of new diagnostics and drugs for neglected tropical diseases (NTDs) and malaria. To advance measures against leishmaniasis, the GHIT Fund has decided to invest JPY 670 Million ($4.2 million) to support a project led by the Ohio State University in collaboration with Nagasaki University and icddr,b, an international health research organisation based in Bangladesh. The GHIT Fund will also invest in two malaria projects: approximately JPY 680 million ($4.2 million) for the development of a malaria therapeutic drug through a partnership between Eisai Co. and Medicines for Malaria Venture (MMV) and approximately JPY 585 million ($3.7 million) for the development of a preventive drug for P. falciparum malaria under the partnership of Program for Appropriate Technology in Health (PATH), GSK Global Health, Eisai and Ehime University.

Vaxxas advances $4.8 M programme for needle-free thermostable mRNA vaccines

Vaxxas, an Australia-based clinical-stage biotechnology company commercialising a novel high-density microarray patch (HD-MAP) vaccination platform, has announced that Norway-based Coalition for Epidemic Preparedness Innovations (CEPI) has approved the progression of a $4.8 million (AU$7.2 million) programme to develop heat-stable, dried-formulation mRNA vaccines delivered using

Vaxxas' needle-free high-density microarray patch (HD-MAP).

Vaxxas will partner with South Korea-based vaccine developer SK bioscience in this next phase of the programme, advancing the company's mRNA vaccine for Japanese Encephalitis Virus (JEV) on Vaxxas' HD-MAP towards a Phase I clinical study. The companies are also working on a programme, funded by global charitable organisation Wellcome, to advance the development of a HD-MAP/Typhoid conjugate vaccine candidate.

Dr. Reddy's Lab inks oncology deal of $131 M with Shanghai Henlius Biotech

Dr. Reddy's Laboratories SA, wholly-owned subsidiary of India-based Dr. Reddy's Laboratories Ltd has entered into a license agreement with Shanghai Henlius Biotech, Inc. related to the development and commercialisation of HLX15, Henlius's investigational daratumumab biosimilar candidate to Darzalex & Darzalex Faspro. HLX15 is a recombinant anti-CD38 fully human monoclonal antibody injection, with intravenous as well as subcutaneous formulations. HLX15 is being developed as a biosimilar of Darzalex & Darzalex Faspro, which are indicated for the treatment of multiple myeloma. The agreement combines Dr. Reddy's global commercial presence with Henlius' proven capabilities in developing biosimilars for markets worldwide. Under the terms of the agreement, Henlius will be responsible for development, manufacturing and commercial supply, and may receive up to a total of $131.6 million, including an upfront payment of $33 million and milestone payments.

PureHealth acquires majority stake in Hellenic Healthcare Group for $2.3 B

PureHealth Holding PJSC, the largest healthcare group in the Middle East, has agreed to acquire a 60 per cent stake in Hellenic Healthcare Group (HHG), the largest private healthcare provider in Greece and Cyprus, in a transaction that values HHG at $2.3 billion. HHG is currently owned 90 per cent by CVC Capital Partners VI and 10 per cent by the founder of HHG. PureHealth will acquire a 60 per cent stake in HHG, with CVC Capital Partners retaining 35 per cent ownership, while the remaining 5 per cent stake in the company is held by the founder. Following completion of the transaction, CVC Capital Partners VI and HHG Management will retain a 40 per cent stake in HHG, continuing as a strategic partner to support the company's growth and transformation. This partnership ensures that HHG will benefit from the combined expertise, resources, and global networks of both PureHealth and CVC, driving operational excellence and unlocking further opportunities in the healthcare sector.

LG to develop AI model for protein multistate structure prediction

LG AI Research recently signed a joint research agreement at the Global Lounge of LG Science Park in Magok, Gangseo-gu, Seoul, with Prof. Min-Kyung Baek from the school of Biological Sciences at Seoul National University to develop a next-generation protein structure prediction AI. In collaboration with Prof. Min-Kyung Baek's research team, LG AI Research aims to develop an artificial intelligence (AI) model for protein multistate structure prediction by the end of the year, addressing current technological limitations. This breakthrough is expected to provide deeper insights into biological processes and accelerate drug development. LG expects that this joint research will further accelerate the discovery of Alzheimer's factors and the development of new drugs, which are currently being conducted in collaboration with The Jackson Laboratory (JAX), a US-based nonprofit genomics research organisation. Since early last year, LG AI Research has been collaborating with The Jackson Laboratory to develop predictive AI technologies for diagnosing and treating Alzheimer's and cancer.

Jubilant Biosys expands footprint in Europe for Biologics and Antibody Drug Conjugate services

Jubilant Biosys Innovative Research Services Pte Limited, Singapore (JBIRSPL), a subsidiary of Jubilant Biosys Limited, a wholly owned subsidiary of Jubilant Pharmova Limited, has executed the transaction definitive agreements with Pierre Fabre (PF) SA, and its affiliate entities, for JBIRSPL to acquire 80 per cent equity capital in JASMIN (new company incorporated by PF in France, as a Société par Actions Simplifiée (SAS)), with remaining 20 per cent retained by PF. At closing of the transaction, JASMIN shall acquire Pierre Fabre's R&D Centre (including R&D Site and R&D activities) at Saint-Julien-en-Genevois, France, and JBIRSPL would also execute a Shareholders' Agreement and other transition agreements with PF. This strategic agreement will enable Jubilant Biosys Limited to expand its footprint in Europe in areas like Biologics (mAbs) and Antibody Drug Conjugate (ADC), in addition to its existing services including integrated drug discovery services from India.

Chugai and GSK sign collaboration agreement for anti-dengue virus antibody AID351

Japan's Chugai Pharmaceutical Co. has signed a collaboration agreement with GSK's Global Health Unit (GSK GH) for the development of an anti-dengue virus antibody. Under this agreement, GSK GH will perform activities and evaluate potential funding for the initiation of clinical studies of AID351. The anti-dengue virus antibody joint development project to overcome dengue fever, one of the Neglected Tropical Diseases (NTDs as defined by the World Health Organization (WHO), has been advancing through

collaboration between Chugai Pharmabody Research (CPR), Chugai Pharmaceutical's research base in Singapore, and A*STAR Singapore Immunology Network (A*STAR SIgN), with an antibody derived from A*STAR SIgN and the National University of Singapore (NUS) as the lead. During this period, the project has received grant funding twice from the Global Health Innovative Technology (GHIT) Fund. GSK Global Health's goal is to change the trajectory of high burden infectious diseases in lower income countries. Dengue disease is one of the neglected tropical diseases, for which there is a gap in treatment. It exists in countries with tropical or subtropical conditions with vector-favourable climate conditions and poverty impeding access to efficient health care coverage.

MediBuddy partners with Japan's Elecom to launch smart health devices in India

MediBuddy, India's largest digital healthcare company, has announced a strategic partnership with ELECOM, a leading Japanese electronics company, to jointly develop and introduce cutting-edge smart health IoT devices to the Indian market. This partnership marks a significant step toward MediBuddy's vision of making high quality healthcare accessible to a billion people by fostering innovation in preventive health management. In the initial phase, the partnership will focus on launching integrated healthcare solutions through ELECOM's products, enhancing accessibility across India. With India experiencing a rapid rise in lifestyle-related diseases, causing 6 million fatalities annually, ELECOM aims to safeguard health by merging digital technology with healthcare products to deliver optimal solutions. Additionally, this will further leverage health and medical data from these advanced monitoring devices to provide personalised health insights and preventive care programmes for lifestyle-related diseases. By harnessing this data, MediBuddy aims to deliver more targeted interventions and improve health outcomes across the country by making daily health management more convenient. All medical records will automatically integrate into the MediBuddy app enabling the doctor to improve patient wellbeing.

XDENT LAB expands largest removable denture factory in Vietnam

XDENT LAB, one of the leading providers in the field of Removable Denture manufacturing in Vietnam, has officially announced the expansion of its production facility, making it the largest in the country. This strategic move not only marks a significant leap for XDENT LAB in the dental industry but also reinforces its pioneering position in Lab-to-Lab services, targeting the US market. The new facility is strategically designed to optimise the production process of Removable Dentures, meeting the strict standards of the US market, with a total area of 1,500 sq m. This expansion allows XDENT LAB to boost its production capacity, providing faster and more efficient services to international partners looking for a reliable Vietnam Dental Lab. The increased capacity also enables the company to meet the growing demand from the US market, where precision and quality are paramount. Beyond expanding production capacity, XDENT LAB is also a leader in developing the Lab-to-Lab model, an optimised outsourcing solution for US dental labs.

NephroPlus increases footprint in the Philippines with acquisition of 7 dialysis centres

NephroPlus, Asia's largest dialysis care network, has acquired seven new dialysis clinics in the Philippines, enhancing its position as a leading dialysis provider in the country. With this expansion, NephroPlus now operates 36 clinics in the Philippines, serving nearly 2,000 patients. This move reinforces its commitment to delivering high-quality, patient-centric dialysis care globally. The acquisition is part of NephroPlus's expansive international strategy, following its recent entry into Saudi Arabia via a Joint Venture agreement. The company now operates in five countries, positioning itself as a global leader in specialised dialysis care. As India cements its role as a hub for medical innovation, NephroPlus continues to drive change through technology-enabled remote monitoring, clinical data analytics, and publishing outcomes in international forums. The company has made significant investments to enhance operational efficiency and patient outcomes in the Philippines. These investments have generated approximately 400 jobs across clinical and operational roles.

AdvanCell partners with Lilly to develop new targeted alpha therapies for cancer treatment in Australia

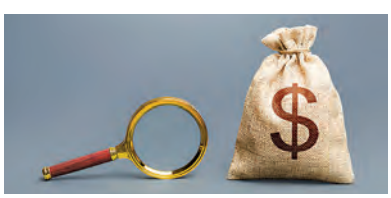
AdvanCell, a radiopharmaceutical company, has announced the expansion of the scope and scale of its strategic collaboration with Eli Lilly and Company for the research and development of innovative treatments for various cancers. Under the new agreement, the parties will leverage AdvanCell's Pb-212 production technology and radionuclide development infrastructure, as well as Lilly's drug candidate programmes and deep drug development expertise, to facilitate the development and accelerate clinical advancement of an expanded portfolio of targeted alpha therapies. AdvanCell's competitive advantage in technology development and the infrastructure put in place to accelerate early-stage clinical trials in Australia enable AdvanCell to rapidly develop and advance novel Pb-212-containing radiotherapies from discovery to clinical trials.

Hikma and M42 sign strategic MoU to advance healthcare innovation in UAE

Hikma Pharmaceuticals PLC, a British pharmaceutical group, has signed a strategic memorandum of understanding (MoU) with M42, a global health leader powered by artificial intelligence (AI) and technology, to advance healthcare innovation in the United Arab Emirates (UAE) in the fight against colorectal cancer. The MoU aims to accelerate the implementation of more precise, preventive and predictive cancer care programmes, utilising cutting-edge genomics screening technology. Under this agreement, Hikma and Abu Dhabi-based startup M42 will enhance their collaboration to promote the use of Shield, a non-invasive laboratory-developed test (LDT) by Guardant Health Inc., for colorectal cancer (CRC) screening, aiming to improve screening adherence rates in the UAE. Shield is the first blood test to be approved by the US FDA as a primary screening option for CRC, meaning healthcare providers can offer Shield in a manner similar to all other non-invasive methods recommended in screening guidelines. The Abu Dhabi Public Health Centre (ADPHC), in partnership with M42, recently introduced the non-invasive blood-based liquid biopsy test Shield for colorectal cancer screening as part of the IFHAS comprehensive health screening programme.

Sequential & AMILI secure $1.8M UK-Singapore R&D project

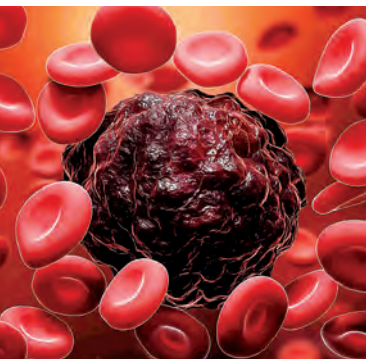
Sequential Skin, a world leader in skin microbiome testing, and AMILI, a leading expert in gut microbiome science, have been awarded the prestigious UK-Singapore Collaborative R&D Grant. The $1.8 million project, supported by Innovate UK and Enterprise SG, will make significant strides in characterising the interplay between the skin and gut microbiome, offering a groundbreaking approach to evaluating inflammatory skin disorders (ISDs) such as atopic dermatitis and psoriasis.



Sequential has built a database of over 25,000 clinical skin microbiome samples and has pioneered the world's early skin microbiome at-home tests that were made commercially available in 2019. The previous recipient of an Innovate UK Smart Grant, with labs in US, Europe and Asia, Sequential is currently working with over 80 personal care and pharmaceutical companies innovating in the skin microbiome field. AMILI, headquartered in Singapore, has been at the forefront of gut microbiome research. Since AMILI founders performed the first gut microbiome transplants in the region in 2014, AMILI has focused on developing and deeply analysing Asia's largest multi-ethnic gut microbiome database to map the relationships and mechanistic pathways between changes in the gut microbiome and health conditions.

Immuneel unveils India's first global CAR T-cell therapy for Non-Hodgkin's Lymphoma

In a significant step forward for India's cancer treatment, Immuneel Therapeutics has unveiled Qartemi, country's first global CAR T-cell therapy for adult B-cell Non-Hodgkin Lymphoma (B-NHL), a group of blood cancers. A personalised therapy for adult patients with relapsed or refractory B-NHL, Immuneel, a Bengaluru-based cell and gene therapy startup, addresses a critical gap in India's cancer immunotherapy landscape. This groundbreaking therapy, benchmarked to global standards, is now available locally, offering renewed hope to patients for whom conventional therapies including chemotherapy prove ineffective. Immuneel initiated India's first CAR T-cell therapy trial in 2022 for a novel autologous CD19 directed CAR T-cell therapy in patients with relapsed / refractory B cell malignancies. The IMAGINE trial was conducted across Narayana Hospital in Bengaluru, Apollo Cancer Hospital in Chennai and PGIMER in Chandigarh. The results from the IMAGINE trial showed that the efficacy and safety of Qartemi is similar to CAR T-cell therapies approved by the USFDA.

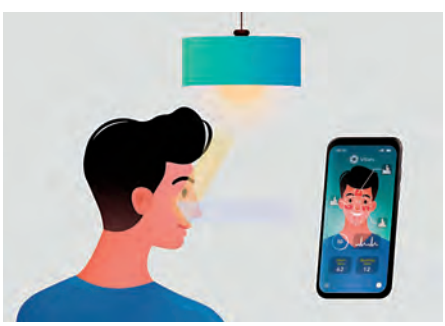


JETRO collaborates with Mayo Clinic to support Japanese digital health startups

Japan External Trade Organisation (JETRO), in collaboration with the Mayo Clinic Platform (operated by the world-renowned US-based medical institution Mayo Clinic), has announced the selection of five startups to participate in the second phase of the "HealthTech Gateway 'AI Medical in the US'" acceleration programme. This phase began in January 2025 to provide approximately 30 weeks of support. In Phase 2, participants will have access to the Mayo Clinic Platform's medical data platform, enabling them to leverage data crucial for US and global expansion. Additionally, support for product development and validation, mentoring opportunities, and other resources will be provided. In April 2025, participants will travel to Minnesota, USA, for a Demo Day event, including a five-minute pitch and networking with the Minnesota ecosystem stakeholders. These programmes aim to comprehensively support market entry into the US.

PanopticAI gets US FDA clearance for contactless vital signs monitoring software

PanopticAI, a startup in remote patient monitoring space, has received 510(k) clearance from the US Food and Drug Administration (FDA) for its contactless vital signs monitoring software. The PanopticAI Vital Signs app is the first FDA-cleared mobile application for contactless pulse rate measurement using the built-in camera of iPhones and iPads. This also distinguishes PanopticAI as the first Hong Kong-based company to achieve FDA clearance for a Software as a Medical Device (SaMD). PanopticAI's technology leverages proprietary remote photoplethysmography (rPPG) algorithms to transform readily available smartphones and tablets into medical-grade vital sign monitors. Advanced AI and signal processing techniques are used to analyse subtle colour changes in the skin captured by the device's camera, accurately measuring vital signs like pulse rate in just 30 seconds. This FDA clearance represents a significant milestone in PanopticAI's mission to make healthcare more accessible and scalable.



PAHO calls for better access to essential cancer medicines in Latin American and Caribbean

The Pan American Health Organization (PAHO) is urging governments in Latin America and the Caribbean to prioritise access to essential cancer medicines, supplies, and equipment. Cancer remains one of the leading causes of death in the Americas region, claiming the lives of more than 1.4 million people and resulting in more than 4 million new cases annually. While progress has been made, several barriers still exist, including high costs, inefficient procurement systems, and limited distribution networks. Addressing these challenges requires a comprehensive approach, including updated treatment protocols and pooled procurement to increase predictability and address the high price of cancer medicines. PAHO also continues its work with global partners to improve childhood cancer care. Through the Global Platform for Access to Childhood Cancer Medicines, PAHO is working with WHO, St. Jude Children's Research Hospital, and UNICEF to ensure a continuous supply of affordable, quality cancer medicines to low- and middle-income countries (LMICs).

Paris pushing mRNA vaccine development timelines to new speeds

Scientists in Paris are set to advance new technology that could streamline the production of mRNA-based vaccines while also improving global access to the technology. Norway-based Coalition for Epidemic Preparedness Innovations (CEPI) is providing $4.7 million to DNA Script to advance their capability to automate the manufacture of synthetic DNA templates, the starting blueprint required for producing mRNA. This funding could help to accelerate mRNA vaccine development timelines and enhance readiness to produce such vaccines, particularly in Global South regions. The process of producing mRNA itself takes only around seven days, but the creation of a DNA template can take up to a month, creating a bottleneck in the manufacturing process. That's because these templates are traditionally generated through biologically manufactured processes, which are both costly and time-consuming.

UK launches world-leading AI trial to tackle breast cancer

The Department of Health and Social Care in the UK government has announced that nearly 700,000 women across the country will take part in a world-leading trial to test how cutting-edge artificial intelligence (AI) tools can be used to catch breast cancer cases earlier. As government ramps up the use of new technology across the board, 30 testing sites across the country will be enhanced with the latest digital AI technologies, ready to invite women already booked in for routine screenings on the National Health Service (NHS) to take part. The technology will assist radiologists, screening patients to identify changes in breast tissue that show possible signs of cancer and refer them for further investigations if required. The EDITH trial (Early Detection using Information Technology in Health) is backed by £11 million of government support via the National Institute for Health and Care Research (NIHR). It is the latest example of how British scientists are transforming cancer care, building on the promising potential of cutting-edge innovations to tackle one of the UK's biggest killers.

World Bank supports Bosnia and Herzegovina in strengthening healthcare

The World Bank's Board of Executive Directors has approved a $75 million Second Health Sectors Programmatic Development Policy Loan for Bosnia and Herzegovina (BiH). This is the second in a two-operation series designed to support BiH's efforts to strengthen the financial sustainability of its healthcare system and enhance the quality of health services for citizens. The programme supports enactment of policies aimed at improving the financial stability of health institutions by helping clear existing health sector arrears and establishing accountability and governance measures to prevent new ones. It also includes measures for better delivery of health services and preventive care, alongside reforms to improve environmental management and strengthen tobacco control. This programme complements the ongoing World Bank-funded Health Systems Improvement Project, and benefits from the technical assistance provided by the World Bank and other development partners to strengthen the health sectors.

African regulators sign pact to strengthen regulatory systems

The Africa Centres for Disease Control and Prevention (Africa CDC) and African Union Development Agency – New Partnership for Africa's Development (AUDA-NEPAD) have announced the signing of a Memorandum of Understanding (MoU) among Africa's WHO Maturity Level 3 National Regulatory Authorities (NRAs). These agencies have established robust systems to ensure the safety, efficacy and quality of medical products in line with international regulatory standards. The agreement marks a significant milestone in strengthening regulatory systems across the continent by fostering collaboration and reliance on regulatory decisions among signatory agencies while also creating an enabling environment for the local production of medical products. It aims to create a framework that streamlines regulatory decisions to speed up the approval of medicines, vaccines & medical devices, while promoting collaboration on vaccine lot releases.

NIH to lead implementation of National Plan to End Parkinson's Act in US

With support from the US Department of Health and Human Services (HHS) Office of the Assistant Secretary for Health (OASH), the National Institutes of Health (NIH) is leading the implementation of the Dr. Emmanuel Bilirakis and Jennifer Wexton National Plan to End Parkinson's Act, which was signed into law on July 2, 2024. The Act establishes a Federal Advisory Council on Parkinson's Research, Care, and Services and calls for the creation and regular updating of a national plan to prevent, diagnose, treat, and cure Parkinson's,

ameliorate symptoms, and slow or stop progression. In addition to Parkinson's disease, the national plan will also target other neurodegenerative Parkinsonisms, including multiple system atrophy, corticobasal degeneration, progressive supranuclear palsy, and Parkinson's-related dementia. The goals of the Act are to coordinate Parkinson's-related research and services across federal agencies; speed the development of safe and effective treatments; improve early diagnosis; facilitate coordination of care and treatment; reduce the impact of Parkinson's on the physical, mental, and social health of individuals living with Parkinson's and their caregivers and families; and increase international coordination.

WHO certifies Georgia malaria-free

Following a nearly century-long effort, Georgia has been certified malaria-free by the World Health Organization (WHO) on January 23. With this announcement, Georgia joins the ranks of 45 countries and 1 territory that have achieved this milestone. Certification of malaria elimination is granted by WHO when a country has proven, beyond reasonable doubt, that the chain of indigenous transmission has been interrupted nationwide for at least the previous three consecutive years. Malaria has plagued Georgia since ancient times. Before the introduction of systematic control efforts in the early 1900s, at least 3 malaria parasite species—P. falciparum, P. malariae and P. vivax—were endemic in the country. In the 1920s, an estimated 30 per cent of the population suffered from malaria caused by the P. vivax malaria species. In 2024, during the Georgia's malaria-free certification process, members of the Technical Advisory Group on Malaria Elimination and Certification, an independent WHO advisory body, noted that Georgia has a well-functioning and adequately resourced health system, strong public-private cooperation, and political commitment to maintaining a malaria-free status.

WHO enables vaccine access for outbreak of Sudan Ebola virus disease in Uganda

WHO and partners have boosted their support to the Ugandan government's response to an outbreak of Sudan virus disease outbreak (SVD, part of the Ebola family), including by facilitating access to a candidate vaccine and candidate treatments (a monoclonal antibody and an antiviral). This is the first trial to assess the clinical efficacy of a vaccine against Ebola Sudan virus disease. IAVI, the provider of the vaccine, conducted trials for safety and immunogenicity. It is also the first clinical trial of the vaccine during an outbreak. WHO worked with the principal investigators and national authorities and the vaccine developer to review cold chain documentation and ensure the doses were stored correctly over the previous years. As part of the signed agreement with the Ministry of Health in Uganda, WHO has a signed agreement with IAVI for additional doses of the candidate vaccine to be made available.

WHO partners with Siriraj Hospital in Thailand to address growing burden of injuries and falls

The World Health Organization (WHO) has signed a Memorandum of Understanding (MoU) with Siriraj Hospital, Mahidol University, Thailand, to strengthen collaboration on trauma, injury, and fall prevention across the WHO South-East Asia Region to address the growing health, social, and economic challenges posed by these issues. As part of the partnership, Siriraj Hospital will support Member States by enhancing capacity building, data management, research, and prevention efforts. This collaboration will include health workforce training, conducting regional workshops, and advancing cutting-edge research to strengthen prevention, care, and data systems across the Region. While fall-related injuries affect people of all age groups, older adults remain particularly vulnerable, with up to 42 per cent of those over 70 experiencing falls annually. Falls are also a significant cause of death among individuals aged 5–29, accounting for 15 per cent of all injury-related deaths in this age group.

Mitigating PATENT CLIFF Fallout

Monoclonal antibodies (mAbs) represent a $279.8 billion market, projected to reach $804 billion by 2033, according to a report from Dimension Market Research. With patents for many of these valuable drugs set to expire in the coming years, the industry faces significant challenges. In this story, we examine 11 blockbuster mAbs whose patents will expire between 2025 and 2030. These expirations, affecting some of pharma's biggest players, will have a major impact on the market and their revenue streams.

By 2030, pharmaceutical companies are expected to lose over $236 billion in revenue due to the impending 'patent cliff,' as 190 drugs, including 69 blockbusters, lose exclusivity. This represents about 46 per cent of sales at risk for the top ten pharma companies over the next decade, according to a report by Deloitte.

This is currently what experts call 'wave 2' of patent expirations. The first wave (2010–2020) fueled the growth of the generics industry. Now, the second wave involves the expiration of key monoclonal antibody patents, such as Keytruda, presenting a massive multi-billion dollar opportunity for biosimilars.

To mitigate revenue loss from these blockbuster drugs, pharmaceutical companies are exploring various strategies, including partnerships, mergers and acquisitions, and patent thickets.

"Based on the current status of biosimilars in development, we will see more diversification of businesses (less pure players), more mergers, acquisitions and partnerships. For developers to continue to evaluate the investment required to launch future products in high-cost drug categories, there has to be a level of confidence that the market will support the lower cost biosimilars when they are approved years down the line," said ***Linda MacDonald, Executive Vice President and Commercial Division Lead at Samsung Bioepis.***

Unlike generics, many biosimilars won't be interchangeable or directly substitutable. Also, because biosimilars are more expensive to develop and manufacture, their producers won't be able to reduce prices as significantly as generic drug makers do.

"My personal view is that the evidence so far suggests there will be a balance of both approaches and there will be fragmented strategies going forward. A lot will depend on the commercial, patent and technology situation around an individual biologic and - in the US at least - the formulary adoption status. In general, biosimilars present more challenges compared with standard chemical generics due to their manufacturing complexity, time and cost," said ***Ian Haydock, Editor-In-Chief, Asia-Pacific, Insights at Citeline (formerly Pharma Intelligence).***

Experts also believe that, although there will be a loss of revenue, the impact will be gradual and can be mitigated to some extent. Biosimilars

uptake has been slower in the US than in Europe.

"A look at actual case studies including AbbVie's mega-blockbuster Humira and others shows a variety of originator strategies, including price reductions, patent protection moves (including legal action), modified rebate practices, Pharmacy Benefits Manager (PBM) partnerships and patient assistance programmes. The development of new formulations and acquisition of novel successor products, either through in-house R&D or licensing/M&A activity, present other options. In Humira's case, biosimilar erosion was carefully planned for by AbbVie and their forecasts turned out to be generally accurate (biosimilar penetration tends to be lower in chronic versus acute indications, for instance), showing that the patent cliff impact can be managed," said Ian Haydock.

According to IQVIA, only 10 per cent of the molecules set to lose patent protection from 2025 to 2034 have biosimilars in development. And biosimilars take 7-10 years to develop and up to $500 million for development.

"The market has to be sustainable – tough, especially in the US. There is an enormous need for a thriving biosimilar market in the US as it is the best solution to high drug costs. The US is the single largest biologics market in the world for originators and the home to much of biotech investment – and that needs to continue," said Linda.

Nonetheless, this shift is set to transform the pharma industry. The rise of biosimilars could also improve access to medicines, which, ultimately, should be the fundamental goal, ensuring that life-saving treatments are available to more people.

Key mABs' patent expiring by 2030

Here, we highlight 11 monoclonal antibody patents (with revenue more than $1 billion) set to expire between 2025 and 2030, poised to impact some of the biggest players in the pharmaceutical industry.

1. Yervoy (ipilimumab)
Company: Bristol Myers Squibb (BMS)
2024 sales: $2.53 billion
Patent expiry: 2025

Ipilimumab, sold under the brand name Yervoy, is a monoclonal antibody medication that works to activate the immune system by targeting CTLA-4 and is used as an anticancer drug for lung cancer (NSCLC), melanoma, renal cell carcinoma, liver

cancer, colorectal cancer, esophageal cancer, and pleural mesothelioma. Yervoy (ipilimumab) is one of BMS' top selling cancer drugs and clocked $2.53 billion in 2024.

The exclusivity period is based on the composition of matter patent, which expires in 2025 and currently, no approved biosimilar is available, although few are in development. Ipilimumab biosimilar is under clinical development by Innovent Biologics and currently in phase II for Metastatic Biliary Tract Cancer. Another firm working on the biosimilar is Shanghai Henlius Biotech announced that the first subject was dosed for a phase 1 clinical trial of the company's independently developed ipilimumab biosimilar HLX13 (recombinant anti-CTLA-4 fully human monoclonal antibody injection) in China.

2. Prolia (denosumab)
Company: Amgen
2024 sales: $4.3 billion
Patent expiry: 2025

Prolia (denosumab) is a long-standing drug used primarily in the United States, Europe, and the Asia Pacific region. It contains the same active ingredient as XGEVA (denosumab), but it is approved for different indications, patient populations, doses, and frequencies of administration. Launched in the U.S. and Europe in 2010, Prolia is primarily used in the treatment of postmenopausal women with osteoporosis who are at high risk of fracture, either due to a history of osteoporotic fractures or multiple fracture risk factors.

In 2024, Prolia generated $4.3 billion in sales. However, the company anticipates a decline in sales starting in 2025 due to the upcoming launch of biosimilars, as the drug's exclusivity is set to expire this year.

The US FDA has already approved two biosimilars to Prolia. In 2024, the FDA approved AndozJubbonti (denosumab-bbdz) injection as an interchangeable biosimilar to US licensed Prolia. In February 2025, Samsung Bioepis received FDA approval for its biosimilar, OSPOMYV (denosumab-dssb, SB16), in a 60 mg pre-filled syringe. Additionally, Celltrion's denosumab biosimilar has been approved in the European Union. Teva's Prolia biosimilar candidate has also been accepted for review by both the US FDA and the European Medicines Agency (EMA), with approval expected later this year.

3. Perjeta (Pertuzumab)
Company: Roche
2024 sales: CHF 3.616 billion ($4.029 billion)
Patent expiry: 2025-2026

Pertuzumab (Perjeta) is a recombinant humanised monoclonal antibody that targets the dimerisation domain II of the HER2 receptor on the cell surface and is used for the treatment of breast cancer. It is one of the best selling cancer drugs and clocked CHF 3.616 billion.

The group's basic primary patent expires in 2025 in the US and EU and the group currently anticipates biosimilar could be available in the market in 2026.

Several companies are developing biosimilars for Perjeta. Qilu Pharmaceutical Co., Ltd., based in Jinan, China, is developing QL1209, which is currently in phase 3 trials. Zydus Cadila and Dr. Reddy's Laboratories have also entered into a licensing agreement to co-market Zydus' biosimilar of pertuzumab. In 2025, the FDA accepted a Biologics License Application (BLA) for a pertuzumab biosimilar developed by Shanghai Henlius Biotech, indicating progress in the competitive biosimilar market for this cancer treatment.

4. Opdivo (nivolumab)
Company: Bristol Myers Squibb
2024 sales: $9.3 billion
Patent expiry: 2026-2027

Opdivo (nivolumab) is a fully human monoclonal antibody that targets the PD-1 receptor on T and NKT cells, enhancing immune responses against cancer. Approved since 2014, Opdivo has received indications for several cancers, including melanoma, head and neck cancer, lung cancer, kidney cancer, and blood cancer. Additionally, the Opdivo + Yervoy regimen has been approved in multiple markets for melanoma treatment. Ongoing trials

Drugs losing patents between 2025 and 2030				
No	**Drug**	**Company**	**Revenue (in $ Billion)**	**Patent expiry**
1	Yervoy (ipilimumab)	Bristol Myers Squibb	2.53	2025
2	Prolia (denosumab)	Amgen	4.3	2025
3	Perjeta (Pertuzumab)	Roche	CHF 3.616 (4.029)	2025-2026
4	Opdivo (nivolumab)	Bristol Myers Squibb	9.3	2026-2027
5	DARZALEX (Daratumumab)	Genmab/J&J	11.7	2026
6	Dupixent (dupilumab)	Regeneron/Sanofi	€13 (13.62)	2027
7	SOLIRIS (eculizumab)	AstraZeneca	2.5	2027
8	Ocrevus (ocrelizumab)	Roche	6.95 (CHF 6.7)	2028-2029
9	Keytruda (Pembrolizumab)	Merck	29.5	2028
10	Repatha (evolocumab)	Amgen	2.2	2028-2030
11	Cosentyx (secukinumab)	Novartis	6.14	2029-2030

are exploring its potential in other tumor types and disease areas.

Opdivo is Bristol-Myers Squibb's top-selling cancer drug, with sales reaching $9.3 billion in 2024.

Bristol-Myers Squibb and Ono jointly hold the patent for nivolumab as a composition of matter, which is set to expire in the U.S. in 2027 and in the EU in 2026 (excluding potential patent term extensions). In Japan, the composition of matter patent for nivolumab will expire in 2031, including a granted patent term extension.

While Zydus Life Sciences' biosimilar nivolumab has been approved in India, several other companies are actively developing biosimilars. Sydney-based NeuClone Pharmaceuticals, in collaboration with Serum Institute of India, is advancing biosimilar candidates for nivolumab in the preclinical stage. Additionally, Swedish firm Xbrane Biopharma and Intas have partnered to jointly develop an Opdivo biosimilar, while China's Luye Pharma is also working on its version. Amgen's Opdivo biosimilar is currently in phase 3 trials.

5. Darzalex (Daratumumab)
Company: Genmab/J&J
2024 sales: $11. 7 billion
Patent expiry: 2026

Daratumumab, sold under the brand name Darzalex, is an anti-cancer drug used to treat multiple myeloma. Originally developed by Genmab, the drug is now being jointly developed with Janssen Biotech, a subsidiary of Johnson & Johnson, which acquired worldwide commercialisation rights.

In 2024, Darzalex generated net sales of $11.67 billion, making it one of the best-selling anti-cancer drugs. The composition of matter patents for daratumumab in the U.S., Europe, and Japan are set to expire in March 2026.

Several companies are developing biosimilars to Darzalex. One such biosimilar, HLX 15, is being developed by Shanghai Henlius Biotech and licensed to Dr. Reddy's Laboratories. HLX 15 is a humanised IgG1K monoclonal antibody indicated for the treatment of multiple myeloma.

On November 28, 2024, Celltrion announced the initiation of global phase 3 clinical trials for its biosimilar, CT-P44, which is based on daratumumab. This follows the submission of its global phase 3 clinical trial plan to the European Medicines Agency (EMA).

Additionally, Xdarzane, developed by Xbrane Biopharma, another biosimilar candidate to Darzalex, is currently in the preclinical development stage. Focused on creating a cost-effective production process, Xdarzane aims to demonstrate biochemical similarity to the original drug.

6. Dupixent (Dupilumab)
Company: Regeneron/Sanofi
2024 sales: €13 billion ($13.62 billion)
Patent expiry: 2027

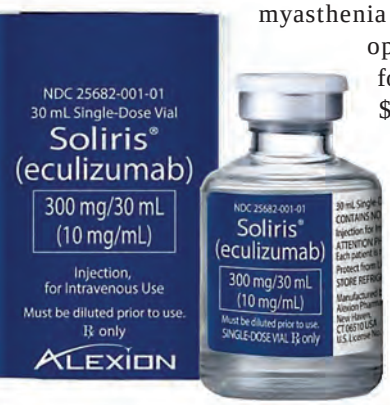
Dupilumab, jointly developed by Regeneron and Sanofi and marketed under the brand name Dupixent, is a monoclonal antibody that blocks interleukin 4 (IL-4) and interleukin 13 (IL-13) receptor signaling (IL-4R, IL-13R). It is used to treat

a variety of allergic diseases, including eczema (atopic dermatitis), eosinophilic or oral-corticosteroid-dependent asthma, chronic rhinosinusitis with nasal polyps, COPD with an eosinophilic phenotype, eosinophilic esophagitis (EOE), and prurigo nodularis.

Dupixent is one of the bestselling drugs, with 2024 sales reaching €13 billion ($13.62 billion) in the atopic dermatitis treatment market. Its patent (methods of treatment) starts to expire in 2027 and currently, Bio-Thera is the only company developing a biosimilar for Dupixent.

7. Soliris (eculizumab)
Company: AstraZeneca
2024 sales: $2.5 billion
Patent expiry: 2027

Eculizumab, sold under the brand name Soliris, is a recombinant humanised monoclonal antibody used to treat conditions such as paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS), generalised myasthenia gravis, and neuromyelitis optica. It's an important drug for AstraZeneca and cocked $2.5 billion in sales.



Although Soliris will lose its exclusivity by 2027, two biosimilars have already been approved by the US FDA in 2024. In May 2024, the FDA approved Bkemv (eculizumab-aeeb) as the first interchangeable biosimilar to Soliris. Developed by Amgen, Bkemv is approved for the treatment of PNH and aHUS, the same indications as Soliris.

In July 2024, the FDA also approved Epysqli (eculizumab-aagh), a biosimilar developed by Samsung Bioepis. Epysqli is approved for the treatment of PNH and aHUS, marking it as the second biosimilar to Soliris.

8. Ocrevus (ocrelizumab)
Company: Roche
Sales: $6.95 billion (CHF 6.7 billion)
Patent expiry: 2028-2029

Ocrevus (ocrelizumab) is a humanised anti-CD20 monoclonal antibody that targets the CD20 marker on B lymphocytes, a type of immune cell involved in multiple sclerosis (MS). It acts as an immunosuppressive drug and is the first and only therapy approved for both relapsing and primary progressive forms of MS. Ocrevus is administered biannually (every six months) and was first approved in 2017. Since then, it has become Roche's top-selling drug, generating over CHF 6 billion ($6.95 billion) in sales last year and capturing around 22 per cent of the MS market.

According to GlobalData, Ocrevus' patents are set to expire in Europe in 2028 and in the U.S. in 2029, paving the way for potential biosimilars to enter the market. Several companies are actively developing biosimilars for Ocrevus.

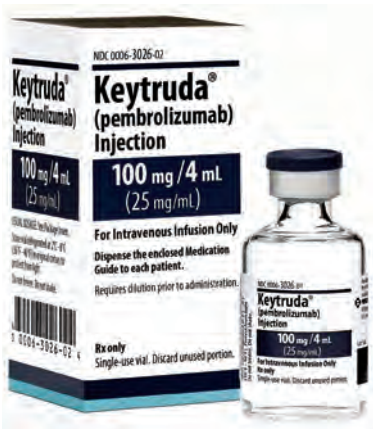
CinnaGen, the largest biotechnology company in Iran and the Middle East and North Africa region, has developed a follow-on biologic to ocrelizumab, called Xacrel. Xacrel was approved by the Iran FDA in 2021, and is currently available exclusively in Iran for treating both relapsing-remitting multiple sclerosis (RMS) and primary progressive multiple sclerosis (PPMS).

Amgen is also working on an ocrelizumab biosimilar, ABP 692, which is currently in phase 3 trials. The phase 3 study (NCT06700343) will assess the pharmacokinetic and pharmacodynamic similarity between ABP 692 and Ocrevus in patients with relapsing-remitting multiple sclerosis, with enrollment beginning in February 2025 in the US.

Celltrion is also developing an ocrelizumab biosimilar, CT-P53. In August 2023, the European Medicines Agency (EMA) granted partial approval for its Phase 3 Investigational New Drug (IND) application. The study (NCT05906992), which is currently recruiting participants in Poland, aims to further evaluate CT-P53.

9. Keytruda (pembrolizumab)
Company: Merck
2024 sales: $29.5 billion
Patent expiry: 2028

Keytruda (pembrolizumab) is an anti-PD-1 therapy that enhances the body's immune system to detect and fight tumour cells. It is used to treat a variety of cancers, including melanoma, lung cancer, head and neck cancer, Hodgkin lymphoma, stomach cancer, cervical cancer, and certain types of breast cancer.



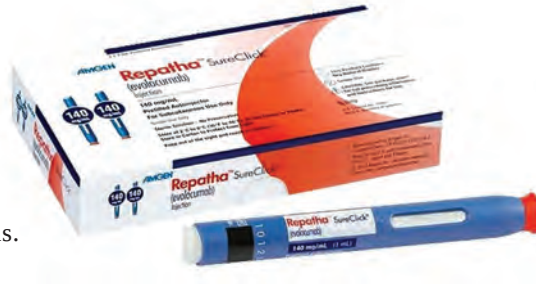
As one of Merck's top-selling drugs, Keytruda has been a cornerstone of the company's oncology portfolio. In 2024, Keytruda is projected to be the highest-ranked drug worldwide by sales, with Merck's global sales reaching $29.5 billion, a growth of 18 per cent from the previous year.

Keytruda is also one of the industry's most talked-about patent cliffs. The drug faces a significant patent expiration in 2028,which has spurred a wave of biosimilar development as companies aim for a share of this lucrative market. Major players, including Samsung, Amgen, Sandoz, and Celltrion, all are working on biosimilars.

In 2024, Samsung Bioepis initiated a phase III trial for its proposed Keytruda biosimilar, SB27. Formycon AG has also enrolled the first patient in the phase III "Lotus" trial, comparing the safety and efficacy of its biosimilar, FYB206, to Keytruda. Bio-Thera has started an integrated phase I/III trial for its biosimilar, BAT3306. Additionally, Celltrion received FDA approval for its phase 3 clinical trial plan for CT-P51, a biosimilar to Keytruda. Henlius has had its IND application for its pembrolizumab biosimilar approved by the NMPA in China.

10. Repatha (evolocumab)
Company: Amgen
2024 sales: $2.2 billion
Patent expiry: 2028-2030

Evolocumab, sold under the brand name Repatha, is a monoclonal antibody and immunotherapy medication used to treat hyperlipidemia. manufactured by Amgen,



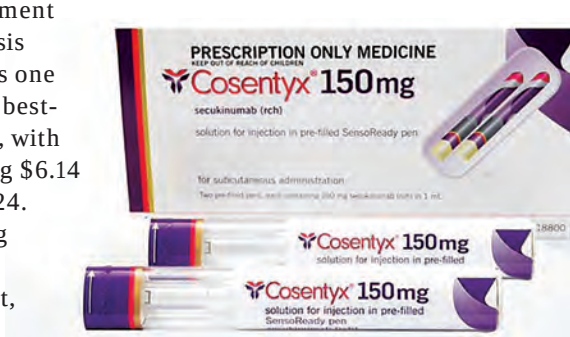
Repatha is a PCSK9 inhibitor that helps lower cholesterol levels.

In 2024, Repatha's sales increased by 36 per cent, reaching over $2.2 billion, making it one of Amgen's top-selling drugs.

The patent for Repatha is set to expire in the EU in 2028 and in the U.S. around 2029/30. CinnaGen is the only company developing a biosimilar to evolocumab, which is currently in phase III clinical trials for hyperlipidemia.

11. Cosentyx (secukinumab)
Company: Novartis
2024 sales: $6.14 billion
Patent expiry: 2029-2030

Cosentyx (secukinumab) is a monoclonal antibody classified as an interleukin (IL) inhibitor, specifically targeting the IL-17A protein. It is used to treat various autoimmune conditions, including plaque psoriasis, psoriatic arthritis, ankylosing spondylitis, enthesitis-related arthritis, hidradenitis suppurativa (HS), and non-radiographic axial spondyloarthritis. By blocking IL-17A, Cosentyx helps reduce inflammation and is considered an immunosuppressant. Since its launch in 2015, Cosentyx has become a leading treatment in the psoriasis market and is one of Novartis's best-selling drugs, with sales reaching $6.14 billion in 2024.



According to Novartis' annual report, the patent for Cosentyx will expire in the US in 2029 and in the EU in 2030. Currently, no biosimilars for secukinumab (Cosentyx) have been approved, although some are in development. In 2024, Celltrion received FDA approval for its global Phase 3 clinical trial of CT-P55, a biosimilar to Cosentyx. Meanwhile, Bio-Thera is developing BAT2306, its own secukinumab biosimilar, which is also in phase 3 clinical trials. BS

Ayesha Siddiqui

Collaboration vs Competition: Patent Cliffs

« **Alice Zeng,**
Senior Consultant,
Clarivate

The biosimilar business is growing increasingly fragmented among smaller firms, even as larger corporations are merging. Biosimilars are being developed by more than 40 smaller companies, many of which have no prior experience in the field. Long-term viability and supply reliability are threatened by this fragmentation.

Patent cliffs will be one of the originator's biggest pain points in the next 3-5 years. Between the originator and biosimilar developer, competition is generally more than collaboration. It depends on the different markets and biosimilar developers' volume/growth stage. It's a commercial decision with ROI.

In mature EU markets, stakeholders are well-educated so that we can see biosimilars' deeper and quicker market penetration. Sufficient competition causes lower prices and a limited profit margin. Biosimilar developers also have the ambition to establish their brands, and some have been trying to expand to novel biological products.

To effectively counter biosimilar competition, originator companies are implementing various proactive strategies, including developing second-generation products, product reformulations, improvements in dosing methods, and advancements in supporting devices.

The entry of Humira biosimilars had a profound impact on the European adalimumab market. Following the launch of biosimilars in 2018, Humira sales in Europe saw a remarkable decline, with adalimumab biosimilars capturing approximately 60 per cent volume share within three years. AbbVie has adopted an aggressive approach to mitigate biosimilar competition, implementing price reductions of up to 80 per cent in specific European markets, offering discounts ranging from 10 per cent to 80 per cent during government tender processes, and securing settlement agreements with biosimilar manufacturers for early entry in Europe, while strategically delaying US launches until 2023.

Despite these efforts, adalimumab biosimilars achieved significant market penetration in Europe, although adoption rates varied widely among countries. The UK reached an impressive 90 per cent market share for adalimumab biosimilars, while Denmark achieved nearly 97 per cent and Norway surpassed 90 per cent. In contrast, France has seen lower adoption rates, with a market share of around 41 per cent.

Interestingly, AbbVie's heavy discounting and the influx of potential competitors have resulted in several adalimumab biosimilars approved in Europe not launching or being withdrawn. For example, Sandoz withdrew its adalimumab biosimilar Halimatoz post-approval for commercial reasons. Similarly, Boehringer Ingelheim withdrew Cyltezo before its market entry, focusing its efforts on the US market and halting biosimilar development activities outside the United States. Other approved adalimumab biosimilars, such as Pfizer's Amsparity, which received European Commission market authorization in February 2020, have also been sidelined due to "unfavorable market conditions."

However, in the uneducated market or some impacted by policy or access barriers, we may see some cooperation between originators and biosimilar developers in the short term. The originator can obtain surplus value after patent cliffs and defend the other competitors in the market. Biosimilar developers can enter the market quickly and with lower promotion and marketing costs. In the US, the IRA (Inflation Reduction Act of 2022) may increase partnerships to let biosimilars access the market before the

patent cliff to avoid price negotiation. In China, biosimilar's VBP (volume-based procurement) is coming. A lower price is expected. China already has many well-known and commercialised biopharma companies with biosimilar pipelines, transforming from traditional generic companies and emerging biotech.

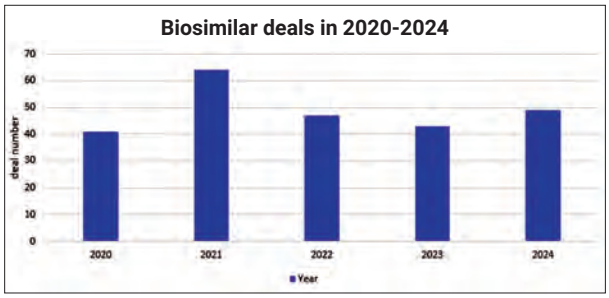
Another observation is that biosimilar developers have more partnerships across different regions/countries. In China, we see both licenses in and out. 3S Biopharma was licensed to develop and commercialise Samsugn Bioepis' multiple biosimilar products in Mainland China. Henlius has more than ten partners to develop and commercialise biosimilar products globally. There are also more partnerships among local biosimilar developers and big local pharma with strong marketing and sales teams or distribution channels.

Strategic partnerships and collaborations between these originator companies and biosimilar developers are on the rise, with many leading pharmaceutical companies adopting a hybrid strategy that involves the development of both originator biologics and biosimilars. Industry giants such as Amgen, Merck & Co., and Pfizer exemplify this approach, leveraging their biologic development and manufacturing expertise to create powerful synergies.

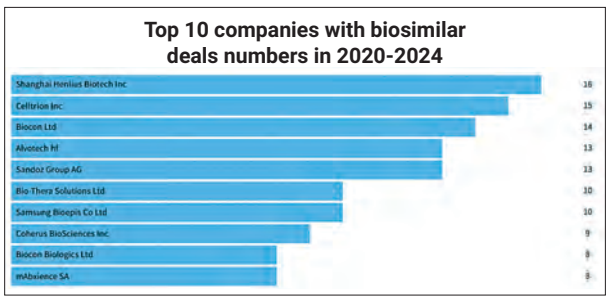
Originator companies are increasingly forming alliances with biosimilar developers to co-develop and commercialise biosimilars, especially in emerging markets. A prime example is mAbxience, a Spanish biosimilar manufacturer majority-owned by Fresenius Kabi and partially owned by Insud Pharma. They have established significant agreements with Teva Pharmaceuticals to develop an anti-PD-1 oncology biosimilar candidate. They are collaborating with Egis on commercialising two biosimilar candidates across eight Central and Eastern European countries, with plans for further expansion. Furthermore, they are working with Abbott to launch several biosimilars targeting oncology, women's health, and respiratory diseases in Latin America, Southeast Asia, and Africa.

These strategic partnerships empower originator companies to sustain a strong presence in the biosimilar market while granting biosimilar developers access to well-established commercial networks and regulatory expertise.

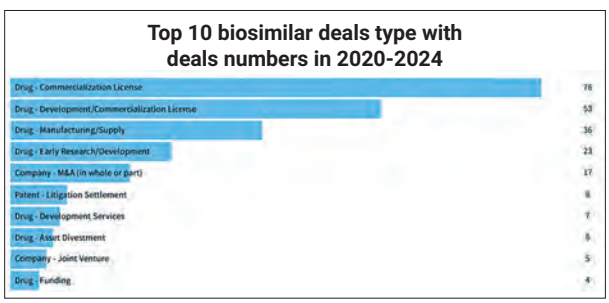
Additionally, a notable trend of mergers and acquisitions is taking place, enabling companies to consolidate resources and capitalise on synergies.



Source: Cortellis Deals Intelligence, 2025-02-07



Source: Cortellis Deals Intelligence, 2025-02-07



Source: Cortellis Deals Intelligence, 2025-02-07

Viatris, for instance, has made a strategic decision to sell its biosimilar business to Biocon, allowing it to focus on its core brand business. This consolidation is essential for achieving the scale and efficiency required to thrive in an increasingly competitive marketplace.

While larger companies are consolidating, the biosimilar market is becoming more fragmented among smaller players. Over 40 smaller companies are developing biosimilars, and many possess limited experience in the field. This fragmentation poses challenges to long-term viability and supply reliability.

The complexity and cost of biosimilar development may lead to a "biosimilar gap" where certain biologics with expiring patents lack corresponding biosimilar initiatives.

We believe multi-level roles (global, regional and by country) and diversified cooperation will enhance the ecosystem's long-term and healthy development." BS

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Trump's Executive Order Impinges WHO Ops

The United States has announced its withdrawal from the World Health Organization (WHO), a move that raises significant concerns due to the US being its largest donor, contributing nearly 18 per cent of the funding. This decision creates a major funding gap for the WHO. What immediate actions will the organisation and its member states take to address this shortfall, and how might it reshape the global leadership landscape in health governance? Let's find out.

Soon after being sworn in as the 47th President of the United States, Donald Trump signed an Executive Order to withdraw the US from the WHO, citing its mishandling of COVID-19, its failure to adopt urgently needed reforms, and its inability to demonstrate independence from the inappropriate political influence of WHO member states. This marks the second time President Trump has announced such a move, the first being during his first term in 2020, but President Joe Biden halted that decision.

Although there are still technical hurdles, countries cannot withdraw from the WHO until a year after giving official notice. Nonetheless, this has created a degree of tension for the WHO, and experts are concerned about the potential consequences. The United States, as the largest donor and key partner, plays a crucial role in funding WHO operations through both assessed contributions and voluntary funding. In the 2022–2023 biennium, the US contributed $1.284 billion, enabling the WHO and its partners to respond to emergencies, prevent disease threats from spreading, and advance vital global health priorities.

"Firstly, it's not clear what the US withdrawal means. The administration's disregard for the rule of law means it might not matter, but it is unclear whether the US can withdraw its membership and assess contributions. Voluntary contributions and coordination can and have been cut off, which will undermine both WHO's capabilities and US soft power," said ***Dr Scott L Greer, Professor of Health Management and Policy, Global Public Health and Political Science at the University of Michigan School of Public Health, Ann Arbor, USA, and Senior Expert Advisor on Health Governance to the European Observatory on Health Systems and Policies, Brussels, Belgium.***

The WHO receives its funding from two primary sources: assessed contributions from member states, which are based on a percentage of each country's gross domestic product (as agreed upon by the United Nations General Assembly), and voluntary contributions from member states and other partners. The US provides 18 per cent of the WHO's overall funding, combining both voluntary and assessed contributions. WHO's most recent two-year budget, reportedly, is $6.8 billion.

This funding structure was a key point of contention in this exit from the WHO. The order argues that the US's member dues—ranging from $100 to $122 million over the past decade, the highest of any member—are 'unfairly onerous' and disproportionate to those of other countries. For example, while China's assessment is similar to that of the US, its population is four times larger. In addition to its assessed contributions, the United States has provided substantial voluntary funding, contributing nearly $1.3 billion for the 2022-2023 biennium.

China or Europe?

There is a possibility that other member nations, particularly high-income and upper-middle-income countries, as well as philanthropic foundations, will increase their donations to help cover the shortfall left by the American withdrawal. Experts are closely watching China and Europe, as they are seen as key players who may step in to fill the funding gap left by the US.

"The likeliest outcome of a US departure is a WHO-led by Europeans. European countries and the EU make up a large part of its assessed and voluntary budget already and have a clear commitment to WHO and multilateralism as seen in their Global Health Strategy and Council Conclusions on global health. Whether Europe can and will add enough financial resources and collaborative resources such as science to make up for the US absence remains to be seen. It is a huge opportunity for any country that wants to step in and lead WHO by making up for the gap left by the United States," said Dr Greer.

Echoing similar sentiments, ***Lakshmy Ramakrishnan, an Associate Fellow with ORF's Centre for New Economic Diplomacy, India*** said, "Member states such as Germany or China could step up to fill the void. The void could also be filled by philanthropies. However, it will be highly unlikely for a single major philanthropy to address the funding gaps, expertise, and technical workforce that the US brought into the WHO. A consideration to remember is that the US has ceased funding to other organisations as well - notably, the dismantling of USAID. This means that - at a global level - an appraisal of global health priorities as well as resource allocation would need to take place before countries and philanthropies can take a call on contributions to the WHO."

Opportunity for the Global South?

There has been a long-standing notion that emerging economies could increase their contributions to multilateral development organisations. In this case, the US withdrawal from the WHO serves as an opportunity for BRICS and the Gulf countries to fill this vacuum (financially and in terms of global health leadership). Public health experts from member states can be sent to support the WHO as well to fill in the technical expertise and workforce gaps. This would only strengthen global health collaborations.

"The upheaval in global health could serve as an impetus to reshape global health where the voices of the Global South can come into the foray. The US has consequently withdrawn from the talks on the pandemic treaty. Aside from the need for structural reforms (transparency and accountability) within the WHO, issues outside of WHO including vaccine hoarding, inequity, the lack of support for a TRIPS waiver during the pandemic, and issues on the sharing of biological data still need deliberation and negotiation," said Lakshmy.

It also brings up an opportunity for Global PPPs (like Gavi) to take a more pronounced and proactive role in global health governance. Their efforts have already been recognised but we may be heading towards an era of lesser dependence on traditional international organisations (e.g. WHO) for catering to our health needs. Again, it is not unclear how this will pan out since the WHO is a nodal point for surveillance, etc.

"Health efforts also form a part of diplomacy and this is often overlooked in world politics. Especially in times when conflicts and naturally occurring disasters and outbreaks are occurring, health assistance is a valuable diplomatic tool. It forms a part of countries' security architecture. So, another line of thought is that regional blocs could have more of a proactive role in acting as regional health security providers. For instance, the African CDC declared the recent mpox outbreak as a public health emergency before the WHO declared it as a PHEIC. In similar ways, the EU, India in South Asia, and Australia in the Indo-Pacific can strengthen their collaborations on tackling health threats. Regional health security agendas in a multipolar world could be fostered. This would be vital as tackling (cross-border health threats) emerging and re-emerging infectious diseases and neglected tropical diseases require a One Health approach and this requires sustainable collaborative efforts," said Lakshmy.

It wouldn't be out of place to revisit why the WHO was formed and to what extent it has succeeded in its objectives without compromising on medical ethics, political upheavals, socio-economic impacts and conflict of interest/s in forming global policies. President Trump's decision could be debated by experts, both pro and against this historical move, but, as with any organisation, such events could be a trigger for a rejig of WHO's operations, policies and cherished objectives.

While the WHO is not without flaws, its success in eradicating diseases like smallpox, polio, and others highlights the crucial need for global cooperation. Diseases don't recognise borders, and it's imperative that countries rise above politics to safeguard the healthcare of millions worldwide. BS

Ayesha Siddiqui

“Biotech sector in Taiwan moves fast, making it easier to pivot and innovate”

« **Vivian Ling,** Chief Executive Officer & Chief R&D Officer, Caliway Biopharmaceuticals, Taiwan

Caliway Biopharmaceuticals has recently announced the completion of its initial public offering (IPO) and up-listing from the Emerging Stock Market to the Taipei Exchange (TWSE-6919). The round raised approximately $206 million (NT$6.4 billion), marking it the largest IPO in Taiwan's biotech industry history and valuing the company at nearly $3 billion. The company is poised for a transformation in 2025, advancing its groundbreaking clinical programmes and strengthening its global market presence. Following its recent record-breaking IPO, BioSpectrum Asia took an opportunity to speak with Vivian Ling, Chief Executive Officer & Chief R&D Officer, Caliway Biopharmaceuticals to explore their innovative contributions in biopharmaceuticals. ***Edited excerpts:***

Which products are currently under development?

2025 will be a defining year for Caliway as we push ahead with key clinical advancements and corporate milestones, bringing CBL-514 closer to market. CBL-514, a first-in-class small-molecule drug designed to selectively induce adipocyte apoptosis, provides a non-invasive alternative to liposuction for non-surgical fat reduction in medical aesthetics. We are preparing to secure IND approvals for two pivotal Phase 3 studies from the US FDA and Health Canada, a critical step in advancing CBL-514 as the world’s first investigational drug for large-area localised fat reduction. Beyond fat reduction, we’re also submitting a Phase 2 IND application for a new indication focused on improving body weight rebound, expanding CBL-514’s potential applications.

In Q1, Caliway announced positive Phase 2b study results for CBL-514 (0205 Study), the second and final Phase 2b before moving into Phase 3. In Q2, we are preparing for regulatory discussions with the FDA (EOP2) and EMA to align on the next steps for CBL-514’s late-stage development.

A key focus in Q4 will be completing patient enrollment for the Phase 2b study of CBL-514 in Dercum’s Disease (CBL-514 0202DD). CBL-0202DD is being developed as a potential first-in-class therapy for Dercum’s Disease, a rare and painful condition, and has already been granted Fast Track Designation by the FDA and Orphan Drug Designation by both the FDA and EMA. In the early-stage pipeline, CBA-539 offers a novel approach to hyperpigmentation and skin ageing by inhibiting melanin production and transmission, reducing dark spots and evening skin tone, while also stimulating collagen production to improve skin elasticity and firmness for natural, long-lasting results. Expanding into therapeutic applications, CBL-0201OB targets post-weight loss fat accumulation in combination with GLP-1, with a Phase 2 IND submission planned for Q4 2025.

On the corporate front, we are moving forward with a stock split to enhance market liquidity and investor engagement. Additionally, Caliway is now part of the MSCI World Small Cap Index, originally a Q4 goal further strengthening our global investor presence.

In October 2024, we completed our IPO, raising $206 million, making it the largest IPO in Taiwan’s biotech industry history and positioning us among the top biotech IPOs in the US in 2024. This strong financial foundation provides the necessary resources to advance CBL-514 into global pivotal Phase 3 studies, explore additional indications, and further expand our pipeline.

How do you plan to utilise the funds raised from your recent IPO to advance R&D?

We are strategically deploying IPO funds to accelerate clinical development, expand global partnerships, and strengthen commercialisation efforts. Our key areas of investment include CBL-514 Phase 3 Studies. A significant portion of the funds is being directed toward launching pivotal global multi-centre Phase 3 studies for CBL-514, ensuring a smooth regulatory pathway in key markets. Focusing on new indications development, we are expanding CBL-514's applications beyond fat reduction by advancing studies for Dercum's Disease and weight rebound prevention, broadening its potential.

To leverage international licensing and investment experts, we are actively engaging with global investment and licensing professionals to expedite partnership negotiations, increase visibility among potential collaborators, and secure the most favourable commercialisation deals.

For clinical collaboration with KOLs and investigators, we are strengthening relationships with renowned clinical researchers to expand study participation, enhance scientific credibility, and increase visibility in international markets.

We are also expanding global business development and market positioning; and engaging global pharmaceutical companies for licensing and partnerships. We are actively negotiating potential global licensing agreements discussions and strategic partnerships to drive CBL-514's commercial success.

We are further strengthening our presence at key global industry events to connect with strategic partners and investors by participating in global industry conferences.

Most recently, we participated in IMCAS 2025 in Paris, where we presented the advancements in clinical progress. These efforts maximise our growth potential, drive regulatory approvals, and ensure long-term commercial success.

Could you tell us about strategic partnerships or licensing agreements with other pharmaceutical companies, key to accelerating the development and commercialisation of your products?

Strategic partnerships are a key driver of Caliway's growth. We are actively engaging with leading pharmaceutical companies for licensing and co-development opportunities to accelerate CBL-514's commercialisation. We are also deepening industry connections through key industry events, including BIO, IMCAS, AMWC, JP Morgan Healthcare Conference, and the World Orphan Drug Congress, ensuring we stay at the forefront of global biotech and aesthetic medicine collaborations. These partnerships will be crucial in accelerating product commercialisation and maximising CBL-514's global impact.

What are your strategies for expanding the market reach of CBL-514, especially in regions like Taiwan, China, Korea, and Southeast Asia?

We are executing a multi-faceted market entry strategy to ensure a structured and phased approach to regulatory approvals and market commercialisation. CBL-514 is a 505(b)(1) first-in-class small-molecule drug designed to address an unmet need in non-surgical fat reduction. Given its innovative mechanism of action and strong clinical data, our primary entry strategy is to focus first on regulatory approvals in the US, our key reference market. Once established, we will gradually expand into additional key regions, including Asia. We are actively engaging with global pharmaceutical companies for potential licensing and other strategic partnerships to accelerate commercialisation. Our pivotal global Phase 3 studies will further strengthen CBL-514's market valuation and licensing potential, paving the way for successful entry into international markets.

Focusing on the Taiwan biotech market in particular, what are the existing challenges and opportunities?

Biotech development comes with its challenges. Regulatory processes can be complex, which may impact drug development timelines. Another key challenge is the shortage of specialised R&D talent, particularly in pharmaceutical sciences and clinical research. That said, Taiwan has significant advantages that make it an attractive hub for biotech innovation. Taiwan's healthcare system is highly advanced, cost-effective, and well-structured. The high density of hospitals, cutting-edge medical technology, and experienced medical professionals make it an ideal environment for research, especially in niche indications and rare diseases. Taiwan's market agility and adaptability also set it apart. The biotech sector here moves fast, making it easier to pivot and innovate. Additionally, many global pharma companies use Taiwan as a strategic entry point, launching products before expanding into larger markets. With its strong medical ecosystem, advanced infrastructure, and strategic position in the region, Taiwan offers a unique and competitive environment for biotech growth and drug development. BS

Vrushti Kothari
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“Personalised medicine is now a reality, not just an aspiration”

« **Antoinette Gawin,** President and CEO, Terumo Blood and Cell Technologies, Japan

Terumo Blood and Cell Technologies, (a subsidiary of Terumo Corporation, Japan) is at the forefront of advancing blood- and cell-based therapies. In an interview with BioSpectrum Asia, Antoinette Gawin, President and CEO,Terumo Blood and Cell Technologies outlines the company’s current strategy, key projects, the importance of the APAC region, and her perspective on evolving trends in the industry. ***Edited excerpts:***

Can you share how the company’s focus has evolved since its founding, and what areas are central to Terumo's current strategy?

We are part of Terumo, a global company that has been contributing to society through healthcare for over 100 years. Headquartered in Japan, our name comes from our first innovation - the humble thermometer. Our division, Terumo Blood and Cell Technologies (Terumo BCT), began as a Colorado-based startup 60 years ago, innovating around equipment that collects and processes our fragile, yet powerful, blood and cells.

Today, our portfolio has grown beyond equipment, providing data management, optimisation services and clinical expertise to expand the application of transfusion medicine and increase access to the foundational power of blood as an essential medicine. This includes expanding therapeutic applications of our current filtration technology, enabling treatment of cancers with stem cell transplants, while shaping the source materials to fuel plasma-derived therapies and emerging cell therapies that address rare diseases.

What major trends in the healthcare industry do you see shaping the future of your product lines and how is Terumo adapting to these changes?

Personalised medicine is now a reality, not just an aspiration. Each human has unique blood and a unique genetic profile. As we learn more about specific diseases and patient populations, our apheresis technology can filter blood for genetically inherited anomalies, such as the sickle cell-shaped red cell in those with sickle cell disease, then replace it with a healthy red blood cell. We can tailor the collection of cells to improve the success rate of cell therapy or tailor the focus of starting material needed to discover a permanent cure. As we deepen our knowledge of genomics, proteomics and the function of specific cell types, we can filter even more selectively and tailor treatments to a specific patient.

Additionally, we have built a sophisticated Patient Access function. This acknowledges our philosophy that great technology that doesn’t get into the hands of patients is a waste. Patient Access connects clinical, health economics and patient challenges to influence reimbursement frameworks around the world. This may include connecting diverse stakeholders, from patient advocates to government entities who can mobilise funding sources, influence standards of care, and create awareness around rare diseases and underserved populations.

Sickle Cell disease is one example, where existing therapies can prevent chronic pain and, in some cases, unnecessary death. We’ve worked with stakeholders across the UK health system to update treatment guidelines and expand investment by £1.5 million. This broadened access to red blood cell exchange (RBCx) therapy and brought care closer to patients.

Can you discuss the company’s approach to tailoring solutions for diverse healthcare needs across different regions?

We prioritise understanding the complexities of the local healthcare ecosystem. Healthcare remains a uniquely local delivery system, influenced heavily by local operating practices, reimbursement schemes and the diverse needs of the patient populations.

For example, in a mature healthcare market, access to safe blood is taken for granted. Those suffering trauma or postpartum bleeding don't consider where the blood used in their emergency transfusion is coming from. Contrast that with countries where one is required to obtain a prescription for blood and pay in advance, and others where family members and likely donors are asked to be present during treatment in case blood is required.

Ninety per cent of us will need blood at some point in our lives. We work closely with our customers to share best practices from blood donation campaigns worldwide – from 'flash mobs' in India to NASCAR campaigns in the US.

Our innovations include automating the processing of blood, currently performed manually in many locations. This is a game changer as it increases the yield of each donation, creates a consistent product and eliminates the intensive labour required to produce a viable product.

We have applied this concept to our innovations for cell collections and cell therapy manufacturing. Transitioning from manual lab activities to a closed system automation enables consistency and predictability, two elements critical to gaining regulatory approval for new drugs, and foundational to scaling the delivery of these emerging therapies.

We continue to invest in local manufacturing and supply chains, such as our recent investment in Hangzhou which brings more innovations fit for purpose to the Chinese market.

Asia is increasingly being recognised as a key player in the global healthcare market. What role does Terumo see for Asia in its global strategy, and what opportunities does the region present?

Our heritage as an Asian company encourages long-term investment, building solutions to shape standards in the industries we serve. It is embedded in our mission of Contributing to Society through Healthcare.

Just as we led the transition from manual to automated blood processing, we have automated key elements of the cell collection and manufacturing process. Our closed system allows consistency and repeatability, critical as these therapies begin to scale.

Diverse immune cell therapies technologies, including CAR-T, TCR-T, and CAR-NK, are rapidly expanding across Asia, with China leading in 40 per cent of global clinical trials and approvals. Cost-effective, scalable solutions must be tailored to address the diversity of local economic conditions, regulatory frameworks, and patient accessibility needs. We streamline CAR-T production through a fast, simple workflow, enabling the delivery of high-dose, high-quality cells. Currently, this unique protocol that we co-developed with Eureka Bio is being implemented by early adopters in China.

Therapies from mesenchymal stem cells (MSCs) include applications in regenerative medicine, immune modulation, and inflammatory diseases. In Korea, a partner recently integrated our self-contained, automated Quantum platform into its GMP manufacturing standards to produce MSC-based therapies.

Additionally, a leading organisation has incorporated the Quantum platform into its MSC training courses to support Korean biotech companies, providing trainees with hands-on experience using an automated, scalable, GMP-compliant solution.

Can you highlight some recent advancements or upcoming projects that exemplify innovation?

Despite huge growth in plasma-derived therapies, drug developers struggled to provide sufficient, high-quality source plasma. We leveraged our core competencies to launch the Rika Plasma Donation System. This includes a faster plasma collection device, allowing a donor to donate in 35 minutes, and a digital ecosystem that simplifies the reporting, quality systems and tracking for a plasma centre manager, as well as tools to remotely monitor and update a broadly distributed fleet of devices.

In cell therapy, our portfolio supports the journey of a cell —from patient collection to modification and manufacturing, then reinfused to the patient. As our Optia platform technology is the gold standard for cell collections, many partners reach out to explore new therapeutic applications such as acute kidney injury and sepsis. Our willingness to collaborate and build for the long term distinguishes us in the market. BS

Ayesha Siddiqui

ADCs on the rise: A Trojan Horse Race for Patients

« **Léo Marx,**
Medicinal Chemistry & Bioconjugation Manager, Debiopharm

« **Dr Marianna Muller,**
MD/PharmD, Senior Medical Director, Debiopharm

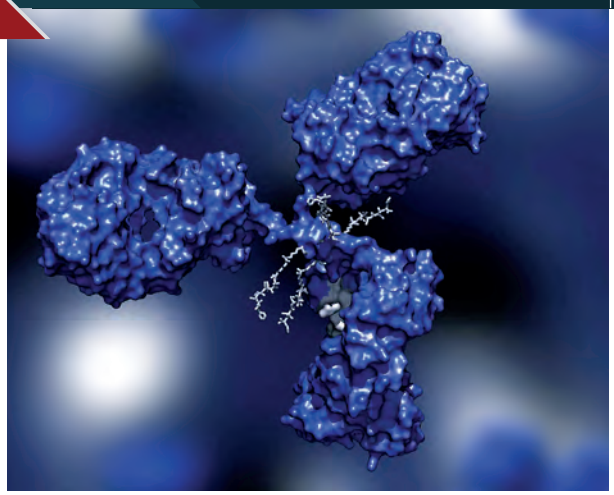
Antibody-Drug Conjugates (ADCs) have emerged as a major therapeutic approach creating new opportunities for a range of cancer treatments. The recent scientific and clinical progress in the ADC field underscores its importance for ongoing research.

The first Antibody-Drug Conjugate (ADC) prototypes were developed more than 55 years ago by researchers of the Institut de Chimie des Substances Naturelles (Institute of Chemistry of Natural Substances, ICSN) who showed that chemotherapies such as Methotrexate covalently linked to polyclonal antibodies could deliver immunoglobin conjugates with improved cytotoxicity in vitro. It wasn't until the year 2000 that the modality achieved clinical validity with the approval of Mylotarg, an ADC based on a DNA alkylating payload. This milestone triggered an ever-growing diversity of clinical programmes, which first led to the emergence of antitubulin ADCs from 2010.

Despite the early successes of auristatin and maytansinoid-based ADCs (Kadcyla and Adcetris), the technology also suffered several setbacks leading to project discontinuations. Later on between 2019 and 2020, the approval of Padcev, Enhertu, and Trodelvy sparked renewed optimism for the therapeutic potential of ADCs. These precisely-designed ADCs have shown promising clinical outcomes, significantly reducing the risk of disease progression or death in breast cancer patients. Despite these advances and successful treatments such as Kadcyla and Enhertu, challenges persist due to high discontinuation rates across multiple payload mechanisms.

Off-target toxicity in ADCs often necessitates dosage reductions, potentially leading to less effective cancer treatment. Traditional methods of repurposing established targets and linker-payload combinations frequently fall short. To balance efficacy and safety, careful ADC design with better target selection, improved linkers, and optimised payloads is essential. Learning from past experience can guide the development of ideal clinical candidates. The evolution of ADCs has been driven by site-specific conjugation technologies and innovative payload-linker strategies over the past two decades. Addressing high discontinuation rates requires a data-driven approach that leverages research data and technological advancements for developing next-generation ADCs.

The recent approval of Dapotomab-Deruxtecan confirmed that only a few payload modalities have led to clinical success despite the investigation of a wide range of cytotoxins, while the development of linker and conjugation strategies has played a subtle role in ADC elevation. For example, the incorporation of protease cleavable units in Vedotin and Deruxtecan linkers has allowed the release of cell permeable active entities to treat solid tumors with heterogeneous levels of expression of the targeted receptor. Site conjugation selection and linker solubilisation also represent two relevant ADC design strategies in view of the key role they play in maintaining hydrophilicity while containing unspecific ADC uptake associated with higher clearance and toxicity.



To stay ahead of the game in this "trojan horse" race, pharmaceutical companies focus on new target identification to bring differentiated ADCs to the clinic and eventually to the market for patients. Once a promising target and an associated internalising antibody have been identified, it is essential for research scientists to make thoughtful design decisions before moving new ADCs into preclinical and clinical phases. During that stage, it is also crucial to match key properties between the antibody and the linker-payload, such as, matching the receptor level expression and the overall payload potency (modulable with the Drug-Antibody Ratio [DAR]). The expression profile of the antibody target in healthy tissues can also influence the selection of the toxin class. ADC discovery groups need a variety of linker-payload and conjugation approaches to iteratively design, test and optimise ADC lead molecules.

The major pharmaceutical players who have recently joined the field of ADCs address this challenge through key external acquisitions aiming to simultaneously in-license a first ADC asset ready to enter their pipeline along with an ADC technology platform, which supports the growth of new ADC design. Several ADC-focused biotech companies have developed their internal linker chemistry platform, while some antibody-focused companies can choose to rely on strategic partnering to position assets in the field of ADCs. At Debiopharm, these strategies have enriched our ADC pipeline and will enable other companies to use our linker platform to develop new assets.

After intense exploration of linker possibilities, payload classes and novel targets, it is exciting to see that researchers remain creative and innovative to broaden the possibilities that bio-conjugates will offer to patients. In the early 2020s, ADCs derived from bi-specific antibodies were often perceived as complex and risky, while more than 100 preclinical programmes in the field are currently active and dozens have reached clinical evaluation. Other bioengineering approaches focus on antibody fragments, which hold the promise to improve conjugate diffusion through the tight endothelial barrier to improve conjugate penetration in tumoral tissues.

Innovative linker and payload design also aim to develop new ADCs beyond traditional cytotoxic payloads. For example, immunostimulants such as toll-like receptor (TLR) agonists are being investigated to activate immune cells present in the tumor micro-environments. Others are exploring protein degrader conjugates, which should facilitate a potent yet more targeted attack on cancer cells, reducing potential toxicities. Some are even considering ADCs with two cytotoxins, which, for example, could bypass certain resistance mechanisms.

Another important and promising development strategy is the combinability of ADCs with other therapeutic modalities. ADCs are currently being investigated in combination with chemotherapy, molecularly targeted agents, radiotherapy, immunotherapy and endocrine therapy in both preclinical and clinical studies. Combination therapies typically decrease the chance of drug resistance and can use two agents with different mechanisms to achieve improved treatment outcomes. ADC monotherapies may not be effective enough for certain tumor types, hence the increasing interest in combination therapies. These trials mainly aim to advance their usage into earlier stages of disease or therapy lines. The recent success of the combination of Keytruda and Padcev in bladder cancer underscores the potential effectiveness of such clinical strategies.

Ultimately, ADCs have emerged as a major therapeutic approach creating new opportunities for a range of cancer treatments. The recent scientific and clinical progress in the ADC field underscores its importance for ongoing research. The development of ADCs can be enhanced through a better understanding of novel strategies, evaluation of safety and efficacy, identification of success and failure patterns, and optimisation of R&D decisions. Antibody engineering and site-specific conjugation technologies also show potential to enhance the therapeutic index of preclinical studies. A comprehensive approach combining careful target selection with optimisation of the antibody, linker, and payload components tailored to specific diseases shows promise for future approvals. Collaborations between pharmaceutical companies, biotech firms, and academic institutions are accelerating innovation in ADC development while mitigating inherent risks. BS

Rise of ADCs: Expanding Applications and the Road to Commercialisation

« **Benjamin Hein,** Head of Life Science Services, Merck KGaA, Darmstadt, Germany

The development of antibody-drug conjugates (ADCs) has advanced significantly in the biopharmaceutical sector; in the last five years, eight of the 14 ADCs that are currently approved have obtained regulatory approval. The quantity of pre-clinical to commercial ADC compounds in the innovative modality pipeline increased by more than 25 per cent year over year, according to a market trend. ADCs have the potential to transform targeted medicine and give patients everywhere new hope with further development and wise funding.

Over the past decade, interest in Antibody-Drug Conjugates (ADCs) has surged, driven by their promise for patients, advancements in research, clinical adoption, and market expansion. It is estimated that the global market for ADCs could reach upwards of more than €24 billion by 2030, according to a Grand View Research report.

While initially focused on oncology, ADC development is now extending into non-cancerous diseases, such as cardiovascular and inflammatory diseases, marking a significant milestone for the biopharmaceutical industry and an opportunity for further growth of the modality. A year-over-year market trend reveals that the number of pre-clinical to commercial ADC molecules in the novel modality pipeline grew more than 25 per cent.

Because of their unique structure and mechanism of action, ADCs require special regulatory considerations when compared to biologics and small molecule drugs. Still, developers are finding success amidst this complex regulatory landscape, underscoring the growing potential of these bioconjugates. A significant portion of ADC projects are outsourced to contract development and manufacturing organisations (CDMOs) and with the continued expansion of pipelines, this trend is likely to continue.

Growing Impact of ADCs

ADCs represent a transformative approach to oncology, enabling targeted therapies that minimise damage to healthy tissues. They consist of a monoclonal antibody, a chemotherapy drug (payload), and a chemical linker that ensures precise drug release within target cells. This approach enhances efficacy while minimising off-target toxicity, making ADCs a more precise alternative to traditional chemotherapy. As the market for this novel modality grows and the medical community adopts them as first-line treatments, it may mean that fewer patients need invasive treatments like chemotherapy and radiation that cause significant side effects.

The biopharmaceutical industry has witnessed remarkable growth in ADC development, with eight of the 14 currently approved ADCs receiving regulatory approval in the past five years. Our Life Science business at Merck KGaA, Darmstadt, Germany, enables customers with comprehensive solutions along the entire journey from molecule to medicine with more than 15 years of experience in ADC supply, contributing to the production of nearly 50 per cent of the commercially available ADCs today. Our expertise extends to commercial-scale production of linker payloads, as well as biologics manufacturing.

Navigating Global Regulatory Landscape

ADCs combine the complexity of biologics manufacturing with the environmental controls required for highly potent compounds. This combination necessitates a holistic view of ADC

manufacturing and controls to build a detailed roadmap for commercialisation.

ADCs must also comply with stringent regulatory requirements from national-level regulatory agencies, like the US Food and Drug Administration (FDA), European Medicines Agency (EMA), and Health Sciences Authority (HSA), which demand high levels of characterisation, impurity profiling, and adherence to good manufacturing practices (GMP). Robust analytical methods are required to assess purity, potency, and stability, adding complexity to manufacturing—particularly at a commercial scale.

As more ADCs advance to market, there is an increasing need for CDMOs with expertise in executing late-stage studies to support regulatory filings. CDMOs investing in commercial-scale ADC manufacturing must establish efficient supply chains and implement advanced facility and process controls to ensure product quality, security, and scalability.

Ensuring Robust ADC Manufacturing

To start the journey of commercialisation, determining what is required and expected for commercial ADC manufacturing includes control strategies, risk assessment, process characterisation and validation. Extensive preparation leads to getting the approval to manufacture commercial batches.

Before these therapies can reach patients, the world's leading researchers and therapeutic manufacturers must have access to state-of-the-art tools, services and expertise to develop these novel modalities. A strong control strategy, defined as a comprehensive plan that ensures the consistent quality and safety of the final product throughout its lifecycle, is essential for ADC commercialisation, from process development to regulatory approval.

Key considerations in ADC process control include:

- **Microbial Control:** Manufacturing a biologic requires a well-defined control strategy for endotoxins and bioburden. Consider an approach that involves setting in-process endotoxin acceptance criteria based on the worst-case raw material input and historical process data.
- **Quality by Design (QbD):** Once downstream conjugation and purification are optimised and scaled, quality by design (QbD) is used to gain a deep understanding of the inputs and outputs of the process and establish controls to ensure critical quality attributes (CQAs). A step attribute matrix (SAM) is the first formal step in understanding how material inputs and unit operations of the process may affect product quality attributes.
- **Process Characterisation:** A key aspect of process characterisation is qualifying the scale-down model. This model ensures that the bench-scale model is predictive of the GMP scale; if it isn't, the full-scale process can't be scientifically supported with data generated at the small scale.
- **Commercial Control Strategy:** As part of the validation master plan scoping, additional risk assessments needed for commercial manufacture should be identified, along with existing risk assessments which should be reviewed and updated to support additional controls for commercial manufacture.
- **Regulatory Readiness:** Subject matter expert-led inspections focus on control strategies and facility robustness. Walk-throughs and mock audits are invaluable for helping subject matter experts become comfortable with the audit process and know what to expect.

A well-defined control strategy—spanning microbial control, risk assessments, and process validation—lays the foundation for successful commercialisation, ensuring efficient, high-quality production of life-saving therapies.

Future Outlook for ADCs

The future of ADCs is marked by continuous innovation, expanded clinical applications, and improved manufacturing scalability. Advances in linker technologies and novel payloads are enhancing precision and efficacy, making ADCs more effective against resistant cancers. Beyond oncology, researchers are exploring ADCs for autoimmune and infectious diseases, broadening their therapeutic potential. Additionally, the integration of ADCs with immunotherapies is showing promise in improving patient outcomes.

As demand grows, improvements in manufacturing processes and scalability will be critical to ensuring broader accessibility and commercial success. With continued advancements and strategic investments, ADCs are poised to revolutionise targeted therapy, offering new hope for patients worldwide.

To navigate the increasingly complex regulatory landscape, partnering with an experienced CDMO that understands evolving compliance requirements is essential. Collaborating with a trusted partner early in development can streamline regulatory approvals, optimize production and mitigate risks, ultimately accelerating the path to commercialization and expanding access to patients in need. BS

How Degrader-Antibody Conjugates Are Transforming Precision Medicine for Oncology & Beyond

« **Dr Suk Namgoong,** Lecturer, Chungbuk National University and Advisor, Orum Therapeutics, Korea and USA

Targeted cancer therapy has advanced significantly with the creation of Degrader-antibody conjugates (DACs). The shortcomings of conventional ADCs are addressed by DACs, which combine the specificity of antibodies with the special capacity of protein degraders to eradicate important oncogenic drivers.

Degrader-antibody conjugates (DACs) represent a natural evolution in targeted precision medicines for oncology and other indications, building on the advances of Antibody drug conjugates (ADCs) while addressing their key shortcomings. DACs use targeted protein degraders (TPDs) as their payload—combining the precision of antibodies with the catalytic potential of protein degraders. Unlike ADCs, which release a one-time burst of cytotoxic activity upon internalisation, DACs deliver TPD molecules that trigger the sustained elimination of oncogenic proteins. When the antibody binds to its target antigen on a tumor cell, the conjugated protein degrader is internalised and recruits components of the ubiquitin-proteasome system (the cell's protein recycling machinery) to mark specific proteins for destruction. This dual-selectivity mechanism—tumour-specific antibody targeting coupled with cancer-specific protein degradation—offers an unprecedented level of precision, significantly reducing off-target effects and expanding the therapeutic window.

Overcoming the Limitations of Traditional Modalities

While small molecule TPDs have shown promise in both preclinical and clinical studies, they come with challenges. Their systemic distribution can lead to off-target protein degradation in healthy tissues, and their high molecular weights (often exceeding Lipinski's rule of five guidelines) complicate oral bioavailability and pharmacokinetics. DACs overcome these issues by exploiting the targeting power of antibodies, ensuring that the protein degrader is delivered directly to cancer cells. This targeted approach minimises systemic exposure, reduces the necessary dose, and potentially lowers systemic toxicity.

Illustrating DAC Innovation

A pioneering example of DAC development comes from Orum Therapeutics with ORM-6151 from the company's Dual-Precision Targeted Protein Degradation (TPD²) technology. Designed to target acute myeloid leukemia (AML), ORM-6151 combines an antibody directed against the CD33 antigen with a novel protein degrader that induces the degradation of GSPT1—a protein essential for regulating protein synthesis. In preclinical studies, ORM-6151 demonstrated robust anti-tumor activity while maintaining a favorable safety profile compared to conventional small molecule degraders. This breakthrough attracted significant commercial interest, with Bristol Myers Squibb acquiring rights to the ORM-6151 programme in November 2023. In addition, Vertex Pharmaceuticals and Orum established a collaboration in July 2024 to use Orum's TPD² technology for developing novel targeted conditioning agents for use with gene editing. This collaboration underscores the broader therapeutic potential of DAC technology beyond oncology applications.

A Call to Innovation

In summary, the development of DACs marks a significant evolution in targeted cancer therapy. By integrating the specificity of antibodies with the unique capability of protein degraders to eliminate key oncogenic drivers, DACs offer a novel and promising solution to the limitations of traditional ADCs. Early clinical candidates like ORM-6151, coupled with strategic commercial partnerships, provide compelling evidence that DACs could reshape the landscape of precision oncology. As research continues and more clinical data emerge—including efforts to target proteins beyond GSPT1—stakeholders are encouraged to support and explore this innovative modality. DACs have the potential to broaden therapeutic options for patients and set a new standard in the treatment of cancer and other significant diseases. BS

Empowering Women in STEM: Viet Nam's Journey Towards Innovation and Equality

2025 marks the 10th anniversary of the International Day of Women and Girls in Science (IDWGS) (observed on February 11) and the 30th anniversary of the Beijing Declaration and Platform for Action, two significant milestones in the global effort to promote gender equality and women's empowerment. Recognising the importance of gender inclusivity, Viet Nam has taken major policy steps to empower female researchers and entrepreneurs. By investing in education, policy reforms, and celebrating the achievements of women scientists, the country is setting a global example for inclusive development.

« **Dang Hoang Giang,** Ambassador Extraordinary and Plenipotentiary, Permanent Representative of Viet Nam to the United Nations

This year marks the 10th anniversary of the International Day of Women in STEM, highlighting a decade of progress in closing gender disparities in science, technology, engineering, and mathematics (STEM). While there have been significant global advancements, women remain under-represented in STEM, particularly in leadership roles and high-tech industries.

Despite making up 49.7 per cent of the global population, according to UNESCO, only 28 per cent of researchers worldwide are women, with even lower numbers in leadership positions and emerging sectors like AI and biotechnology. In Asia, the gender gap is even more pronounced. India, for example, reports that only 14 per cent of STEM academic positions are held by women, according to IWWAGE report

One key challenge is the "leaky pipeline" phenomenon, where women leave STEM careers at higher rates due to cultural biases, workplace inequities, and family responsibilities. This issue is not just about representation but also economic loss. According to the Asian Development Bank, gender gaps in STEM cost the Asia-Pacific region an estimated $42 billion annually, slowing economic growth and innovation. Furthermore, homogeneous teams in fields like biotechnology and pharmaceuticals risk overlooking solutions that address diverse populations, limiting breakthroughs in precision medicine and public health.

According to a McKinsey Global Institute report it is estimated that achieving gender parity in STEM could boost global GDP by $12 trillion by 2030, reinforcing the urgency of inclusive policies to increase women representation in STEM sectors, both in quantity and quality.

Despite these challenges, Viet Nam stands out as a regional leader in women's participation in STEM. According to the Ministry of Science and Technology, Vietnamese women make up 47 per cent of the country's Research and Development (R&D) workforce—significantly higher than the global average. However, this strong participation has yet to translate into proportional leadership roles, as only 26 per cent of research projects are led by women. This disparity highlights the need for targeted efforts to ensure greater representation of women in decision-making positions within STEM fields.

Recognising the importance of gender inclusivity, Viet Nam has taken major policy steps to empower female researchers and entrepreneurs. Resolution 57 (December 2024) and the National Assembly's Science & Technology Policy (February 2025) aim to foster gender equality in STEM leadership and research. These policies complement the National Strategy for Science, Technology, and Innovation (STI) Development for 2030, which prioritises expanding women's participation in technology, research, and leadership. With these frameworks, Viet Nam is positioning women at the centre of its goal to become a high-income, innovation-driven economy by 2045.

Vietnamese women have played a pivotal role in advancing STEM both nationally and globally, demonstrating expertise in fields such as nanotechnology, biomedical research, artificial intelligence, and environmental science. Several distinguished scientists have led groundbreaking innovations, including:

- Associate Professor Ho Thi Thanh Van

– A leading researcher in fuel cell technology, contributing significantly to sustainable energy solutions.

● Dr Tran Ha Lien Phuong – A biomedical engineer recognised with the L'Oréal-UNESCO Women in Science Award for her pioneering work in nano-drug delivery for cancer treatment.

● Professor Dr Nguyen Thi Kim Thanh – A nanotechnology expert awarded the Rosalind Franklin Medal in the UK for her groundbreaking research in biomedical nanomaterials.

● Professor Dr Le Minh Thang – Head of the Department of Organic and Petrochemical Technology at Hanoi University of Science and Technology, developed an affordable catalytic converter that transforms exhaust gases into harmless components and received the Kovalevskaya Prize in 2022.

● Associate Professor Nguyen Minh Tan – Director of the Institute for R&D of Natural Products (INAPRO-HUST), invented Juice Evaporation Technology (JEVA) and was honoured with the Best Innovation Award in the first Hitachi Global Foundation Asia Innovation Award in 2020. In 2025, she will be awarded the Kovalevskaya Prize.

● Dr Le Thai Ha – Recognised among the top 100,000 most influential scientists worldwide, she has published over 70 research papers in leading international journals across energy economics, environmental economics, and applied economics.

And there are many more. These women exemplify Vietnam's growing influence in STEM, driving scientific advancements that contribute to both national progress and global innovation.

Viet Nam has demonstrated a strong commitment to STEM education, beginning with the General Education Sector Development Program (2017), which integrated STEM principles into all levels of education. While a formal National Program on STEM Education has yet to be established, several key initiatives are already driving progress:

● Women in STEM Leadership Program (Đà Nẵng, 2016) – A mentorship initiative that supports female STEM students, equipping them with the skills needed for careers in high-tech industries.

● ASEAN-UK SAGE & British Council Scholarships (2024) – Five Vietnamese women were awarded fully funded master's degrees in STEM fields in the UK, enhancing Vietnam's representation in the global STEM landscape.

● STEM Teacher Training Program (Bắc Ninh, 2024) – A pilot initiative focused on increasing gender inclusivity among female STEM educators, fostering supportive learning environments for young girls.

These initiatives are empowering women with the skills and opportunities necessary to thrive in emerging industries such as artificial intelligence, semiconductors, and clean energy, positioning Viet Nam as a leader in STEM innovation.

Viet Nam has made remarkable progress, increasing female university enrollment in STEM from 30 per cent to 54.6 per cent between 2006 and 2020. However, challenges persist, especially in career advancement, research funding, and STEM leadership. The key challenges include:

● Limited access to career information – Many young women lack awareness of STEM career opportunities.

● Gender biases in STEM culture – Societal expectations often discourage women from pursuing careers in science and technology.

● Lack of mentorship and professional networks – Fewer female mentors in STEM limit opportunities for young women.

To overcome these barriers, Viet Nam must take a holistic and multi-faceted approach that includes:

● Expanding STEM career guidance – Implement national awareness programmes targeting girls aged 6-14.

● Increasing funding for women-led research – Ensure equal access to government research grants for female scientists.

● Strengthening industry-academia collaboration – Encourage private sector partnerships to provide mentorship and internships for female students.

● Promoting women in STEM leadership – Establish women-focused scholarships and training programs at science universities.

Viet Nam's commitment to gender equality in STEM is not only fostering innovation but also driving economic growth. By investing in education, policy reforms, and celebrating the achievements of women scientists, the country is setting a global example for inclusive development.

As Viet Nam continues its transition toward a high-income, technology-driven economy by 2045, empowering women in STEM will be critical for sustaining innovation, competitiveness, and national progress. Bridging the gender gap in STEM is not just an imperative but a pre-condition for the country's economic development. With its strong policy framework and growing participation of women in science and technology, Viet Nam offers a compelling model for other nations striving for gender equality in STEM and stands ready to strengthen international cooperation towards this goal. BS

A Wake-Up Call for International Women's Day

International Women's Day (IWD) (celebrated on March 8) has been around for over a hundred years, as have many of the issues still impacting women's advancement. Since 1911, IWD belongs to all who care about women's equality. At the current rate of progress, it will take until 2158, which is roughly five generations from now, to reach full gender parity, according to data from the World Economic Forum. Focusing on the need to Accelerate Action (theme for IWD 2025) emphasizes the importance of taking swift and decisive steps to achieve gender equality. Talking about the status of women in Australian life sciences space, the article calls for an action for better health, great businesses and a stronger economy.

« **Stuart Dignam,** CEO, MTPConnect, Australia

It is never lost on me or my team at MTPConnect that there is a paucity of funding allocated to women's health research. And by paucity, I mean an embarrassing dearth.

So the theme for International Women's Day of 'Accelerate Action' couldn't be more appropriate -- for gender and health equality.

As Australia's life science innovation accelerator, it's a theme we embrace at MTPConnect. It's embedded in our DNA.

The statistics are bleak.

On the research front, just five per cent of global R&D is allocated to women's health, with four of that five per cent focused on women's cancers, leaving just one per cent for all other conditions.

The industry perspective is just as stark.

Only 22 per cent of Australian startups are founded by women according to Deloitte Australia. Globally, from 2021 onward, the percentage of female founders has been steadily shrinking, according to Carta Inc's equity report.

Money for female founders is getting harder to come by too. Cut Through Ventures latest report into Australia's startup funding shows only 15 per cent of startup funding going to teams with at least one female founder, down from 18 per cent in 2023.

And while these startups are attracting early-stage seed funding, they are missing out on larger, later stage deals which hampers scale-up and commercial potential.

Even pitching for funds is getting harder. Blackbird Ventures data for 2024 showed just 31 per cent of the startups that pitched to its investment committee had a woman in the founding team, down six per cent from the previous year.

A gender imbalance persists in STEM (science, technology, engineering and maths) leadership roles, with just 26 per cent of senior managers and 10 per cent of CEO roles held by women (according to the Stem Equity Monitor).

Women remain underrepresented in leadership and board positions. A report by the Australian Institute of Company Directors found that only one in 10 of the top 200 listed companies are chaired by women, and that women made up only around 35 per cent of directors on ASX 200 and ASX 300 boards.

Wherever you look, there is underrepresentation and underfunding. There is gender and health inequality.

But there is also progress.

Female founders in Australia's life science sector have made significant contributions globally, leading groundbreaking research, innovative startups and transformative companies.

Companies like SpeeDx, Laronix, Opthea, Currus Biologics, Navbit, Aravax, Hemideina, Presagen (now Qubigen), Alyra Biotech, Kali Healthcare, Baymatob, Carina Biotech and SDIP Innovations come immediately to mind. They are all powered by female founders.

Accelerating action is not an academic DEI (diversity, equity and inclusion) aspiration. It's about delivering global health equality and it makes good business and compelling economic sense.

Think of the '3 Ps' framework; population,

AusBiotech to host 'The Women in Life Sciences Luncheon' on March 7

AusBiotech, a well-connected network of over 3,000 members in the life sciences, is hosting first The Women in Life Sciences Luncheon, in association with Medicines Australia in Sydney on March 7. The Luncheon will bring together over 600 leaders, changemakers, and allies to mark International Women's Day.

This year's Luncheon embraces the call to #Accelerate Action. It will spark a conversation on how the industry can tackle the systemic and persistent barriers that result in unbalanced gender representation at the highest levels of the life sciences industry —specifically in Board, CEO, and executive roles.

The 2025 Women in Life Sciences Luncheon will feature inspiring and powerful voices who will speak to why women's leadership matters, the persistent barriers that remain, and how it can be solutions focused on changing the trajectory.

The Luncheon will have a Women in Life Science Leadership Summit with dynamic discussions and skill-building opportunities. This inspiring forum will foster a unique environment of knowledge sharing, mentorship and empowerment for women at all career stages.

"In an industry dedicated to solving some of the world's most pressing healthcare challenges, we can't afford to leave any talent untapped. We know diverse teams consistently deliver better

outcomes for companies, by drawing on a broader range of perspectives, experiences, and ideas. Our 2025 Women in Life Sciences Luncheon will feature inspiring and powerful voices who will speak to why women's leadership matters, the persistent barriers that remain, and how we can be solutions focused on changing the trajectory," said Rebekah Cassidy, CEO, AusBiotech.

Rebekah will be chairing a panel discussion comprising Dr Saraid Billiards, CEO, Association of Australian Medical Research Institutes; Chris Newton, Founder, Stakeholder Capital; Naomi Edwards FAICD, Chair, Australian Institute of Company Directors; Dr Rebecca McQualter, CEO, Chimeric Therapeutics; Dr Terence Fitzsimmons, Managing Director, Australian Gender Equality Council and Christine Cockburn, CEO, Rare Cancers Australia.

participation and productivity. These are key elements of our GDP per capita.

More funding for women's health research, more female founders and more venture capital for their companies to bring more medical products to market will improve health and wellbeing, drive up population, participation and productivity - and profoundly contribute to Australia's economic growth and prosperity.

A 2024 World Economic Forum report, done with the McKinsey Health Institute, found that closing investment gaps in women's healthcare could boost the global economy $1 trillion - annually - by 2040.

Hardly niche.

In the life sciences sector, we wrestle every day with complex health and medical problems, trying to find cures, save lives and help people live better, longer.

Accelerating action for gender and health equality is not rocket science, but we do need to step-up.

There is an ongoing role for everyone across pharma, biotech, medtech, finance and venture capital, research and academia and government.

At MTPConnect, we are strengthening eligibility criteria for applicant teams to address gender balance in leadership in our accelerator programmes, as well as the non-dilutive funding we provide. This takes the onus away from individual women and places it on groups of people that have the power and resources to enact change.

We are also creating opportunities for future leaders to get more exposure to boards and corporate governance through our previous Guest of the Chair initiative and backing the Women in Leadership Development (WILD) program.

If everyone in our sector does their part, we will more quickly make progress on meeting the health needs of half the world's population, while fully leveraging the potential of Australia's female scientists, researchers and entrepreneurs - for better health, great businesses and a stronger economy.

What is your organisation doing? BS

American University in Dubai partners with University of Pennsylvania to establish new School of Medicine

The American University in Dubai (AUD) has completed a Memorandum of Understanding (MoU) to partner with the University of Pennsylvania's Perelman School of Medicine (Penn Medicine) in establishing the AUD School of Medicine in Dubai. AUD aims to boost the provision of medical education in the UAE by drawing on the expertise of Penn Medicine. The new partnership will see Penn Medicine and AUD collaborate in developing a curriculum for

a Doctor of Medicine degree programme that employs the best practices of US medical education, tailored to the needs of the region. The programme will educate and train medical students to become physicians who can deliver world-class healthcare in the UAE. Graduates of the programme will advance to be agents of change in the field, both nationally and internationally. Set in the context of the UAE national strategy to increase capacity in the healthcare sector, the AUD- Penn Medicine partnership will contribute to the rising demand for medical professionals in the country, by training the next generation of doctors.

UPES announces strategic partnership with Medical University of the Americas

The School of Health Sciences and Technology (SOHST) at UPES, a multi-disciplinary university in India, has announced a strategic first-of-its-kind partnership with the Medical University of the Americas (MUA). This collaboration marks a significant milestone in advancing medical education opportunities for aspiring doctors in India. Under this partnership with MUA, UPES will offer an accelerated pathway into medical education with admissions to the prestigious 5-Year BSc/ MD undergraduate programme, with applications commenced in February 2025 for August 2025 intake. The programme consists of one year at UPES, followed by two years of pre-clinical education at MUA's campus on St. Kitts, Nevis Island, and two years of clinical rotations in affiliated hospitals in the US. In the first year, students will be enrolled at the SOHST at UPES, in the Pre-Medical Certificate Programme. Upon successful completion of the first year, they will earn around 47 credits which can be transferred for progression to the MUA.

Singapore launches Centre for Infectious Disease Emergency Response

The Yong Loo Lin School of Medicine, National University of Singapore (NUS Medicine) has announced the official launch of the Centre for Infectious Disease Emergency Response (CIDER), an innovative initiative aimed at enhancing pandemic preparedness and strengthening responses to infectious disease emergencies. Led by infectious diseases and global health expert and Centre Director Professor Dale Fisher, CIDER will serve as an education and operational hub for public health professionals, researchers, and policymakers across Singapore and internationally. The Centre is part of NUS Medicine's ongoing commitment to building a robust global health infrastructure. Through a wide range of training, teaching, and operational initiatives, CIDER will play a crucial role in enabling healthcare professionals to tackle infectious disease outbreaks with improved resilience and response capabilities. As part of its mission, CIDER will focus on expanding the regional capacity to prevent, prepare for, detect, and respond to infectious disease emergencies, with a long-term vision to foster global health equity.

Julie Kim to succeed Christophe Weber as CEO of Takeda in June 2026

Japan headquartered pharmaceutical firm Takeda has announced that its Board of Directors have made the decision unanimously to appoint Julie Kim, currently president of Takeda's US Business Unit, as the successor to Christophe Weber, Takeda's president, chief executive officer (CEO) and representative director, when Weber retires from the company in June 2026. Julie will be proposed as a candidate for election to the Board at Takeda's Annual General Shareholders Meeting held in June 2026. Weber will not hold a Board seat after retiring from Takeda. She has been the president of the US Business Unit and US country head since 2022, and a member of the Takeda Executive Team since 2019. With three decades of experience in healthcare, Julie has held leadership positions at global, regional, country and functional levels. Her extensive background covers a range of therapeutic areas, international market access, general management, marketing and emerging market development. A committed community leader, she participated in the Massachusetts Governor's Economic Development Planning Council in 2023 as the lead for the Life Sciences working group to advise the administration on how the life sciences industry can continue to drive economic growth for the state.

Syngene CEO Jonathan Hunt steps down, Peter Bains takes over

Syngene International Limited has announced that Jonathan Hunt has stepped down from his role as Managing Director (MD) & Chief Executive Officer (CEO) as well as from the Board of Directors to pursue other opportunities in due course. Consequent to this, the Board has appointed Peter Bains as the CEO Designate of Syngene. Both changes are effective February 10, 2025. Peter Bains has over three decades of experience in the biotech and pharmaceutical industry. He also served as CEO of Syngene from June 2010 to March 2016 and was instrumental in creating a strong foundation for the business and taking it public in 2015. Bain's deep domain experience, knowledge, and familiarity with the business, together with his leadership acumen makes him eminently qualified to step into this role.

Daiichi Sankyo appoints Hiroyuki Okuzawa as CEO

Daiichi Sankyo Company has appointed Hiroyuki Okuzawa, 62, to succeed Sunao Manabe, DVM, PhD as Chief Executive Officer (CEO), effective April 1, 2025. Dr Manabe will transition from his current role of Representative Director, Executive Chairperson and CEO to Representative Director and Executive Chairperson while Okuzawa will transition to Representative Director, President and CEO. In order to ensure the solid achievement of FY2025 goals and to strengthen its management structure, Daiichi Sankyo's Board of Directors appointed Okuzawa as the new CEO at the board meeting on January 31, 2025, based on the Nomination Committee's report. This transition in April 2025 will occur as Daiichi Sankyo enters the final year of its current five-year business plan and it starts full scale preparation for the next five-year business plan (FY2026-2030). Okuzawa joined Daiichi Sankyo in 1986 and has served as Representative Director, President and Chief Operating Officer (COO) since 2023. He also held the role of Chief Financial Officer (CFO) for two years and other senior leadership roles in international business, corporate strategy and human resources during his tenure at Daiichi Sankyo.

BioAsia 2025 announces Genome Valley Excellence Award to Singapore's Prof. Patrick Tan

BioAsia, Asia's largest annual global biotechnology and life sciences forum organised by the Government of Telangana, has announced that the prestigious Genome Valley Excellence Award has been conferred upon Prof. Patrick Tan, Executive Director of PRECISE (Precision Health Research, Singapore), National University of Singapore, for his outstanding contributions to precision medicine, cancer genomics, and population health research. Prof. Tan has played a transformative role in advancing biomedical research and personalised healthcare, particularly through his leadership at PRECISE. His pioneering work in integrating genomics with clinical care has shaped the future of medicine, making healthcare more predictive, personalised, and precise. Prof. Tan's contributions to the fields of cancer genomics and population health are globally recognised. His research has led to groundbreaking discoveries in cancer biology, especially in gastrointestinal cancers, and the identification of novel biomarkers for targeted therapies. At PRECISE, Prof. Tan has spearheaded Singapore's national precision medicine programme, which integrates advanced genomic research with artificial intelligence to create predictive models for disease prevention and treatment.

Aphra names Justin Untersteiner as CEO

The Australian Health Practitioner Regulation Agency (Ahpra) has appointed Justin Untersteiner as Chief Executive Officer (CEO). Untersteiner who will join Ahpra in April brings over 20 years' experience in regulation and compliance, most recently as Chief Operating Officer at the Australian Financial Complaints Authority (AFCA). At AFCA, he designed and led a significant change programme that included a major IT overhaul, the design and implementation of a new industry funding model, along with delivering numerous positive changes that improved the organisation's operations and efficiency. Untersteiner is an experienced senior executive who has delivered strategic transformation initiatives across a range of complex national organisations in the government and not-for-profit sectors, in a career focusing on consumer protection and public safety.

Axel Klarmeyer joins as CEO at Chamlion International

China-based Chamlion, a pioneer in integrated dental 3D printing solutions, has announced the appointment of Axel Klarmeyer as the Chief Executive Officer (CEO) of Chamlion International, overseeing the company's international business operations. Axel's extensive industry experience and leadership will be pivotal in advancing Chamlion's strategic growth and expanding its footprint globally. Klarmeyer brings over 20 years of leadership experience in the dental and medical device sectors. Prior to joining Chamlion, he served as the CEO and Chief Sales Officer of BEGO, where he successfully led international expansion efforts and drove product innovation in dental technology. Klarmeyer 's extensive expertise in business strategy, market development, and operational excellence will be instrumental in strengthening Chamlion's position in international markets. He will leverage his experience to expand Chamlion's presence first and foremost in Europe and North America, to drive greater efficiency, innovation, and accessibility in dental prosthetic production worldwide.

Hong Kong develops world's smallest multifunctional biomedical robot

Researchers from the School of Engineering of the Hong Kong University of Science and Technology have successfully developed the world's smallest multifunctional biomedical robot, which is 60 per cent smaller than current models. Capable of imaging, high-precision motion, and multifunctional operations like sampling, drug delivery, and laser ablation, the robot offers competitive imaging performance and a tenfold improvement in obstacle detection, paving the

way for robotic applications in narrow and challenging channels of the human body, such as the lung's end bronchi and the oviducts. With a slim profile of just 0.95 mm, 60 per cent smaller than current endoscopic robots, this robot has accomplished an "impossible trinity" by simultaneously integrating all three significant specifications in one robot. It offers competitive imaging performance and extends obstacle detection distance up to ~9.4 mm, a tenfold improvement from theoretical limits. It also achieves remarkable motion precision (less than 30 μm) & substantially widens the imaging region by ~25 times the inherent view.

India develops drug delivery system to revolutionise treatment of Rheumatoid Arthritis

Researchers from Institute of Nano Science and Technology (INST) Mohali, an autonomous institution of the Department of Science and Technology (DST), Government of India, have developed an innovative "self-actuating" drug delivery system that could revolutionise the treatment of rheumatoid arthritis (RA) by targeting inflammation directly within the joints so that therapeutic agents are released only when needed. It is a smart system that responds directly to the biochemical signals in the inflamed synovial environment. By targeting specific inflammatory enzymes present in the joints, the system ensures that therapeutic agents are released only when needed, offering a more precise and safer treatment option for RA patients. This breakthrough could offer a safer, more effective alternative to current RA treatments by eliminating the need for frequent drug injections and reducing systemic toxicity. The system enhances drug effectiveness by improving bioavailability and retention in the affected joints, leading to longer-lasting relief with fewer doses.

Singapore builds 3D scalable 'gut-on-a-chip' model to study human intestine

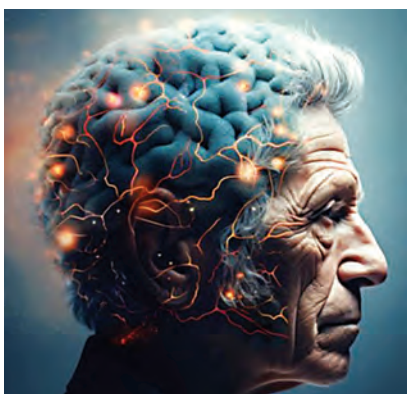
In a breakthrough for the advanced study of gut health, scientists at the National University of Singapore (NUS) have developed a 3D microscopic version of the human intestines condensed into a small chip about half the size of a five-cent coin. This new cell culturing platform, known as the Gut-Microbiome on a chip (GMoC), provides a realistic in vitro microgut model that allows researchers to examine the interactions of gut microbes and their collective impact on gut health. The chip offers a scalable, reproducible, and efficient method to dissect the roles of gut microbes and their community, which is of key interest for the preventive healthcare and pharmaceuticals industry. The research team is focused on further developing the device, aiming to enhance its complexity to better replicate the human intestines. This includes incorporating complex mechanical cues, enhancing cellular complexity, and creating oxygen gradients within the GMoC system. On the biological front, the team also aims to use the device to further investigate the assembly, interactions, and behaviour of diverse microbial communities under various stimuli including nutrients and antibiotics. This will contribute to our overall understanding of how these interactions impact gut health.

Japan designs biohybrid hand gestures with complex finger movements

A biohybrid hand which can move objects and do a scissor gesture has been built by a team at the University of Tokyo and Waseda University in Japan. The researchers used thin strings of lab-grown muscle tissue bundled into sushi-like rolls to give the fingers enough strength to contract. These multiple muscle tissue actuators (MuMuTAs), created by the researchers, are a major development towards building larger biohybrid limbs. While currently limited to the lab environment, MuMuTAs have the potential to advance future biohybrid prosthetics, aid drug testing on muscle tissue and broaden the potential of biohybrid robotics to mimic real-life forms. The hand is made of a 3D-printed plastic base, with tendons of human muscle tissue which move the fingers. Until now, biohybrid devices have typically been on a much smaller scale (about 1-centimeter long) or limited to simpler or single-joint movements. By contrast, the biohybrid hand is 18 cm in length and has multijointed fingers, which can be moved individually to make gestures or in combination to manipulate objects.

Korea offers breakthrough in Alzheimer's treatment

A 3D model accurately mimicking the Blood-Brain Barrier (BBB) in a laboratory environment has been successfully developed by research teams led by Professor Jinah Jang from the Departments of Mechanical Engineering, Life Sciences, IT Convergence Engineering, and the Graduate School of Convergence at Pohang University of Science and Technology (POSTECH), and Professor Sun Ha Paek from the Department of Neurosurgery at Seoul National University Hospital, in South Korea. Neurodegenerative diseases, including Alzheimer's, Parkinson's disease, and amyotrophic lateral sclerosis (ALS), result from the progressive decline of brain and nervous system functions, primarily due to ageing. Chronic neuroinflammation, a key driver of these disorders, arises from the intricate interactions between cerebral blood vessels and neural cells, where the BBB plays a pivotal regulatory role. However, existing BBB models have been unable to replicate the complex three-dimensional 3D structure of cerebral blood vessels, posing significant challenges for research and drug development.



Australia offers new treatment hope for childhood cancers

University of Queensland (UQ) research using "natural killer" cells may lead to the first new treatment for a devastating childhood cancer in 40 years. The team has developed new therapeutic strategies for hard-to-treat paediatric sarcomas that have high rates of metastasis, recurrence or treatment resistance. Paediatric sarcomas, including Ewing sarcoma, osteosarcoma and rhabdomyosarcoma, represent 5-10 per cent of all childhood

cancers but are responsible for more deaths than brain cancer, melanoma, leukaemia and lymphoma. There is a five-year survival rate of approximately 20 per cent for patients in advanced stages of disease. The new therapeutic strategy uses engineered immune cells, called natural killer cells, to target and destroy sarcoma tumours. The treatment could also have an impact on other hard-to-cure diseases such as triple negative breast cancer. The study was a collaboration of researchers from UQ in Australia, Queensland Children's Hospital, University of New South Wales and The University of Otago, New Zealand.

BD announces intent to separate biosciences and diagnostic solutions business

BD (Becton, Dickinson and Company), a leading global medical technology company headquartered in the US, has announced its board of directors has unanimously authorised BD management to pursue a plan to separate BD's Biosciences and Diagnostic Solutions business from the rest of BD to enhance strategic focus and growth-oriented investments and capital allocation for both BD and the separated business and enhance value creation for shareholders. The separation decision was the result of a comprehensive business portfolio evaluation launched by BD in early 2024. The company believes the separation is expected to unlock value on two fronts: The creation of a New BD that is recognised as a focused, innovative and growth-oriented medical technology leader with four attractive segments aligned to both essential needs and higher-growth trends in healthcare, and the Biosciences and Diagnostic Solutions business that is expected to become a differentiated leader in Life Sciences Tools and Diagnostics. Following the separation, new BD will be a pure-play medical technology company with leading positions in large and growing end-markets. With this profile, new BD expects to drive concentrated investments in high-impact R&D and disciplined capital allocation including growth accretive M&A, which positions the company to deliver differentiated and durable growth rates in MedTech.

Thermo Fisher introduces Invitrogen EVOS S1000 Spatial Imaging System

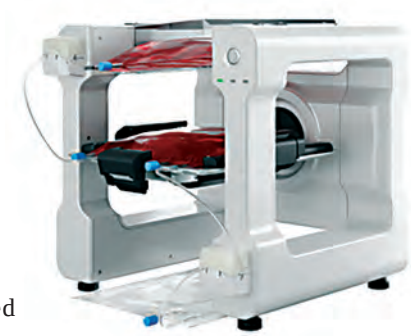
Thermo Fisher Scientific Inc., the world leader in serving science, has introduced the Invitrogen EVOS S1000 Spatial Imaging System. This advanced system addresses the limitations of current fluorescent microscopy technologies by enabling researchers to generate a multiplexed high-quality image for multiple samples within several hours, thereby lowering the barrier to entry into spatial tissue proteomics. The EVOS S1000, from Thermo Fisher Scientific's innovative line of cell imaging microscopes and systems, leverages advanced and patented spectral technology, allowing researchers to capture images of up to 9 different targets simultaneously, which helps reduce the need for multiple rounds of imaging and preserves tissue integrity. The system's compatibility with a wide range of reagents and antibodies enables seamless integration into existing laboratory setups, helping meet the growing demand for multiplex imaging.

Bio X Cell expands global reach with new distribution centre in China

Bio X Cell, the world's leading provider of functional antibodies for translational research, is strengthening its global distribution network with the opening of a new distribution centre in Beijing, China. This expansion marks the latest step in Bio X Cell's growing international presence, complementing its flagship distribution centre in Germany, as well as partnerships that extend the Bio X Cell name to Singapore and Korea, along with its headquarters and manufacturing facility in New Hampshire. The new Beijing distribution centre will enhance service to researchers and institutions across China by increasing inventory availability to expedite order fulfillment. By establishing a stronger regional presence in APAC, Bio X Cell aims to better support its customers in one of the world's most dynamic and rapidly growing biomedical research markets. The strategic expansion aligns with the Bio X Cell mission to provide researchers with uninterrupted access to premium antibodies while maintaining its reputation for superior quality and customer service. With this addition, Bio X Cell continues to reinforce its role as a trusted global supplier in the life sciences industry.

PHC partners with CCRM in Canada to develop primary T-cell expansion culture processes

Japan-based PHC Corporation has signed a Master Collaboration Agreement with CCRM (based in Canada) to work together on the development of primary T-cell expansion culture processes that will seek to accelerate the manufacturing of cell and gene therapy (CGT) products. This joint initiative will integrate LiCellGrow, PHC's cell expansion system under development, with CCRM's deep knowledge of regenerative medicine and biomanufacturing to establish new culture processes to improve cell culture efficiency and quality for CGTs. The joint research with CCRM will allow PHC to analyse culture conditions using "LiCellGrow" to establish optimal culture processes for primary T-cells. The collaboration will seek to accelerate LiCellGrow's development, contributing to improved cell quality, enhanced manufacturing efficiency, and cost reduction in the production of cell-based therapeutics. PHC has developed proprietary In-Line monitoring technology to track key indicators of cell metabolism in real-time, which can help researchers address issues like cell quality and reproducibility, and establish optimal cell culture methods.



Inventia announces groundbreaking advancement in 3D cell culture technology

Inventia Life Science, an innovator in 3D cell culture technologies, has announced the launch of RASTRUM Allegro, a groundbreaking advancement in 3D cell culture technology designed to accelerate drug discovery and disease research with unprecedented scalability, reproducibility, and efficiency. RASTRUM Allegro addresses key challenges faced by researchers, including the need for consistent, scalable 3D models that generate meaningful insights and limited availability of patient-derived cells, which are often challenging to expand and maintain in traditional 3D culture environments. This next-generation platform empowers scientists to create complex, reproducible 3D cell models with minimal hands-on time, making advanced biology more accessible. The product makes it easier than ever to create high-throughput 3D cell culture assays that offer both speed and affordability.

Shimadzu strengthens business operations in India with new plant

In order to strengthen business operations in India, which is expected to experience high economic growth, Japan's Shimadzu Corporation will establish the manufacturing subsidiary Shimadzu Manufacturing India Private Limited (SMI) in Bengaluru, Karnataka. Construction of the new plant is scheduled to be completed and operations are to be started in the spring of 2027. Currently, Shimadzu products are supplied to India from Japan or Shimadzu Malaysia Sdn. Bhd. (SML) in Malaysia. Building the new plant will not only strengthen the supply chain but also respond to governmental incentives for domestic production ("Make in India"). SMI will begin manufacturing liquid chromatograph (LC), gas chromatograph (GC), UV-VIS spectrophotometer (UV), liquid chromatograph mass spectrometer (LC-MS), and gas chromatograph mass spectrometer (GC-MS) products in 2027. In addition to analytical and measuring instruments, future manufacturing of medical systems and industrial machinery products are also being considered.

Renewing Collective Commitment Against Cancer

At the World Summit Against Cancer for the New Millennium, the Charter of Paris Against Cancer was signed 25 years ago on February 4, 2000. The World Health Organization (WHO) recognises the unique experiences of each patient and the importance of people-centred care provided collaboratively by healthcare providers, families, friends, and the community on this year's World Cancer Day. The theme, United by Unique, serves as a reminder of the collective commitment against cancer.

Nearly 10 million deaths globally were attributed to cancer in 2020, according to a WHO report released on February 3. In 2020, lung cancer accounted for 1.80 million deaths, followed by colon and rectum (916,000), liver (830,000), stomach (769,000), and breast (685,000). In addition, it noted that almost 400,000 children get cancer every year. The most prevalent malignancies differ from nation to nation. In 23 nations, cervical cancer is the most prevalent type.

The WHO South-East Asia Region (SEARO) had 2.4 million new cases of cancer in 2022, including 56,000 children, and 1.5 million deaths. Among all the WHO regions, SEARO region had the highest number of cancers of lips and oral cavity, uterine cervix, and childhood cancers. It is estimated that by 2050, there will be an 85 per cent increase in the number of new cases and deaths in the region.

The WHO also noted that by avoiding risk factors and using current evidence-based preventative techniques, between 30 and 50 per cent of malignancies can now be averted. Early cancer detection, as well as the proper treatment and care of cancer patients, can also lessen the burden of cancer. Many cancers have a high chance of cure if diagnosed early and treated appropriately.

Countries in the SEARO region have achieved significant strides in cancer control in recent years. Two nations have incorporated cancer into their national NCD plans to strategically direct their cancer preventive and control efforts, and six nations have national plans specifically devoted to cancer control. Over 90 per cent of the target groups were tested for breast, cervical, and stomach cancers, with screened positives being associated with diagnosis and treatment, as part of Bhutan's successful 2020 Health Flagship project. The idea is now being included into the nation's regular health services.

Through the Cancer Anywhere programme, Thailand has adopted universal health coverage approach to cancer management. Eight countries have introduced nationwide Human Papillomavirus (HPV) vaccination. A global initiative for childhood cancer is being implemented in 10 countries through a regional network of institutions. Seven countries have operational population-based cancer registries. In 10 countries, tertiary level cancer care is generally available, reaching 50 per cent or more patients in need. The region has seen the fastest rate of decline in tobacco use which is a major risk factor for several high burden cancers.

There are, however, persistent challenges. The response to cancer control is not uniform among countries. National cancer control programmes and plans are not fully aligned with evidence or best practices resulting in their ineffective implementation. Policies and guidance on control of cancer-causing agents prevalent in the region is lacking. Existing cancer prevention policies and programmes are not fully implemented, leading to millions of avoidable cases. Cancer services are included in health benefit packages in only six countries. Screening for specific cancers is low. For example, cervical cancer screening has less than 50 per cent coverage in seven countries, which is much below the target of 70 per cent required for elimination of cervical cancer as a public health problem.

Treatment is often more expensive and less successful when it is diagnosed later. There is still a lack of national capacity to handle the rising cancer burden. Not every country in the region has a national surveillance system with cancer indicators for regular reporting or a working population-based cancer registry. We will only be better prepared to address the growing cancer burden if countries work together, with encouragement from the WHO and its partners. BS

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