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Evolving Market Dynamics in Biopharma and Genomic Medicines

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Krishna Karnati, Commercial General Manager, Genomic Medicine APAC at Cytiva explains trends driving precision medicine demand in APAC

Precision medicine is becoming more prevalent, with pharmaceutical companies and healthcare regimen to develop highly targeted drugs therapeutics for both communicable and noncommunicable diseases (NCD) such as cancers and many difficult to treat ailments. In the APAC healthcare market, Precision Medicine and Gene Therapy in oncology are key dominating segments with the increasing reliance on genomic medicine. By 2027, precision medicine treatment expenditures in APAC are anticipated to reach $18.2 billion, up from $8.32 billion in 2022. The prospects for foreign direct investment (FDI) in the region remain resilient, with favorable environments particularly in South-East Asia countries, driven by factors such as robust infrastructure and digitalisation, a resurgence in manufacturing and investment. Drug developers are filling the clinical gaps to expedite the growth potentials and to troubleshoot the challenges. **Krishna Karnati, Commercial General Manager, Genomic Medicine APAC,**

Cytiva shares more strategic approaches and trends in the current biopharma market landscape which are driving innovation for the competitive advantage.

- **What are the trends driving precision medicine demand in APAC?**

There are several trends that are driving demand for precision medicine in APAC. The power of genomics and immunotherapies are driving progress in precision medicine. There is an increasing shift from reactively treating, to proactively preventing diseases such as hereditary forms of cancer through early detection and interventions. Furthermore, developments in health IT and adoption of electronic health records across APAC have paved the way for a more comprehensive storage of data on a patient's health history including genetic history, which can accelerate and be integrated into research and clinical settings. , there's a need to address higher incidences of cancer in the region and improve quality of life. Approximately half of global cancer cases are found here. mRNA has shown promise in managing cancer, especially virus-related cancers, which account for 20per cent of cancers.

There is a surge in the trend of drug development companies investing in mRNA R&D to test this technology against various other diseases. With its cell-free production, scalability, and standardised production methods, mRNA is a high-potential technology ideal for precision medicine with precise biomarker targets. mRNA will increasingly address infectious diseases such as dengue and malaria and drive the access to vivid drugs. Beyond infectious diseases, mRNA will also address the needs in the oncology space through personalised medicine.

Other than mRNA, we observed that genomic medicines such as cell therapies have proven to be effective for patients with leukemia and lymphoma and are expected to bring major improvements to many other cancer treatments over the next decade.

- **How will the biopharma market be revolutionised in the coming years by new and emerging technologies? How is Cytiva responding to evolving market dynamics in biopharma and genomic medicines?**

Cytiva is responding to evolving market dynamics by providing end-to-end technology solutions, and services, to develop platform processes across multiple modalities. increasing demand for access to CDMO facilities across the landscape, including Australia and Japan as companies seeking additional manufacturing capacity for their diverse range of therapeutic modalities

In Australia, for example, Cytiva and the University of Adelaide worked together with BioCina, an Australian-based multi-product biologics contract development and manufacturing organisation (CDMO), to expand its facility in Adelaide to manufacture mRNA-based vaccines and therapies.

In India, there is a growing need to install manufacturing capacities with pioneers in small molecules entering the large molecule space e.g. nucleic acid therapies (mRNA, siRNA), leveraging their experience in chemical synthesis.

Globally, Cytiva manufacturing technologies have enabled 5 out of 6 approved CAR-T therapies from development through to commercial production. With our FlexFactory biomanufacturing platform, we've helped Genepeutic Bio, a leader in Thailand's life sciences sector, establish the first GMP-certified cell therapy manufacturing facility in the country so it can deliver chimeric antigen receptor-T (CAR T) cell therapies to a few hundred patients with relapsed and refractory blood cancers such as acute lymphoid leukemia (ALL) in Thailand and Southeast Asia by 2025.

With regard to growth trajectory this year, molecule (asset) movements across genomic medicines show positive signs. Specific to cell therapies, we've observed that there are molecule additions across all clinical phases, largely under preclinical phases, followed by those in Phase 1 and Phase 2 across CAR T, natural killer (NK), chimeric antigen receptor natural killer (CAR NK), and tumor-infiltrating lymphocytes (TILs). Globally, the growth rates for nucleic acid-based therapies (mRNA, siRNA) are astronomical in Phase 1 and 2, starting with a low baseline of molecules.

Across advanced therapies in Asia Pacific, we're anticipating movements from Phase 2 to commercial stage in the coming years. This movement is driving growth in manufacturing footprint across nucleic acid therapies, viral vectors and cell therapies to a great extent, with CDMOs leading from the front, to install manufacturing capacities and with larger biopharma companies entering the foray. We're also seeing growth in the translational space, where there is a focus to launch clinical assets backed by government grants and support.

- **Asia is cultivating innovative start-up ecosystems. What are the key enablers that can elevate the region to become successful in developing and delivering genomic medicines to the global market?**

To become more successful in delivering genomic medicines to the global market, firstly startups need more support and can't do it alone. Cytiva is involved in initiatives such as 'BioChallenge' supporting biotech startup innovation, while 'Fast Trak' process development services acts as a manufacturing center of excellence to help startups optimise scalability and resource utilisation. Fast Trak Bioprocess Training and Education not only groom the next generation of bioprocessing talent and enhance specialist knowledge; they help customers to mitigate bottlenecks in the process, or in some cases develop the complete processes for scale up or scale out.

Secondly, working closely with industry and governments can accelerate progress. Currently, we observe collaborative efforts between countries and institutions that are shaping the R&D landscape in genomic medicine in APAC - for example, the NATi program for Oligo and mRNA in Singapore and Korean National Institute of Bioprocessing Research and Training (K-NIBRT) to deliver educational programming on biopharmaceutical and cell therapy development and manufacturing.

In addition, Asian countries have been actively participating in industry associations and academic societies including ISCT (International Society for Cell & Gene Therapy) and ISSCR (International Society for Stem cell research), ISEV (International society for extracellular vesicles). Through these platforms and among the regional chapters, Asian players are actively seeking clarity on regulatory pathways and shaping R&D excellence.

Thirdly, the clinical development of mRNA-based treatments requires significant capital investment to foster ongoing innovation. Despite the economic challenges experienced across various sectors in the past year, there's a bright spot in the form of increased innovation and investment in Advanced Therapy Medicinal Products (ATMPs) within the APAC region (as indicated by the Alliance of Regenerative Medicine report).

Governments and the industry have been actively providing funding support to establish mRNA capabilities, with infectious diseases as an immediate target. For instance, Ricoh started a Biomedical Startup Fund in Japan to support mRNA drug discovery and invest in local startups in the drug research field, enhancing their support for mRNA drug development. Quite recently, ARCALIS, a partnership between Axcelead and Arcturus, received $115 million in grants from the Japanese government. This funding will be used to build a factory and buy equipment for mRNA drug production meeting Good Manufacturing Practice (cGMP) standards. This global trend is reinforced by The Coalition for Epidemic Preparedness Innovations (CEPI), which recently pledged funding of up to $3.6 million to propel Gennova Biopharmaceutical's self-amplifying thermostable mRNA vaccine platform. This funding is specifically directed towards expediting the development of vaccine candidates targeting "Disease X."

The cumulative efforts and financial support of various countries and organisations in supporting mRNA research and development is crucial not only for immediate applications targeting infectious diseases but also for creating a robust knowledge and platform base that can be leveraged to expand mRNA applications into other critical areas, including cancer therapeutics.