BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

How Radiopharmaceuticals Are Transforming Cancer Treatment

May 3, 2023 | Analysis | By Ayesha Siddiqui

A new class of drugs, radiopharmaceuticals, are gaining traction with several regulatory approvals and investments in recent years. Big pharma firms are taking an active interest and have propelled the developments in the sector. Chief among them is Swiss firm Novartis whose $6 billion investment paid off with the approval of Pluvicto in March 2022. Almost every pharma firm is trying to get a foot in the door by investing in or acquiring radiopharmaceutical developers. BioSpectrum Asia explores the growing interest in radiopharmaceuticals and the recent advances in the field.



A key goal for any innovative cancer treatment is the ability to deliver an anti-cancer agent directly to the tumour and avoid a negative impact on healthy tissue. This concept is central to the development of Targeted Radionuclide Therapy (TRT), which is an emerging class of cancer therapeutics that uses the power of radiation in a targeted way to destroy tumour tissue. Several TRT therapies have demonstrated positive outcomes in clinical evaluation and have reached the market, providing new hope for patients suffering from hard-to-treat cancers. This sparked the interest of big pharma that's betting big on radiopharmaceuticals.

Novartis is clearly the trailblazer focusing on radiopharmaceuticals, spending $6 billion in 2017 and 2018 to buy Advanced Accelerator Applications and Endocyte. In March 2022, the Swiss drugmaker won U.S. approval for Pluvicto to treat an advanced form of prostate cancer. In March 2023, the firm inked a deal worth $1.75 billion with Bicycle Therapeutics to develop, manufacture and commercialise Bicycle radio-conjugates (BRCs) for multiple agreed-upon oncology targets.

In August 2022, American drugmaker Merck participated in an $84 million funding round of US-based startup Aktis Oncology. Novartis and Bristol Myers Squibb are other investors in Atkis.

German drugmaker Bayer was an early entrant in the field, its Xofigo (radium 223) won US approval back in 2013 for prostate cancer. In 2021, the firm acquired Noria Therapeutics Inc. (Noria) and PSMA Therapeutics Inc. to expand its radiopharmaceutical pipeline.

Not to be left behind, the British drugmaker AstraZeneca jumped on the field, by partnering with Fusion Pharmaceuticals in 2020.

Not only big pharma, but smaller biotech firms have also cropped up looking to cash-in on the hot field. In October 2022, Eclipse and Mayo Clinic created Nucleus RadioPharma to better serve cancer patients. In September 2022, The University of Texas MD Anderson Cancer Center and Australian firm Radiopharm Theranostics launched Radiopharm Ventures, LLC, a joint venture company created to develop novel radiopharmaceutical therapeutic products for cancer.

“There is clearly a rising interest in radiopharmaceutical products from both drug development companies and investors. This is likely to be driven by the commercial success of recently approved products such as Lutathera (AAA/Novartis) and Pluvicto (Endocyte/Novartis) and by recent significant investments in biotech over the 12 months. This is exemplified by the Series A round of $75 million announced by Aktis in March 2021 and the Series D of $160 million announced by Rayzebio in September 2022. Ariceum is another example of growing interest from European as well as VCs in the field. More than 30 companies are actively developing theranostic pairs across US and Europe, and there is growing interest in Asia as illustrated by the involvement of the company Grand Pharmaceutical in China,” said **Serge Sagodira, Chief Business Officer, Ariceum Therapeutics, Germany**. The firm recently raised EUR 22.75 million in extended Series A funding.

Current landscape

The potential of radiopharmaceuticals has been known for decades, ever since the use of Radioactive iodine-131 in the 1940s to treat thyroid cancer. New technologies for targeting other cancer biomarkers are greatly expanding the use of radiopharmaceuticals beyond thyroid cancer into areas of unmet need, such as prostate cancer. With indications expanding rapidly, radiopharmaceuticals could soon become a new pillar of cancer treatment.

“Although these new anti-cancer drugs have been in development for years, recent innovations and market launches have brought a lot of attention to the therapeutic principle of TRT and its potential. The interest in the space can also be seen in the increasing number of financings and deals for companies that are focused on radiopharmaceutical development and TRT. It is exciting to see the progress in this area of medical science and be a part of the growing awareness of how it can potentially improve clinical outcomes and quality of life for cancer patients. We are truly seeing the rise of a powerful new drug class for cancer treatment. There will be further advances in the selection of targeting molecules and the continual improvement of radioisotope manufacturing and supply chain that will allow the field to broaden the scope of patients it can serve,” said **Steffen Schuster, CEO of ITM Isotope Technologies Munich SE (ITM)**. ITM is a leading player in this space. The firm has several products in the pipeline including two in late-stage trials.

There are currently 671 clinical trials underway as of April 20, 2023 on clincialtrials.gov investigating the use of radiopharmaceuticals for a wide range of cancer indications, including breast, prostate cancer, lung, and lymphoma, among others.

It’s not just big pharma and western counterparts that are fascinated with radiopharmaceuticals. Closer home in Asia Pacific, a lot of companies are tapping into the potential of radiopharmaceuticals. Leading among them is Australian firm Telix Pharma who’s Extensive, late-stage radiopharmaceutical pipeline. In the first quarter of 2023, the firm reported $100 million revenue.

Another Australian firm, Radiopharm Theranostics has also focused on developing radiopharmaceuticals for diagnosing and treating diseases with high unmet medical needs. In September 2022, the US FDA granted an orphan drug designation (ODD) to its lead asset LRRC15 antibody DUNP19 for the treatment of patients with osteosarcoma. Clarity Pharma is another leading Australian firm in the space.



Japanese biotech Perseus Proteomics and PeptiDream are also leading the radiopharmaceuticals development. In September 2021,PeptiDream acquired the radiopharmaceutical business of FUJIFILM Toyama Chemical Co., Ltd. from Fujifilm Corporation for ¥22.1 billion.

Gland Pharma, China's largest drugmaker, has invested $28 million in ITM, a leading player in the field. China's CASI Pharmaceuticals is another leading player in this space.

Challenges remain

Radiopharmaceutical development poses unique challenges. They are difficult to manufacture and require specialised facilities. Novartis' Pluvicto has been plagued with manufacturing woes since its approval in March 2022. The firm had to halt its production owing to potential quality issues in May 2022. As of March 2023, the drug is facing production shortage.

"One of the specific challenges of TRT is the nature of radioisotopes and the need to provide the therapy to patients in a timely way, with the right dose at the right time and place for each patient. Based on the breadth of the potential of TRT, this requires a worldwide production and supply network as well as a sophisticated process to ensure radioisotopes are delivered to clinics and patients before they decay. A great deal of specialised knowledge is needed to support the on-time delivery and dosing. The demand for TRT treatments has grown exponentially and ITM continues to expand its leading global production and supply network to meet the needs of patients now and in the future," said Steffen.

A couple of radiopharmaceutical contract development and manufacturing organisations (CDMO) have come up that could help in addressing these woes. In March 2023, AtomVie announced plans to build a new contract manufacturing facility specifically for radiopharmaceuticals. In November 2022, NorthStar Medical Radioisotopes established a new CDMO services unit.

"In addition to logistical challenges, one would add isotopes supply as one the main challenges as the use of radiopharmaceuticals gets expanded. In addition, the requirement for a multidisciplinary team including nuclear medicine, radiation oncology and general oncology could be seen as a constraint but this might disappear with the increasing number of drugs that could reach the market in the future," added Sagodira.

Road map

Data Bridge Market Research analyses that the radiopharmaceuticals market, which was worth $5.32 billion in 2022, would rise to $12.18 billion by 2030. No wonder, big pharma and smaller biotech firms are scrambling to get the bigger piece of the pie.

The increasing prevalence of cancerous diseases on account of the rising ageing population and unhealthy dietary patterns represent the key factors contributing to the growing use of radiopharmaceuticals across the globe. Apart from this, the escalating number of diagnostic centres is also supporting the market. Moreover, the rising number of oncologists that are suggesting disease-targeted cancer therapy, which utilises drugs to target specific proteins and genes involved in the development of cancer cells, are positively influencing the overall sales.

Furthermore, the use of radiolabeled peptides and monoclonal antibodies for the diagnosis and treatment of cancerous tumours, along with rising healthcare expenditures, is strengthening the market growth. According to the IMARC report the increasing use of radiopharmaceuticals by oncologists to track radioactivity throughout the body and determine the presence of cancer cells and the increasing shift towards positron emission tomography (PET) and single-photon emission computerised tomography (SPECT) scans will drive the growth of the market.

Ayesha Siddiqui