ALL THINGS NUCLEAR-PORTLAND LIFE UNIFYING SCIENCES NEWSLETTER

WINTER EDITION

Radiopharmaceuticals Continue to Stay in Focus, Spurred by High Profile Mergers & Acquisitions (M&A) Deals

Dear Investors,

We are pleased to be sharing our insights into recent developments related to precision oncology, with an emphasis on the radiopharmaceutical industry, which experienced a particularly strong finish for 2023 with a record M&A transaction involving Eli Lilly and Company discussed below.

With 2023 now in the books, we would be remis not to remark its relevance in further shaping the landscape of Targeted Radiopharmaceutical Therapies (TRTs) and nuclear medicine. The last quarter of 2023 brought a flurry of M&A and business development deals for the radiopharmaceutical companies, as well as promising clinical developments, and funding success indicative of an industry that is well positioned for long term growth.

Financing for innovative radiopharmaceutical drugs witnessed an increase over the past five years, reaching over US$1 billion in 2023. In September, Eli Lilly and Company (Lilly) invested $175 million in a Series B financing round for US-based biotech, Mariana Oncology Inc., who is pursuing a therapeutic for small cell lung cancer, with their lead drug , MC-339, which is anticipated to enter clinical trials next year. Lilly also completed its $1.4 billion acquisition of POINT Biopharma Global Inc. (POINT), a radiopharmaceutical company with a pipeline of clinical and preclinical-stage radioligand therapies in development for the treatment of cancer. The acquisition did not lack some drama, as some of POINT's lead investors argued for a higher offer, which likely temporarily drove the price of POINT to as high as $14.00. It settled eventually for the proposed price of $12.50, likely in response to what turned out to what we believe to be underwhelming interim results from the phase III SPLASH trial for the treatment of prostate cancer. In another deal, Bristol-Myers Squibb Company committed to acquiring the clinical-stage radiopharmaceutical therapeutics (RPT) company RayzeBio, Inc. (Rayzebio) for a total equity value of nearly $4.1 billion (about $3.6 billion net of cash). The acquisition, we understand, is part of BMS' strategy to build a radiopharmaceutical platform. RayzeBio has a pipeline comprising therapies for solid tumors that include gastroenteropancreatic neuroendocrine tumors (GEP-NETs), small cell lung cancer, hepatocellular carcinoma, and other solid tumors.

Beyond the recent appetite of big pharma for late-stage radiopharmaceutical companies, venture capital firms are also part of the action with several funding announcements reported in the fourth quarter. Despite the challenging market conditions in the broader biotech sector, radiopharmaceutical companies including ARTBIO Inc. (ARTBIO), Nucleus RadioPharma, RefleXion Medical, and SHINE Technologies have successfully raised funds, bringing in tens of millions in order to advance their pipelines, further develop technologies and to commercialize assets. Radiopharmaceuticals are continuing to gain recognition as a viable targeted approach for treating cancer demonstrating efficacy and safety. Despite facing some temporary challenges, including supply chain issues as was the case with Novartis AG's (Novartis') Pluvicto earlier in 2023, radiopharmaceutical companies are expanding their portfolios and progressing with clinical trials, therefore gaining investor interest. We would expect this trend to continue throughout 2024.

To this day, there remains an unmet need for more effective treatments in solid tumors. Radiopharmaceutical therapies are one of the key treatment approaches enabling a more precise delivery of a broader spectrum of targeted cancer treatments. In the fourth quarter of 2023, several companies have shown progress in advancing their clinical trial programs into late phases underscoring the potential of continued improvement in cancer care through use of radionuclides. Lantheus Holdings Inc. (Lantheus) and POINT announced the anticipated topline results from the Phase III SPLASH study in Metastatic Castration-Resistant Prostate Cancer. The pivotal Phase

III SPLASH study evaluated the efficacy and safety of 177Lu-PNT2002 in patients with metastatic castration-resistant prostate cancer (mCRPC) after progression on an androgen receptor pathway inhibitor (ARPI). The results of the study were positive and demonstrated statistically significant improvement in radiographic progression-free survival (rPFS), albeit expectations have not been exceeded by the current dataset. Telix Pharmaceuticals Ltd. (Telix) announced positive results from the Phase II OPALESCENCE trial of its carbonic anhydrase IX (CAIX)-targeting positron emission tomography (PET) imaging candidate, TLX250-CDx (89Zr-DFO-girentuximab), in patients with triple-negative breast cancer (TNBC) and also announced the initiation of its Phase III ProstACT GLOBAL study of its investigational prostate-specific membrane antigen (PSMA) targeting radio-antibody drug conjugate (rADC) therapy, TLX591 (177Lu-rosopatamab tetraxetan). The pilot prospective study of twelve metastatic patients demonstrated the expression of Carbonic anhydrase IX (CAIX) in TNBC and effective targeting with radiolabelled girentuximab. Clarity Pharmaceuticals Ltd. has been making headways by completing recruitment for a diagnostic Phase II trial in neuroendocrine tumors ahead of schedule commencing its registrational Phase III 64Cu-SAR-bisPSMA diagnostic trial in prostate cancer, CLARIFY, as well as recruiting its first patients in its theranostic 64Cu/67Cu SAR Bombesin Phase I/II trial in mCRPC.

Theranostic radiopharmaceuticals are offering promise for millions who currently have limited treatment options and therefore, companies active in this field have received a lot of attention and continued funding support within the precision oncology space. As the theranostics landscape evolves, radiopharmaceuticals are well-positioned, we believe, to become the new standard of care for treating many cancer types and to continue to disrupt the oncology drug market over the coming years. Equally, the addition of radiopharmaceuticals as a tool in the expanding toolbox of medical oncology, has the potential to lead to combinations with other emerging oncology therapies such as, in particular, immune-oncology solutions.

Thank you for your continued support as we navigate these exciting developments in the radiopharmaceutical and broader precision oncology landscape.

Warm regards,

*The PLUS** Team*

Sources

https://www.biospace.com/article/radiopharmaceuticals-bring-in-big-money-to-target-irreversible-tumor-damage-/

https://www.labiotech.eu/in-depth/radiopharmaceutical-market-funding-surge/

M&A Activity

Bristol Myers Squibb Adds to its Oncology Platform with Acquisition of RayzeBio

Bristol Myers Squibb and RayzeBio, Inc. have disclosed a conclusive merger agreement, in which Bristol Myers Squibb will complete the acquisition of RayzeBio at US$62.50 per share in cash, resulting in an overall equity value of about $4.1 billion, or a net value of $3.6 billion considering the estimated cash acquired. RayzeBio, a clinical-stage radiopharmaceutical therapeutics company, focuses on actinium-based RPTs, along with a pipeline featuring other drug development programs. The ongoing pipeline initiatives are directed towards addressing solid tumors, which includes gastroenteropancreatic neuroendocrine tumors (GEP-NETs), small-cell lung cancer, hepatocellular carcinoma, and various other cancers. Currently, the ACTION-1 Phase III clinical trial is in progress, focusing on cancer patients with SSTR-positive GEP-NETs who have previously undergone lutetium-177-based somatostatin treatments.

https://news.bms.com/news/details/2023/Bristol-Myers-Squibb-Adds-Premier-Radiopharmaceutical-Platform-with-Acquisition-of-RayzeBio/default.aspx

Lilly Acquires POINT Biopharma to Expand it Radiopharmaceutical Arm

Eli Lilly and Company has successfully finalized its acquisition of POINT Biopharma Global Inc., a radiopharmaceutical company dedicated to developing clinical and preclinical-stage radioligand therapies for cancer treatment. POINT Biopharma's portfolio includes two programs in phase III development: PNT2002 and PNT2003. The first, PNT2002, is a radioligand therapy specifically targeting prostate-specific membrane antigen, intended for the treatment of metastatic castration-resistant prostate cancer following second-line treatment. Currently undergoing evaluation in a pivotal trial named SPLASH, the asset is expected to yield top-line data by the end of this year. The second program, PNT2003, focuses on a somatostatin receptor-targeted radioligand therapy designed for patients with gastroenteropancreatic neuroendocrine tumors.

https://investor.lilly.com/news-releases/news-release-details/lilly-completes-acquisition-point-biopharma

Investments in Radiopharmaceuticals

ARTBIO Closes an Oversubscribed Series A Financing Round

ARTBIO has concluded a highly successful Series A financing round, securing US$90 million in funding. The round, which was oversubscribed and upsized, was co-led by Third Rock Ventures and an undisclosed healthcare fund. Notably, participation was also observed from seed lead investors F-Prime Capital and Omega Funds. This achievement follows the company's earlier seed investment round of $23 million, which was disclosed in June 2023.

https://www.prnewswire.com/news-releases/artbio-raises-oversubscribed-and-upsized-90-million-series-a-financing-to-progress-pipeline-and-isotope-technology-development-for-new-class-of-alpha-radioligand-therapies-302008226.html

Nucleus RadioPharma Completes Funding Round to Develop New Manufacturing Facilities

Nucleus Pharma has concluded an oversubscribed Series A funding round, securing a total of US$56 million. The funding was led by Eclipse and GE HealthCare, and saw active participation from Echo Global, Fox Chase Cancer Center, Granger Management, Mayo Clinic, Mercy Health, and the University of Missouri. This investment will enable Nucleus RadioPharma to establish several new manufacturing facilities across the United States, including in Rochester, Minnesota, near the Mayo Clinic. The company also plans to develop innovative technology for the production, manufacturing, and distribution of radiopharmaceuticals.

https://www.fiercepharma.com/manufacturing/nucleus-radiopharma-draws-56m-series-round-boost-manufacture-radiopharmaceuticals

Novartis Expands Radiopharmaceutical Production into China

Novartis is investing over 600 million Chinese yuan (US$84.6 million) in the construction of a new radiotherapy production facility in Haiyan, located in the Zhejiang province approximately 60 miles from Shanghai, China. Anticipated to become operational for local production in 2026, the plant is subject to regulatory approvals. This new facility in China supplements Novartis' existing radioligand therapy manufacturing sites in Ivrea, Italy; Zaragoza, Spain; Millburn, New Jersey; and Indianapolis, Indiana (awaiting FDA approval for commercial doses supply). Novartis aims to achieve a combined annual capacity of at least 250,000 doses from its existing facilities by around 2024. The expansion is in response to the growing demand for Novartis' PSMA-targeted radiotherapy, Pluvicto, particularly in the context of prostate cancer.

https://www.fiercepharma.com/manufacturing/novartis-expands-radiotherapy-manufacturing-network-85m-plant-china

Canadian Nuclear Laboratories (CNL)/ITM Isotope Technologies Munich SE (ITM) Establish a Joint Venture for Actinium-225 Production

ITM and CNL has jointly announced the formation of Actineer, a joint venture between the two organizations whose mission is to address global demands for Actinium-225 (Ac-225). Actineer aims to advance production capabilities, ensuring a stable supply of Ac-225 at an industrial scale. This initiative intends to support research, drug development, clinical trials, and improve patient access to advanced radiopharmaceuticals for both Canadians and cancer patients globally.

https://financialpost.com/globe-newswire/itm-and-cnl-announce-the-launch-of-actineer-a-new-joint-venture-in-the-global-production-of-actinium-225

The Canadian Medical Isotope Ecosystem Development Fund (CMIEDF) is Established

CMIEDF - will invest in Canadian projects aimed at advancing medical isotope supply and developing emerging technologies in radiotherapeutics and diagnostics. The CMIE initiative, co-led by TRIUMF Innovations and the Centre for Probe Development and Commercialization (CPDC), announced the launch of CMIEDF to accelerate research and development, collaboration, technology adoption, and training. The fund will support industry collaboration and invest in projects that contribute to medical isotope innovation. Funding, drawn from the CA$35 million launch funding awarded by Innovation, Science and Economic Development Canada's Strategic Innovation Fund (SIF), will be directed to recipients for research, development, and commercialization processes. Funding for selected projects will increase with successful project milestones.

https://www.newsfilecorp.com/release/187689/Canadian-Medical-Isotope-Ecosystem-Announces-Development-Fund-to-Foster-Innovation-in-the-Canadian-Isotope-Industry

Clinical Program Update

ITM Obtains Worldwide Exclusive License for Radiolabeled Folate Derivatives from Merck KgaA (Merck)

ITM has announced the execution of a worldwide exclusive license agreement with the life science business of Merck, Darmstadt, Germany. This license grants ITM the rights for the clinical development and commercialization of radiolabeled folate derivatives intended for therapeutic and diagnostic applications against folate-receptor-positive malignant tumors. Under the terms of the agreement, Merck will supply ITM with its folate precursors for radiolabeling, enabling ITM to advance the clinical development of its folate receptor-targeting radiopharmaceutical pipeline candidates. The license has been expanded to cover all folate-receptor-positive malignant tumors.

https://www.itm-radiopharma.com/news/press-releases/press-releases-detail/ITM_Executes_License_Agreement_to_Obtain_Worldwide_Exclusive_License_for_the_Clinical_Development_and_Commercialization_of_Folate-Based_Radiotheranostics-661/#:~:text=Garching%20%2F%20Munich%20Germany%2C%20December%2014,exclusive%20license%20for%20the%20clinical

Guardant Health's Liquid Biopsy to Potentially Reduce Toxicity from Chemotherapy

Guardant Health announced that the initial results from the PEGASUS trial suggest that liquid biopsy may be a valuable tool in post-surgical clinical management for patients with stage III or high-risk stage II colon cancer. The study involves 135 patients from 11 cancer centers in Italy and Spain. PEGASUS is one of the first prospective studies utilizing liquid biopsy, assessing the feasibility of adjusting adjuvant chemotherapy based on the presence or absence of minimal residual disease (MRD) indicated by circulating tumor DNA (ctDNA) detected through the Guardant Reveal blood test at multiple timepoints.

https://investors.guardanthealth.com/press-releases/press-releases/2023/First-results-from-PEGASUS-trial-reported-at-ESMO-show-promise-for-use-of-liquid-biopsy-to-guide-adjuvant-treatment-of-colon-cancer/default.aspx

Lantheus and POINT Biopharma Demonstrate Positive Top-Line Phase 3 Results in Prostate Cancer

Lantheus and POINT have reported positive topline results from the Phase 3 SPLASH trial evaluating the efficacy and safety of 177Lu-PNT2002, a PSMA RLT, in patients with mCRPC after progression on an androgen receptor pathway inhibitor (ARPI). The study demonstrated a statistically significant improvement in radiographic progression-free survival (rPFS), meeting its primary endpoint of 9.5 months compared to 6.0 months for the control arm, showing a 29% reduction in the risk of radiographic progression or death. Additional follow-up data are expected in 2024 in support of a potential New Drug Application (NDA) submission. Additionally, 177Lu-PNT2002 exhibited a favorable safety profile with lower rates of grade ≥3 treatment-emergent adverse events compared to the control arm. Full SPLASH trial results will be presented at a future medical congress.

https://www.globenewswire.com/news-release/2023/12/18/2797730/0/en/Lantheus-and-POINT-Biopharma-Announce-Positive-Topline-Results-from-Pivotal-SPLASH-Trial-in-Metastatic-Castration-Resistant-Prostate-Cancer.html

OncoBeta's Rhenium-188-based Skin Cancer Treatment Shows Effectiveness in Non-Melanoma Skin Cancer

A recent study demonstrated topical rhenium-188 skin cancer therapy to be a highly effective option for treating non-melanoma skin cancer (NMSC). The study included 22 patients with 40 confirmed NMSCs, and the key findings showed a highly effective response rate of 97.5% at 12 months, with 95.0% complete responses. Notably, no adverse events were reported during the application of rhenium-188, and the majority of patients did not experience adverse events during the trial period. Overall, the treatment demonstrated favorable results in addressing NMSC.

https://www.prnewswire.com/news-releases/latest-study-demonstrates-high-efficacy-in-curing-invasive-non-melanoma-skin-cancer-301966878.html

Telix Demonstrates Positive Top-Line Phase 2 Results in Triple-Negative Breast Cancer

Telix reported positive results from the Phase II OPALESCENCE trial of its CAIX-targeting PET imaging candidate, TLX250-CDx, in triple-negative breast cancer (TNBC). In a study of twelve metastatic patients, TLX250-CDx effectively targeted CAIX expression in lesions, including those in the breast, skin, adrenal gland, brain, nodes, and bone. The imaging candidate demonstrated safety and tolerability. The findings suggest TLX250-CDx's potential to detect chemotherapy-resistant and aggressively profiled lesions. Telix aims to expand its CAIX program, exploring future applications for lutetium-177 (177Lu) and actinium-225 (225Ac) based therapies beyond renal cancer.

https://www.prnewswire.com/apac/news-releases/positive-topline-results-from-phase-ii-opalescence-study-of-tlx250-cdx-in-triple-negative-breast-cancer-presented-at-sabcs-302006851.html

Telix Announces First Patient in its ProstACT GLOBAL Radio-Antibody-Based Phase III Study

Telix Pharmaceuticals announced that the first patient has been dosed in the ProstACT GLOBAL trial. The study focuses on TLX591 (177Lu-rosopatamab tetraxetan), an investigational prostate-specific membrane antigen (PSMA)-targeting radio-antibody drug conjugate (rADC) therapy. TLX591 comprises a high-specificity PSMA-targeting antibody, chelator linker, and a radioisotope (177-lutetium). This PSMA-targeted monoclonal antibody (mAb) approach differs in targeting and pharmacology compared to anti-PSMA small molecules. ProstACT GLOBAL is the first Phase III trial evaluating TLX591 in adult patients with PSMA-positive metastatic castrate-resistant prostate cancer (mCRPC). The trial will assess TLX591 administered together with Standard of Care (SoC) versus SoC alone.

https://www.prnewswire.com/news-releases/first-patient-dosed-in-phase-iii-prostact-global-study-of-antibody-based-prostate-cancer-therapy-candidate-tlx591-301985365.html

**About PLUS:

Portland Life and Unifying Sciences (PLUS) is a team within the Portland Holdings group of companies that focuses on healthcare that collaboratively helps the Portland Holdings group of companies to assess investment opportunities. The PLUS team is not a medical team and does not have deep long-standing expertise in TRT or areas relating to precision oncology.

Glossary:

177Lu is an isotopomer of lutetium(III) chloride containing the radioactive isotopeLu, which undergoes beta decay with a half-life of 6.65 days.

64Cu means a beta emitter radionuclide with a Half-Life of 12.7 hours.

67Cu means a beta emitter radionuclide with a Half-Life of 2.58 days.

Castrate-resistant means prostate cancer that no longer responds to testosterone-lowering treatment .

Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs) means slow-growing neoplasms that arise from the neuroendocrine system of the gastrointestinal tract and pancreas. Gastrointestinal tract is mostly the stomach and intestines.

Hepatocellular carcinoma (HCC) is the most common type of primary liver cancer.

Isotope means each of two or more forms of the same element that contain equal numbers of protons but different numbers of neutrons in their nuclei, and hence differ in relative atomic mass but not in chemical properties; in particular, a radioactive form of an element.

Metastasis means the spread of cancer cells from the place where they first formed to another part of the body. In metastasis, cancer cells break away from the original (primary) tumour, travel through the blood or lymph system, and form a new tumour in other organs or tissues of the body. The new, metastatic tumour is the same type of cancer as the primary tumour. The plural form of metastasis is metastases.

Neuroendocrine tumour (NET) means a tumour that forms from cells that release hormones into the blood in response to a signal from the nervous system.

Non-melanoma skin cancer (NMSC) – is the most common type of cancer and refers to all the types of cancer that occur in the skin that are not melanoma. (**Melanoma** is a kind of skin cancer that starts in melanocytes. **Melanocytes** are cells that make the pigment that gives skin its colour).

Precision oncology means molecular profiling of tumors to identify targetable alterations, is rapidly developing and has entered the mainstream of clinical practice.

Prostate-specific membrane antigen (PSMA) means a membrane protein which contributes to prostate cancer's development and is seen in a higher amounts in prostate cancer cells.

Radioligand therapy means a targeted form of cancer treatment that delivers radiation directly to cancer cells.

Radiopharmaceutical means a radioactive drug composed of a radionuclide and a pharmaceutical that is used for diagnosis or therapy.

Somatostatin means a peptide hormone that prevents the release of growth hormone from the pituitary gland.

Somatostatin receptors (SSTRs) means receptors that are expressed in high levels in gastroenteropancreatic neuroendocrine tumors.

Standard of Care (SoC)– medical treatment guideline

Targeted radionuclide therapy (TRT) means a form of treatment that delivers therapeutic doses of radiation to malignant tumours, for example, by administration of a radiolabeled molecule designed to seek out certain cells.

Theranostics means a new field of medicine which combines specific targeted therapy based on specific targeted diagnostic tests.

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