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ITM and POINT Biopharma sign two supply agreements for no-carrier-added Lutetium-177

Future-oriented supply agreements for no-carrier-added Lutetium-177 based Targeted Radionuclide Therapy for prostate cancer patients

ITM Isotopen Technologien München AG (ITM), a biotechnology and radiopharmaceutical group of companies, and POINT Biopharma Inc., a clinical oncology company, announced today that they have signed two supply agreements for the medical radioisotope no-carrier-added Lutetium-177 (n.c.a. ^{177}Lu) / EndolucinBeta® to support clinical and commercial supply of PNT2002, a ^{177}Lu-PSMA radiopharmaceutical for prostate cancer treatment.

Under the terms of the first agreement, ITM has partnered with POINT Biopharma for their clinical development of PNT2002, a ^{177}Lu-PSMA radiopharmaceutical for the treatment of metastatic castrate-resistant prostate cancer. PNT2002 is a radiopharmaceutical candidate with an excellent profile and will be investigated in a phase III clinical trial launching with the enrollment of patients in the fourth quarter of 2020. Additionally, both parties signed a long-term commercial agreement for the supply of n.c.a. ^{177}Lu following the marketing approval of PNT2002. Further terms of the agreements are not disclosed.

ITM's no-carrier-added Lutetium-177 (brand name EndolucinBeta®) is a radiopharmaceutical precursor used for Targeted Radionuclide Therapy in Precision Oncology. ITM manufactures n.c.a. ^{177}Lu for development partnerships, distribution to clinics worldwide, and its own growing Precision Oncology Pipeline. N.c.a. ^{177}Lu has marketing authorization in the EU and DMF in the US. Radiolabeled to disease-specific targeting molecules like antibodies or peptides, the tumor tissue is precisely targeted and destroyed by cytotoxic doses of medium-energy ionizing radiation. ITM has developed a unique methodology to produce a highly pure form of Lutetium-177, containing no metastable Lutetium-177m.

POINT Biopharma has a growing portfolio of best in class pharmaceutical assets and is working to revolutionize radiopharmaceutical drug development and commercialization for cancer treatment. The company specializes in radioligand therapies and is committed to bringing them to market quickly. The company anticipates its clinical trial programs to commence in 2020.

"*ITM has a proven track record of exceeding market demands. Choosing the right partner, with significant capacity, is critical to meeting the needs of our future patients*", said Dr Joe McCann, CEO of POINT Biopharma. "*We look forward to using these radioisotopes for our upcoming products including in our phase three prostate cancer trial starting this year*," Dr McCann added.

Steffen Schuster, CEO of ITM, commented: *"Like ITM, POINT Biopharma is eager to improve treatment outcomes and quality of life of cancer patients with Targeted Radionuclide Therapies. We are very pleased to establish this long-term alliance making significant contribution to innovative and promising therapies for cancer patients worldwide."*

– Ends –

About EndolucinBeta®

EndolucinBeta®, no carrier-added (n.c.a.) Lutetium-177 (^{177}Lu) chloride, is a radiopharmaceutical precursor used in Targeted Radionuclide Therapy for the treatment of various diseases, like cancer. When labeled with a disease-specific carrier molecule (e.g. peptide or antibody), the targeted radiopharmaceutical binds to a tumor specific receptor, according to the lock and key principle. EndolucinBeta® has a half-life of 6.647 days. No-carrier-added Lutetium-177 provides the highest specific activity of more than 3,000 GBq/mg at Activity Reference Time (ART), whereas the day of calibration can be flexibly selected by the customer. Optimal preconditions for efficient radiolabeling of biomolecules over its entire shelf-life of 9 days after production are ensured. EndolucinBeta® exhibits an extraordinary level of radionuclidic purity. EndolucinBeta® does not contain metastable Lutetium-177m. Thus, there is no need for cost intensive clinical disposal management and EndolucinBeta® can therefore be used globally – also in regions facing strict radiation protection regulations.

About Targeted Radionuclide Therapy

Targeted Radionuclide Therapy is a medical specialty using very small amounts of radioactive compounds, called radiopharmaceuticals, to diagnose and treat various diseases, like cancer. Targeted radiopharmaceuticals contain a targeting molecule (e.g. peptide or antibody) and a medical radioactive isotope. The targeting molecule binds to a tumor specific receptor, according to the lock and key principle. In most cases the targeting molecule can be used for both diagnosis and therapy – only the radioisotope has to be changed. This opens up the way for the application of Theranostics in the field of Precision Oncology. For diagnostic applications radioisotopes with short half-lives are used. With highly sensitive molecular imaging technologies like PET (Positron Emission Tomography) or SPECT (Single Photon Emission Tomography), pictures of organs and lesions can be created and diseases can therefore be diagnosed in their early stages. Medical radioisotopes with longer half-lives are applied for treatment. To destroying the tumor minimal cytotoxic doses of ionizing radiation have to be submitted to the tumor site before decay. A highly precise localization of the toxicity ensures that healthy tissue in the surroundings of the targeted tumor is minimally affected.
Please visit as well: www.radioligands.org

About ITM Isotopen Technologien München

ITM Isotopen Technologien München AG is a privately owned biotechnology and radiopharmaceutical group of companies dedicated to the development, production and global supply of targeted diagnostic and therapeutic radiopharmaceuticals and radioisotopes for use in cancer treatment. Since its foundation in 2004, ITM and its subsidiaries have established GMP manufacturing and a robust global supply network of a novel, first-in-class medical radioisotopes and generator platform for a new generation of targeted cancer diagnostics and therapies. Furthermore, ITM is developing a proprietary portfolio and growing pipeline of targeted treatments in various stages of clinical development, which address a range of cancers such as neuroendocrine tumors, glioblastoma, osteosarcoma and bone metastases, as well as folate receptor α positive tumors such as lung, ovarian or breast cancer. ITM's main objectives, together with its scientific, medical and industrial collaboration partners worldwide, are to significantly improve treatment outcomes and quality of life for cancer patients while at the same time reducing side effects and improving health economics through a new generation of Targeted Radionuclide Therapies in Precision Oncology. For more information please visit: www.itm.ag

About POINT Biopharma

POINT Biopharma is a globally focused radiopharmaceutical company with a growing portfolio of best in class pharmaceutical assets. POINT is combining a seasoned management team with strategic partnerships in radio-isotope supply, manufacturing technology and novel direct to patient targeting to revolutionize theranostic drug development and radioligand commercialization. Working closely with its scientific advisors, the Company anticipates commencement of its clinical trial programs in 2020. For more information please visit: www.pointbiopharma.com

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