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## **ITM signs long-term supply agreements with Nordic Nanovector for no-carrier-added Lutetium-177**

ITM Isotopen Technologien München AG (ITM), a biotechnology and radiopharmaceutical group of companies, announced today that ITM's subsidiary, ITG Isotope Technologies Garching GmbH (ITG) and Nordic Nanovector ASA (OSE: NANO) have signed long-term global supply agreements for the medical radioisotope no-carrier-added Lutetium-177 (n.c.a. <sup>177</sup>Lu) EndolucinBeta® to support R&D, clinical and commercial supply of Betalutin® (<sup>177</sup>Lu-Lilotomab-Satetraxetan).

Under the terms of the agreement for the study phase, ITM has partnered with Nordic Nanovector to support its clinical development. At the same time, both parties signed a commercial agreement for the supply of EndolucinBeta® post Marketing Approval of Betalutin®. Additional terms of the agreement are not disclosed.

EndolucinBeta®, radiolabeled to anti-CD37 murine antibody lilotomab, is an active component of Betalutin®, a next generation radioimmuno conjugate (RIC) currently under clinical development in patients who suffer from Non-Hodgkin Lymphoma (NHL). Betalutin® is a drug candidate with an excellent profile. As well as leveraging an alternative therapeutic target (anti-CD37 antigen) in recurrent lymphoma patients who have relapsed following anti-CD20-based therapy, it has shown durable responses in heavily pre-treated NHL patients after a one-time administration, combined with a predictable and manageable toxicity, an important feature for elderly NHL patients who may not be suited to chemotherapy.

EndolucinBeta®, a radiopharmaceutical precursor, is used in Targeted Radionuclide Therapy in the field of Precision Oncology and has marketing authorization in the EU. Radiolabeled to disease-specific targeting molecules like antibodies or peptides, the tumor tissue is precisely destroyed by cytotoxic doses of ionizing radiation. ITM has developed a unique methodology to produce a particularly highly pure form of Lutetium-177. No-carrier-added Lutetium-177 contains no metastable Lutetium-177m, therefore there is no need for cost intensive clinical waste management. This is especially important in countries with a release limit of Lutetium-177m into public sewage systems.

Marco Renoldi, Chief Operating Officer at Nordic Nanovector, said: *"We are pleased to extend our collaboration with a long-standing and reliable partner such as ITM. This global supply agreement is a key milestone in the implementation of our CMC (Chemistry, Manufacturing and Controls) strategy for gaining regulatory approval for Betalutin® and its subsequent commercial rollout, as it provides certainty of continued supply of n.c.a. Lutetium-177 throughout clinical development as well as after launch. The agreement with ITM, alongside other manufacturing supply and development agreements in place with specialist manufacturers at all stages of the manufacturing and supply chain for Betalutin® strengthens our confidence in the ability to deliver a reliable and sustainable supply chain in support of the launch of our lead asset."*

Steffen Schuster, CEO of ITM, added: *“Nordic Nanovector is one of our longstanding partners, as ITM has been supplying n.c.a. Lutetium-177 to Nordic Nanovector since 2010. We are delighted that Nordic Nanovector has reaffirmed their confidence through this long term supply agreement for EndolucinBeta®. In addition to the development of our own pipeline, we have once again been able to gain a strategic partner for the development of targeted radiopharmaceuticals in Precision Oncology, thereby making a significant contribution to advancing a promising treatment option for difficult-to-treat cancers. With our manufacturing facilities around the world and our unrivaled logistics network, we feel well equipped to reliably meet our partners’ needs and to enter into further strategic relationships.”*

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#### **About EndolucinBeta®**

EndolucinBeta® is a radiopharmaceutical precursor with a half-life of 6.647 days, usable for radiolabeling of disease-specific carrier molecules. The active substance of EndolucinBeta® is no-carrier-added (n.c.a.) Lutetium (<sup>177</sup>Lu) chloride. No-carrier-added <sup>177</sup>Lu provides the highest specific activity of more than 3,000 GBq/mg, whereby the day of calibration can be flexibly selected by the customer. Due to its high specific activity, optimal preconditions for efficient radiolabeling of biomolecules over its entire shelf-life of 9 days after production are ensured. Furthermore EndolucinBeta® exhibits an extraordinary level of radionuclidic purity. EndolucinBeta® does not contain metastable <sup>177m</sup>Lu, thus, there is no need for cost intensive clinical waste management. Marketing authorization holder of EndolucinBeta® is ITM’s subsidiary ITG.

#### **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.

### **About ITM Isotopen Technologien München**

ITM Isotopen Technologien München AG is a privately held biotechnology and radiopharmaceutical group of companies dedicated to the development, production and global supply of targeted diagnostic and therapeutic radiopharmaceuticals and radionuclides 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 innovative, first-in-class medical radionuclides and generator platforms 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 and bone metastases. ITM's main objectives, together with its scientific, medical and industrial collaboration partners worldwide, are to significantly improve 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 about ITM, please visit: [www.itm.ag](http://www.itm.ag)

### **About Nordic Nanovector**

Nordic Nanovector is committed to develop and deliver innovative therapies to patients to address major unmet medical needs and advance cancer care. The Company aspires to become a leader in the development of targeted therapies for haematological cancers. Nordic Nanovector's lead clinical-stage candidate is Betalutin®, a novel CD37-targeting antibody-radionuclide-conjugate designed to advance the treatment of non-Hodgkin's lymphoma (NHL). NHL is an indication with substantial unmet medical need, representing a growing market forecast to be worth nearly USD 29 billion by 2026. Nordic Nanovector intends to retain marketing rights and to actively participate in the commercialisation of Betalutin® in core markets. Further information can be found at [www.nordicnanovector.com](http://www.nordicnanovector.com).

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