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ITM and CIRC sign technology license agreement for the production and distribution of medical radioisotopes in China

ITM Isotopen Technologien München AG (ITM), a biotechnology and radiopharmaceutical group of companies, and Chengdu Gaotong Isotope Co., Ltd., a subsidiary of China Isotope & Radiation Corporation (CIRC), a nuclear technology application products manufacturer and supplier, announced today that they have signed a technology license agreement for the production and distribution of ITM Germanium-68/Gallium-68 Generators and no-carrier-added (n.c.a) Lutetium-177 (EndolucinBeta®) in China.

ITM and CIRC have already been working together in a successful partnership for almost 10 years in which CIRC has distributed ITM's medical radioisotopes, generators and equipment to the Chinese market. China's radiopharmaceutical market is now growing rapidly in line with the fast expanding clinical evidence and use of Targeted Radionuclide Therapies worldwide.

In order to meet the rising demand for Targeted Radionuclide Therapy in China, ITM and CIRC have decided to enter into a technology license agreement. Under the terms of the agreement, CIRC's subsidiary Gaotong will implement the production of ⁶⁸Ge/⁶⁸Ga Generators and n.c.a. Lutetium-177 (EndolucinBeta®), in China for the Chinese market, as well as joining ITM's global network of OEM suppliers in support of ITM's international framework agreements with strategic partners. Additional terms of the agreement are not disclosed.

The global ITM OEM Network serves the worldwide radiopharmaceutical market with OEM partners in the US, Australia and South Africa providing security of supply and scalability of medical radioisotopes for the exponentially growing use of Theranostics in Precision Oncology. With this new partnership, CIRC is now the fourth partner to join the global ITM OEM Processing and Production Network.

"ITM has developed a strong presence in the Chinese market through CIRC as our distribution partner, supplying ⁶⁸Ge/⁶⁸Ga Generators and no-carrier-added Lutetium-177 since 2010", said Steffen Schuster, CEO of ITM. "Now we are excited to take our established partnership to the next level. This agreement with CIRC allows us to share our manufacturing expertise in producing high-quality theranostic radioisotopes with a reliable partner who is able to implement and set highest quality standards in China. This gives us the opportunity to provide locally manufactured radioisotopes for Chinese cancer patients and also for cancer patients worldwide via our OEM Network. Through this expanded relationship with CIRC and Gaotong, we are looking forward to making Targeted Radionuclide Therapy available to a growing number of cancer patients and to jointly improving patients' outcomes and quality of life."

Mr. Wu Jian, General Manager of CIRC added: *"We can look back on a long-standing and reliable relationship with ITM through which we have been able to offer the best next generation medical isotope products available to the emerging Chinese radiopharmaceutical market from the very beginning. With this important agreement we are taking the next step in serving Chinese cancer patients through China's nuclear medicine practitioners in a better and timely manner and deepening our relationship with ITM at the same time. We believe that on the basis of our decades of experiences in radionuclides and radiopharmaceutical research and production, by manufacturing radioisotopes according to the unique methodologies developed by ITM and internationally accepted quality standards, particularly the theranostic pair Gallium-68 and the unrivaled no-carrier-added Lutetium-177, we will be able to supply high quality products to help many cancer patients in China and provide an economically sustainable solution for the Chinese Health Care System."*

About $^{68}\text{Ge}/^{68}\text{Ga}$ Generators

The medical radionuclide Gallium-68 (^{68}Ga), which is produced in $^{68}\text{Ge}/^{68}\text{Ga}$ (Germanium-68 / Gallium-68) generators, is used in the field of Targeted Radionuclide Therapy to diagnose cancers like prostate cancer and neuroendocrine tumors. When labeled to a disease-specific targeting molecule, the medical radioisotope can be used to produce diagnostic images via positron emission tomography (PET), which map the location of the specific cancer throughout the body.

The $^{68}\text{Ge}/^{68}\text{Ga}$ Generator is a fully shielded source of radioactive ^{68}Ga and can be applied for radiolabeling of ^{68}Ga peptides for diagnostic purposes. ^{68}Ga is continuously produced by decay of its radioactive parent (^{68}Ge) and is eluted with HCL. The generator column's unique metal free design and its low acidic eluent allow fast and convenient onsite production of short-lived high-quality ^{68}Ga for radiolabeling without prior prepurification.

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 of logistics and storage of contaminated radioactive waste.

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

About China Isotope & Radiation Corporation (CIRC) and Chengdu Gaotong Isotope (CNGT)

China Isotope & Radiation Corporation (CIRC stock code: HK01763), a company incorporated under the laws of the PRC is the holding subsidiary of China National Nuclear Corporation (CNNC) and the largest nuclear enterprise in the aspects of research and development, manufacture, distribution and service of nuclear products in China. CIRC is mainly engaged in research and application of radioisotope and radiation technology, covering radioisotope, radiopharmaceuticals, radioactive source, radiation engineering and processing etc. There are more than 50 production lines capable of supplying over 70 nuclides and 300 kinds of products all together. As of October 18, 2019, CNNC directly and indirectly holds 73.38% of shares of CIRC.

Chengdu Gaotong Isotope Co., Ltd. (CNGT), a company incorporated under the laws of the PRC, owned by CIRC as to 93.15% of its equity interest. CNGT is mainly engaged in the production of radiopharmaceuticals, sealed radioactive sources with activity categorized from 5 to 1, and related technical services, including sealed source reloading, radioactive material transportation and recycling.

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