

RadioMedix and ITM announce agreement for manufacturing of Ge-68/Ga-68 generators in U.S.

Houston (TX, USA) and Garching (Germany), July 26, 2018 – RadioMedix Inc. and ITM Isotopen Technologien München (ITM), a group of specialized radiopharmaceutical companies announced today that ITM’s subsidiary, Isotope Technologies Garching GmbH (ITG), and RadioMedix have signed a manufacturing and supply agreement for the production of the next generation of Ge-68/Ga-68 (Germanium-68/Gallium-68) generators at the new RadioMedix Spica Center (RSC) in Houston, Texas. RSC is a 21 CFR 211 compliant, radiopharmaceutical manufacturing facility dedicated to late stage investigational and commercial stage radiopharmaceuticals.

The medical radionuclide Gallium-68, which is produced in Ge-68/Ga-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 produce diagnostic images via positron emission tomography (PET), which maps the location of the specific cancer throughout the body.

“RadioMedix has been the exclusive distributor of ITG products in North America since 2013, including their Ge-68/Ga-68 generators. With the opening of this state-of-the-art facility, our partnership will address the global supply shortage of Ga-68 generators. RadioMedix Spica Center has been selected as the manufacturing site for the newest generation of ITG generators and given the scale of this new facility, cannot only supply the needs of North America but potentially the global market. Ge-68/Ga-68 generators serve as an on demand source of a positron emitter that has recently revolutionized the R&D and clinical developments in the field of PET Radiopharmaceuticals,” said Dr Ebrahim S. Delpassand, Chairman and CEO of RadioMedix Inc. *“The United States is one of the largest markets for these generators and a local manufacturing site as well as a DMF at the U.S. FDA for this product creates significant efficiencies in availability, cost, and distribution of this product in our country,”* added Dr. Delpassand.

“We are delighted to expand our trusted partnership with RadioMedix for the production of our Ge-68/Ga-68 generators in the U.S.,” said Steffen Schuster, CEO of ITM. *“Targeted Radionuclide Therapy is a unique theranostic approach and has been used increasingly in recent years due to its excellent efficacy with comparatively few side effects. To meet the medical community’s growing demand for radionuclides, we already partnered with a North American nuclear power company to achieve new scalability of the generators’ therapeutic companion, Lutetium-177. Our extended partnership with RadioMedix now gives us the opportunity to significantly improve our supply capabilities of our diagnostic radioisotope, Gallium-68. This cooperation is an important further step, as it helps us secure the supply of high-quality medical radioisotopes for Targeted Radionuclide Therapy to cancer patients worldwide.”*

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RadioMedix Inc

RadioMedix, Inc. is a clinical stage biotechnology company, based in Houston, Texas, focused on development and manufacturing innovative targeted radiopharmaceuticals for the diagnosis, monitoring and therapy of cancer. The company is commercializing PET imaging and targeted radiotherapies using alpha- and beta-labeled drug products. RadioMedix has a strong clinical record serving as a sponsor and collaborator of multiple clinical trials. For more information visit us at www.radiomedix.com.

RadioMedix Spica Center

The RadioMedix SPICA Center (RSC) was established in early 2018, is a 27,000. SQF GMP manufacturing center, located near George Bush International airport, north of Houston, Texas. This state of the art, 21CFR 211 compliant, GMP manufacturing facility is focused on the production of the late stage investigational and commercial stage radiopharmaceuticals. RSC is equipped with 6 clean rooms, incorporating multiple lines of hot cells with fully automated synthesizers and processes. Q/C rooms are designed with the latest analytical instrumentation and modules. Our highly skilled and knowledgeable professionals have significant experience in FDA regulatory requirements for drug development and commercial manufacturing.

ITM Isotopen Technologien München AG

ITM Isotopen Technologien München AG is a privately held group of companies dedicated to the development, production and global supply of innovative diagnostic and therapeutic radionuclides and radiopharmaceuticals. Since its foundation in 2004, ITM and its subsidiaries have established GMP manufacturing and a robust global supply network of novel, first-in-class medical radionuclides 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 cancers 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

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