FDA has issued Drug Master File for ITM's Gallium Generator GeGant®

GeGant® for the U.S. market will be produced and distributed by ITM's long-term partner RadioMedix

Garching/Munich, Germany, and Houston, Texas, U.S., December 8, 2020: ITM Isotopen Technologien München AG (ITM), a biotechnology and radiopharmaceutical group of companies, and RadioMedix Inc., a clinical stage biotechnology company, today announced that the U.S. Food and Drug Administration (FDA) has issued the Drug Master File (DMF no. 34938) for ITM's next generation Germanium-68/Gallium-68 (^{68}Ge/^{68}Ga) Generator, distributed under the brand name GeGant®.The DMF will allow parties interested in developing new drugs for the U.S. market to refer to the DMF and use GeGant® in clinical tests for radiopharmaceuticals and in other settings.

The GeGant® Generators will be manufactured at the RadioMedix Spica Center in Houston, Texas, U.S., a GMP radiopharmaceutical manufacturing facility that is dedicated to late-stage investigational and commercial stage radiopharmaceutical manufacturing and distribution. At this center, thousands of ^{68}Ge/^{68}Ga Generators can be produced, annually. This high production capacity enables ITM and RadioMedix to meet the rapidly increasing demand for Gallium-68 in the United States and across the world.

The medical, short-lived radioisotope Gallium-68 is used for Positron Emission Tomography (PET) imaging when labeled to a tumor-specific targeting molecule for diagnosis and staging of various cancers, like neuroendocrine tumors or prostate cancer. PET-imaging is a state-of-the-art approach for precise localization of tumors or metastases pre-therapy as well as the evaluation of treatment response post-therapy. It is a highly sensitive method, providing quick procedures with short imaging time. GeGant® allows onsite production of high-quality Gallium-68 for radiolabeling with disease specific tracers. As well as showing a low breakthrough of Germanium-68, GeGant® is available in different sizes, and with 4 GBq (100 mCi), being among the largest ^{68}Ge/^{68}Ga Generators on the market.

"*This announcement by the U.S. FDA takes us another step closer toward full adaptation of the GeGant® Generators in the U.S market. The consumption of Gallium-68, as an on-demand positron emitter, will only increase in the field of Nuclear Medicine. There is exponential growth of several exciting molecules labeled with Gallium-68 and RadioMedix's manufacturing bandwidth is prepared to respond to this unmet need*", said Ebrahim Delpassand, M.D., CEO of RadioMedix.

Steffen Schuster, CEO of ITM said: "*The Drug Master File in the U.S. will enable us to take full advantage of our long-term partner RadioMedix's production capacity which is needed to address the rapidly growing demand for Gallium-68 in the United States as one of the largest markets for Targeted Radionuclide Therapies and Diagnostics. Together with Radiomedix, we are looking forward to scaling up the production of GeGant® to provide high quality products for patients in need in North America as well as the global market.*"

- Ends -

About GeGant®

GeGant® is a next generation Germanium-68/Gallium-68 (^{68}Ge/^{68}Ga) Generator for onsite production of the short-lived, medical radioisotope Gallium-68 (^{68}Ga), used in Targeted Radionuclide Therapy for diagnosis and staging of cancers. ^{68}Ga is a radiopharmaceutical precursor, and it is not intended for direct use in patients. Conjugated to a tumor-specific targeting molecule (e.g. peptide or antibody), Gallium-68 is applied for diagnostic imaging via positron emission tomography (PET). It is to be used only for the radiolabeling of targeting molecules that have been specifically developed and approved for radiolabeling with ^{68}Ga. ^{68}Ga-PET-imaging is a state-of-the-art approach for precise localization in diagnostic imaging. As well as for diagnosis and staging of tumors, Gallium-68 based imaging is used for therapy planning and dosimetry in preparation for Targeted Radionuclide Therapy with its therapeutic companion radioisotope Lutetium-177.

GeGant® is a fully shielded source of high-quality Gallium-68 available in different sizes from 1 GBq (30 mCi) to 4 GBq (100 mCi), making it one of the largest ^{68}Ge/^{68}Ga Generators on the market. Gallium-68 is continuously produced by decay of its parent radioisotope Germanium-68 and eluted with low acidic hydrochloric acid. It is suitable for radiolabeling of tumor-specific targeting molecules without prior prepurification.

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 RadioMedix

RadioMedix, Inc. is a clinical stage biotechnology company, based in Houston, Texas, focused on innovative targeted radiopharmaceuticals for diagnosis, monitoring, and therapy of cancer. The company is commercializing radiopharmaceuticals for PET imaging and therapeutic (alpha and beta-labeled) radiopharmaceuticals. RadioMedix has established contract service facilities for academic and industrial partners: cGMP manufacturing and analytical suites for human clinical trials, and commercial phase manufacturing of the radiopharmaceuticals, in addition to Drug Discovery Core and small animal Molecular Imaging Center for the pre-clinical evaluation of new targets in vitro and in vivo. RadioMedix's Spica Center consists of 27,500 SQFT Manufacturing Space, high Value packaging corridor, and capacity for scaling up & supporting multi-probe diagnostics & therapeutic agents for commercialized, centralized manufacturing, and distribution throughout North America & globally. To learn more, visit www.radiomedix.com. For more information about this press release, please contact: media@radiomedix.com

ITM Contact
Nicola Scharrer
Head of Marketing & Communications
Phone: +49 89 329 89 86 151
Email: nicola.scharrer@itm.ag

RadioMedix Contact
Britney Stewart
Media Relations
Phone; 713-358-6500
Email: media@radiomedix.com