



## **ITM and RadioMedix announce Drug Master File Submission for ITM's $^{68}\text{Ge}/^{68}\text{Ga}$ Generator GeGant<sup>®</sup> for the U.S. Market.**

**ITM's long-term partner RadioMedix is producing and distributing GeGant<sup>®</sup> for the U.S. market.**

Garching/Munich, Germany, and Houston, Texas, U.S., July 10, 2020: ITM Isotopen Technologien München AG (ITM), a biotechnology and radiopharmaceutical group of companies, and RadioMedix Inc., a clinical stage biotechnology company, announced today that ITM has filed a Drug Master File (DMF) with the U.S. Food and Drug Administration (FDA) for ITM's next generation Germanium-68/Gallium-68 ( $^{68}\text{Ge}/^{68}\text{Ga}$ ) Generator, which is manufactured at the RadioMedix Spica Center in Houston, Texas, U.S. and distributed under the brand name GeGant<sup>®</sup>.

The RadioMedix Spica Center is a 21 CFR 211 compliant, and GMP radiopharmaceutical manufacturing facility dedicated to late-stage investigational and commercial stage radiopharmaceutical manufacturing and distribution. Thousands of  $^{68}\text{Ge}/^{68}\text{Ga}$  Generators can be produced, annually at this center. This high production capacity enables us to meet the rapidly increasing demand for Gallium-68 in the United States.

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, and for evaluation of response to therapy. PET-imaging is an excellent approach for healthcare professionals looking for precise localization in diagnostic imaging. GeGant<sup>®</sup> allows fast and convenient onsite production of high-quality Gallium-68 for radiolabeling. As well as showing a low breakthrough of Germanium-68, GeGant<sup>®</sup> is available in the sizes of 1 GBq (30 mCi), 2 GBq (50 mCi), and 4 GBq (100 mCi), being among the largest  $^{68}\text{Ge}/^{68}\text{Ga}$  Generators on the market.

*"We are living in an exciting time in the field of nuclear medicine and the menu of targeted PET imaging agents will only grow.  $^{68}\text{Ga}$  is among the most important players in this field" said Dr. Ebrahim Delpassand, CEO of RadioMedix. "We are excited to be able to accomplish this milestone in collaboration with our long-term partner ITM, Germany. RadioMedix will be the manufacturer of ITM  $^{68}\text{Ge}/^{68}\text{Ga}$  Generators, for the first time in the United States. Our high manufacturing capacity will address the significant shortage of this essential device in the market and increases patients' access to a variety of  $^{68}\text{Ga}$  labeled radiopharmaceuticals in the field of oncology." continued Dr. Delpassand.*

Steffen Schuster, CEO of ITM said: *"We are very pleased to see this DMF submission in the U.S. has taken our close and long-term partnership with RadioMedix to a new level and will enable us to take full advantage of RadioMedix's great production opportunities."* Steffen Schuster added: *"With RadioMedix as our strategic partner, we are looking forward to GeGant<sup>®</sup> significantly increasing the availability of Gallium-68 in the U.S. We are confident that we can make a substantial contribution to meeting the growing demand of Targeted Radionuclide Therapies and Diagnostics within the U.S. market."*

- Ends -

### **About GeGant®**

GeGant® is a next generation Germanium-68/Gallium-68 (<sup>68</sup>Ge/<sup>68</sup>Ga) Generator allowing fast and convenient onsite-production of the short-lived, medical radioisotope Gallium-68 (<sup>68</sup>Ga), used in Targeted Radionuclide Therapy for diagnosis and staging of cancers like neuroendocrine tumors or prostate cancer. <sup>68</sup>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 authorized for radiolabeling with <sup>68</sup>Ga. <sup>68</sup>Ga-PET-imaging is an excellent approach for healthcare professionals looking 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 to 4 GBq, making it the largest <sup>68</sup>Ge/<sup>68</sup>Ga Generator 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 purification.

### **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  $\alpha$  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](http://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](http://www.radiomedix.com). For more information about this press release, please contact: [media@radiomedix.com](mailto:media@radiomedix.com)

#### **ITM Contact**

Nicola Scharrer  
Head of Marketing & Communications  
Phone: +49 89 329 89 86 151  
Email: [Nicola.Scharrer@itm.ag](mailto:Nicola.Scharrer@itm.ag)

#### **RadioMedix Contact**

Britney Stewart  
Media Relations.  
Phone; 713-358-6500  
Email: [media@radiomedix.com](mailto:media@radiomedix.com)