

ITM, Helmholtz Munich and University Hospital Münster Announce Start of Phase I Clinical Trial with Radiotherapeutic ITM-31 for Glioblastoma

Garching/Munich, Munich and Münster, Germany, March 13, 2023 – [ITM Isotope Technologies Munich SE \(ITM\)](#), a leading radiopharmaceutical biotech company, [Helmholtz Munich](#) and the Departments of Neurosurgery and Nuclear Medicine at the University Hospital Münster today announced the start of a Phase I clinical trial with ITM's drug candidate ITM-31 (formerly LuCaFab), a novel Targeted Radionuclide Therapy candidate for the treatment of malignant glioblastoma. ITM-31 is a carbonic anhydrase (CA) XII-specific antibody Fab fragment developed by Helmholtz Munich coupled with ITM's medical radioisotope, non-carrier-added lutetium-177 (n.c.a. ¹⁷⁷Lu, EndolucinBeta®). The investigator-initiated trial (IIT) is sponsored by the University Hospital Münster, conducted in hospitals in Münster, Essen, Cologne, Würzburg, and supported by ITM and Helmholtz Munich. Patient recruitment for the study is ongoing.

Glioblastoma is a malignant brain tumor with a median survival of approximately 14 to 15 months from diagnosis.¹ After treatment with standard therapies (surgery, radio- and chemotherapy), there is a risk that individual tumor cells will remain in the tissue and begin to grow again (relapse). Therefore, treatment of tissue surrounding the tumor is of great importance. ITM-31 has been designed specifically to target residual tumor cells in this surrounding tissue, with the aim of mitigating tumor recurrence.

“A treatment capable of selectively eliminating dormant residual tumor cells after surgical removal of glioblastoma and standard radiochemotherapy gives hope for greater success than with the current standard therapy alone. Intracavitary Radionuclide Therapy with ITM-31 could provide such a treatment opportunity,” says **Prof. Walter Stummer, Principal Investigator and Chairman of the Department of Neurosurgery at the University Hospital Münster. Study Coordinator Prof. Hans-Jürgen Reulen** adds: *“Initial compassionate use with ITM-31 (LuCaFab) and previous studies with other radiotherapeutic drug candidates have shown promising results and support the potential of the radiotherapeutic approach for this hard-to-treat cancer type.”*

The Targeted Radionuclide Therapy candidate ITM-31 targets a specific protein (antigen) called CA XII, which is highly expressed on the cell surface of glioblastoma cells, but not found on healthy brain cells. It comprises a CA XII antibody Fab fragment coupled with the radioisotope ¹⁷⁷Lu. ITM-31 is administered directly into the tumor cavity from where it migrates into the surrounding tissue with high specificity, binding to glioblastoma cells which are then irradiated and potentially destroyed while healthy tissue is spared. ITM-31 could thus act as a complementary, adjuvant therapy to the current standard of care approach as it is designed to be applied after initial treatment to glioblastoma to prevent future tumor growth.

“Several published preclinical studies, including ones by our research group, report significant success in the field of Targeted Radionuclide Therapy for brain tumors,” comments **Prof. Reinhard Zeidler, Project Leader at Helmholtz Munich**. *“ITM-31, unlike other radionuclide therapies, applies a 'downsized antibody', a so-called Fab fragment, which spreads throughout the tissue more easily. Such improved pharmaceutical properties have the potential to create further benefits for the treatment of seriously ill patients living with cancer.”*

¹ Ohka et al 2012, Thakkar et al., 2014

*“Together with our partners, our goal is to develop an effective and safe therapeutic option for patients living with this malignant brain tumor,” says **Steffen Schuster, CEO of ITM.** “ITM-31 is a novel treatment approach that is targeted to the cancer cells that evade current treatment regimens, causing glioblastoma to be one of the most aggressive and difficult to treat cancers. This trial is an important first clinical step to developing ITM-31 into a drug potentially capable of circumventing previous hurdles in this high-need indication.”*

About the Phase I clinical trial with ITM-31

The aim of the dose-escalation study (NCT05533242) with up to 15 patients is to collect data on the efficacy, tolerability, and safety of the investigational drug and to evaluate the best possible patient dose for future studies. Before being treated with ITM-31 in the trial, patients undergo 6 months of standard radio-chemotherapy treatment after surgery. Three single doses of the investigational drug are administered over three months.

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ITM Isotope Technologies Munich SE

ITM, a leading radiopharmaceutical biotech company, is dedicated to providing a new generation of radiomolecular precision therapeutics and diagnostics for hard-to-treat tumors. We aim to meet the needs of cancer patients, clinicians and our partners through excellence in development, production and global supply. With improved patient benefit as the driving principle for all we do, ITM advances a broad precision oncology pipeline, including two phase III studies, combining the company’s high-quality radioisotopes with a range of targeting molecules. By leveraging our nearly two decades of pioneering radiopharma expertise, central industry position and established global network, ITM strives to provide patients with more effective targeted treatment to improve clinical outcome and quality of life. www.itm-radiopharma.com

Helmholtz Munich

Helmholtz Munich is a leading biomedical research center. Its mission is to discover breakthrough solutions for better health in a rapidly changing world. It is home to interdisciplinary research teams investigating the development of environmentally triggered diseases. With the power of artificial intelligence and bioengineering, the researchers accelerate the translation process to patients in the areas of therapy and prevention with a focus on diabetes, obesity, allergies and chronic lung diseases. Helmholtz Munich has more than 2,500 employees and is headquartered in Neuherberg, north of Munich. It is a member of the Helmholtz Association, the largest scientific organization in Germany with more than 43,000 employees and 18 research centers. Learn more about Helmholtz Munich (Helmholtz Zentrum München, Deutsches Forschungszentrum für Gesundheit und Umwelt GmbH): www.helmholtz-munich.de/en

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