ITM, Helmholtz Munich and University Hospital Münster Announce First Patient Dosed in Phase I Investigator-Initiated Glioblastoma Trial

A Novel Therapeutic Approach to Treatment using ITM-31

Garching/Munich, Munich and Münster, April 23, 2024 – The Departments of Neurosurgery and Nuclear Medicine at the University Hospital Münster, Helmholtz Munich, and ITM Isotope Technologies Munich SE (ITM), a leading radiopharmaceutical biotech company, today announced that the first patient has been dosed in an investigator-initiated trial (IIT) with ITM's radiopharmaceutical drug candidate, ITM-31 for the potential use in glioblastoma patients. The IIT is sponsored by the University Hospital Münster, conducted in hospitals in Münster, Essen, Cologne, and Würzburg, and supported by Helmholtz Munich and ITM.

After glioblastoma patients receive standard treatment with surgery, radio- and chemotherapy, individual tumor cells often remain undetected in surrounding tissue and grow again leading to relapse. This makes glioblastoma one of the most aggressive, deadliest and hard-to-treat cancers.

"Glioblastoma remains a challenging disease. Eliminating residual tumor cells in the surrounding tissue post-surgery could be crucial to address and prevent relapses. As such, we believe that ITM-31 has the potential to improve current treatment methods in this high-need indication," said **Prof. Walter Stummer, Principal Investigator and Chairman of the Department of Neurosurgery at the University Hospital Münster**. **Study Coordinator, Prof. Hans-Jürgen Reulen** added, *"The phase I study will allow us to further analyze the impact that ITM-31 could make in this patient population, and marks a critical step in the clinical development of this promising radiopharmaceutical drug candidate."*

ITM-31 is a carbonic anhydrase (CA) XII-specific antibody Fab fragment developed by Helmholtz Munich and coupled with ITM's medical radioisotope, non-carrier-added Lutetium-177 (n.c.a. ^{177}Lu, EndolucinBeta®).

"The phase I study builds on previous preclinical data that point to radiopharmaceuticals as a potential new method with which to circumvent previous challenges posed by glioblastoma," commented **Prof. Reinhard Zeidler from Helmholtz Munich**, who spearheaded the basic research and provided scientific oversight throughout the transition to clinical trials.

"Innovative radiopharmaceuticals have the potential to address gaps in current treatment paradigms, particularly in aggressive cancers with poor prognoses such as glioblastoma," said **Steffen Schuster, CEO of ITM.** *"ITM is proud to support this trial conducted by Prof. Stummer and the University Hospital Münster."*

The dose-escalation study (NCT05533242) is enrolling up to 15 patients and will evaluate the impact of ITM-31 on glioblastoma patients by analyzing the tolerability and safety of ITM-31 while evaluating the best possible patient dose for future studies. Patients presenting either no or stable, high-grade glioma residue following standard therapy (surgery and radiochemotherapy, adjuvant chemotherapy),

are eligible for the trial, 6 weeks after completing radiotherapy, at the earliest. Patients will receive their personalized calculated total doses of ITM-31 in three fractions with an interval of 4 weeks between injections.

About 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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