ITM, Helmholtz Munich and the University of Münster Announce Updated Preliminary Phase 1 Data with ITM-31 in Glioblastoma Patients

- Patient enrollment has been completed; all enrolled patients remain alive
- Data presented at the Nuclear Medicine and Neuro-Oncology (NMN) Society Annual Symposium

Garching/Munich and Münster, Germany - June 29, 2026 - ITM Isotope Technologies Munich SE (ITM), a leading radiopharmaceutical biotech company, Helmholtz Munich and the University of Münster today announced updated preliminary results from a Phase 1 clinical trial of investigational candidate, ITM-31 (^{177}Lu-6A10-Fab), an intracavitary targeted radiotherapy, in patients with glioblastoma. These data showed a manageable safety profile, with all patients remaining alive since enrollment began in January 2024. Enrollment is now complete, and the initial six-month follow-up period for all patients is expected to be completed by the end of 2026. Preliminary data were recently presented at the Nuclear Medicine and Neuro-Oncology (NMN) Society Annual Symposium, in Vienna, Austria.

The investigator-initiated Phase 1 trial (NCT05533242) is a prospective, single-arm, multicenter, dose-escalation study evaluating the safety, tolerability, and maximum tolerated dose of ITM-31, as well as progression-free survival (PFS) and overall survival (OS) in patients with newly diagnosed glioblastoma, following surgical resection and standard radio-chemotherapy, with no or minimal residual disease. ITM-31 is designed as a maintenance therapy applied during a period of stability. The study enrolled ten patients across four clinical sites at German university hospitals in Münster, Würzburg, Essen, and Cologne.

ITM-31 is a Lutetium-177-labeled 6A10 Fab fragment targeting carbonic anhydrase XII (CA XII), a cell surface protein expressed in more than 90% of glioblastoma cases but absent in healthy brain tissue. It is administered via intracavitary injection directly into the post-surgical resection cavity, enabling targeted radiation of residual tumor cells, bypassing the blood–brain barrier. Under a licensing agreement with Helmholtz Munich, ITM holds exclusive rights to develop and commercialize ITM-31.

“By delivering ITM-31 directly into the surgical resection cavity, our goal is to achieve high targeted radiation exposure at the site of residual disease, while minimizing systemic toxicity,” said **Dr. Michael Müther, study investigator and neurosurgeon at the University of Münster**. “Given the disease’s high rate of recurrence, strategies that address residual tumor cells locally may play an important role in improving outcomes.”

“We have come a long way from validating our antibody in the first cell assays to bringing it into the clinic. It has been a wonderful experience to partner with the University of Münster and ITM for this first study, and we are hopeful that this approach may ultimately benefit patients with glioblastoma,”

said **Prof. Reinhard Zeidler, group leader at the Institute of Structural Biology, Molecular Targets and Therapeutics Center, Helmholtz Munich**, who identified and developed the CA XII-targeting 6A10 antibody fragment used in ITM-31.

Study design:

- Patients with newly diagnosed glioblastoma received individualized total doses of ITM-31 in three fractions with an interval of 4 weeks between injections after completion of standard of care therapy. There were three dose-escalating cohorts.

Key preliminary findings show:

- ITM-31 demonstrated a manageable safety profile across all cohorts; adverse events were predominantly reversible and manageable with standard treatment.
- No Grade ≥3 hematological toxicities were observed, and dosimetry confirmed radiation exposure remained below established safety thresholds for organs at risk.
- ITM-31 has demonstrated early signs of efficacy in patients with newly diagnosed glioblastoma. All enrolled patients remain alive during ongoing follow-up.

"These preliminary results support the potential of intracavitary targeted radiotherapy with ITM-31 as a novel approach for patients with glioblastoma, where outcomes remain extremely poor following standard of care treatment," said **Dr. Celine Wilke, chief medical officer of ITM**. "The safety profile and early signs of anti-tumor activity observed to date support continued clinical development."

Patients will continue to be followed for up to two years after initial treatment with ITM-31.

Preliminary pilot data were published in *EJNMMI Research* (2023), demonstrating the feasibility and safety of intracavitary administration of [^{177}Lu]6A10-Fab fragments in patients with glioblastoma.

About Glioblastoma

Glioblastoma is the most common and aggressive primary malignant brain tumor in adults, accounting for nearly half of all gliomas and affecting more than 25,000 patients annually in Europe and over 100,000 worldwide. In the United States, approximately 12,000–14,000 new cases are diagnosed each year.

Despite standard treatment with surgery, radiation and chemotherapy, outcomes remain poor, with median overall survival of approximately 15–20 months. Recurrence mostly occurs around the original tumor site, underscoring the need for effective locoregional therapies. The blood-brain barrier further limits the impact of many systemic treatments, highlighting the need for novel therapeutic approaches.

About ITM Isotope Technologies Munich SE

ITM, a leading radiopharmaceutical biotech company, is dedicated to providing a new generation of radiopharmaceutical 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 of medical radioisotopes. With improved patient benefit as the driving principle for all we do, ITM advances a broad precision oncology pipeline, including multiple Phase 3 studies, combining the company's high-quality radioisotopes with a range of targeting molecules. By leveraging our 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

About Helmholtz Munich
Helmholtz Munich is a leading biomedical research center. Its mission is to develop breakthrough solutions for better health in a rapidly changing world. Interdisciplinary research teams focus on environmentally triggered diseases, especially the therapy and prevention of diabetes, obesity, allergies, and chronic lung diseases. With the power of artificial intelligence and bioengineering, researchers accelerate the translation to patients. Helmholtz Munich has more than 2,555 employees and is headquartered in Munich/Neuherberg. It is a member of the Helmholtz Association, with more than 48,000 employees and 18 research centers the largest scientific organization in Germany. More about Helmholtz Munich (Helmholtz Zentrum München Deutsches Forschungszentrum für Gesundheit und Umwelt GmbH): www.helmholtz-munich.de/en

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