

ITM Executes Option to In-license Targeted Radionuclide Therapy Candidate LuCaFab (ITM-31) for the Treatment of Malignant Brain Tumors

Exclusive license from Helmholtz Munich will enable ITM to access IP and know-how to develop and commercialize ITM-31 for glioblastoma patients

Garching/Munich, Germany, October 19, 2022 – [ITM Isotope Technologies Munich SE \(ITM\)](#), a leading radiopharmaceutical biotech company, today announced the execution of an exclusive licensing option for LuCaFab (now ITM-31), a novel Targeted Radionuclide Therapy candidate for the treatment of malignant glioblastoma. ITM-31 is a carbonic anhydrase XII (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. ¹⁷⁷Lu, EndolucinBeta®). The exclusive license from Helmholtz Munich is based on the [option and cooperation agreements](#) announced in January 2022, which the partners entered into with the goal of advancing ITM-31 into clinical development.

Under the terms of the license agreement, ITM will hold exclusive rights to the compound ITM-31 as well as the rights to related patents and know-how for the manufacturing and use of ITM-31.

“Glioblastoma remains one of the most aggressive and difficult to treat cancers globally and we believe that targeted radiotherapy and particularly ITM-31 can make a significant impact for patients by selectively eliminating tumor remnants post-surgery,” said **Steffen Schuster, CEO of ITM**. *“Based on the promising preclinical data we have seen to date and the successful collaboration with Helmholtz Munich and the University Hospital Münster we are confident that we can continue our rapid development plan, further broadening the depth of our clinical pipeline.”*

The Targeted Radionuclide Therapy with 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 glial cells, a specific subpopulation of brain cells. It comprises a CA XII antibody Fab fragment coupled with the radioisotope n.c.a. ¹⁷⁷Lu. ITM-31 is administered directly into the tumor cavity via a reservoir following surgery and standard post-operative therapy (intracavitary), 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.

About Glioblastoma Multiforme

Glioblastoma is one of the most malignant types of primary brain tumors. It is a rare tumor, with about 3-5 new cases per 100,000 individuals per year.¹ Even though surgery, chemotherapy, and radiotherapy have advanced over the last decade, resulting in a gradual improvement in the survival and quality of life of glioblastoma patients, the prognosis remains very poor.² Patients usually have a median survival of approximately 14 to 15 months from diagnosis.³ Glioblastoma is a complex tumor which is very difficult to treat. Surgery is rarely curative as the tumor cells infiltrate the surrounding tissue and the blood-brain barrier places a limitation on medical therapies. Even with macroscopic removal of the tumor and subsequent treatment with external beam radiation and chemotherapy, there is a risk that individual tumor cells will remain in the tissue and begin to grow again (relapse). More than 90% of tumor recurrences occur in the immediate vicinity of the primary tumor. Therefore, the treatment of the tissue surrounding the tumor is of great importance.

¹ Thakkar et al., *Cancer Epidemiol Biomarkers Prev.* 2014 Oct; 23(10): 1985–1996.)

² Gallego, 2015, *Current Oncology* 22(4): e273–e281 and Weller et al., 2013, *Neuro-Oncology* 15(1): 4–27

³ Ohka et al 2012, Thakkar et al., 2014

About ITM-31 (LuCaFab) / Targeted Radionuclide Therapy

Glioblastoma cells can selectively express certain surface antigenic proteins such as CA XII, which are not found on healthy brain cells. Targeted molecules which specifically bind to the proteins can be produced to attack these antigens. This approach falls under the category of Targeted Radionuclide Therapy (TRT), an emerging class of cancer therapeutics, which seeks to deliver radiation directly to the tumor while minimizing radiation exposure to normal tissue. Targeted radiopharmaceuticals are created by linking a therapeutic radioisotope to a targeting molecule that can precisely recognize tumor cells and bind to tumor-specific entities such as receptors expressed on the cell surface. The radioisotope accumulates at the tumor site and decays, releasing a therapeutic amount of ionizing radiation, thereby destroying tumor tissue. Helmholtz Munich has developed a new antibody binding fragment (Fab) targeted to the CA XII antigen, which has been optimized for the treatment of glioblastoma. ITM's non-carrier-added lutetium-177 (n.c.a. ¹⁷⁷Lu, EndolucinBeta®) is coupled to the antibody in order to selectively target and irradiate tumor cells. The resulting compound, ITM-31, is administered via intracavitary injection, meaning it is applied directly into the tumor cavity following the surgical removal of the tumor to attack residual cancerous cells that lead to recurrent disease. LuCaFab thus acts as a complementary, adjuvant therapy to the current standard of care approach to glioblastoma as it is designed to be applied after initial treatment to prevent future tumor growth.

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

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