ITM and Navigo Proteins Announce Research Collaboration to Develop FAP-targeting Radionuclide Therapy to Address Solid Tumors

Companies will work toward accessing a novel strategy for breaking the tumor microenvironment by combining ITM's high-quality radioisotopes with Navigo's precise target-specific affinity ligands against the fibroblast activation protein (FAP)

Garching/Munich, Germany and Halle/Saale, Germany, December 02, 2021 – ITM Isotope Technologies Munich SE, a leading radiopharmaceutical biotech company and Navigo Proteins GmbH, a premier protein engineering company developing optimized scaffold protein-based affinity ligands called Affilin® molecules from its Precision Targeting toolbox, today announced a research collaboration for the development of a fibroblast activation protein (FAP)-targeted radiopharmaceutical program for the treatment of solid tumors. The program is planned to be added to ITM's growing proprietary pipeline of Targeted Radionuclide Therapies spanning multiple radioisotopes and targeting molecules for optimal therapeutic effect. FAP-Targeted Radionuclide Therapy is a promising new approach to treating cancer within the precision oncology field.

Under the terms of the agreement, Navigo's proprietary protein engineering platform will be used to develop and select a FAP-targeting Affilin® molecule which will then be coupled with a therapeutic radioisotope provided by ITM. Following candidate selection, ITM will have the exclusive rights to further advance the radiolabeled FAP-specific Affilin® through clinical testing in potentially multiple cancer indications. The agreement also includes a non-exclusive license for diagnostic use in radio-imaging. Further details of the agreement were not disclosed.

"FAP-targeting approaches have received heightened attention for good reason. We believe this approach holds the potential to treat a wide range of cancer indications. As such, we look forward to exploring this innovative targeted radiopharmaceutical approach for our growing precision oncology pipeline, further expanding its reach and breadth. We believe that developing a new candidate by combining our radioisotopes with an Affilin® ligand targeting FAP has the opportunity to make a difference in the lives of patients," commented Steffen Schuster, CEO of ITM.

FAP is a highly attractive tumor target for Targeted Radionuclide Therapy that is preferentially expressed on cancer cells and in particular on cancer associated fibroblasts (CAFs). It is detectable in most epithelial cancers, including over 90% of breast, lung, colorectal and pancreatic carcinomas. High expression levels are associated with poor prognosis, and therefore warrant additional medical research and focus. ITM and Navigo are addressing this urgent need through their research collaboration and combined efforts to develop a promising FAP-targeted radiopharmaceutical.

"We welcome the opportunity to extend our productive partnership with ITM with yet another promising project. We strongly believe in the potential of our technology to generate high-quality Affilin® ligands targeting FAP and capable of breaking the tumor microenvironment. By joining forces with ITM, we are fully equipped to build a strong FAP-targeting candidate, that ITM will then advance through clinical development," said Henning Afflerbach, CEO of Navigo Proteins.

The therapeutic candidate developed together by ITM and Navigo will enable a direct attack against tumor cells by irradiating them via crossfire effects in a highly precise manner. Through the direct depletion of CAFs it additionally provides a new access point to modify the tumor microenvironment in which CAFs play a central role in upholding the barrier for effective immune cell infiltration.

This agreement further strengthens the existing partnership between the two organizations, combining ITM's deep expertise in developing promising Targeted Radionuclide Therapies for cancer patients with Navigo's proprietary Affilin® molecules and protein engineering proficiency.

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About Targeted Radionuclide Therapy

Targeted Radionuclide Therapy is 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 (e.g., Affilin®, peptide, antibody, small molecule) that can precisely recognize tumor cells and bind to tumor-specific characteristics. As a result, the radioisotope accumulates at the tumor site and decays, releasing a small amount of ionizing radiation, thereby destroying the tumor. The highly precise localization enables targeted treatment with minimal impact to healthy surrounding tissue.

About ITM Isotope Technologies Munich SE

ITM, a privately held radiopharmaceutical biotech company, is dedicated to providing the most precise cancer radiotherapeutics and diagnostics to meet the needs of patients, clinicians and our partners through excellence in development, production and global supply. With patient benefit as the driving principle for all we do, ITM is advancing a broad pipeline combining its high-quality radioisotopes with targeting molecules to develop precision oncology treatments. ITM is leveraging its leadership and nearly two decades of radioisotope expertise combined with its worldwide network to enable nuclear medicine to reach its full potential for helping patients live longer and better. For more information, please visit www.itm-radiopharma.com.

About Navigo Proteins

Navigo Proteins is a premier protein engineering company developing optimized affinity ligands, based on its proprietary platform of selected, small, and stable, yet highly engineerable scaffold proteins. These ligands serve as target-binding proteins in biotherapeutic molecules (PRECISION TARGETING) or for commercial custom affinity purification of biologics (PRECISION CAPTURING®).

Precision Targeting delivers proprietary Affilin® molecules based on human ubiquitin protein as a scaffold – a highly conserved, small (8.5 kDa) and stable, natural, human protein, also present in plasma. Going beyond the creation of target-binding Affilin® molecules, Precision Targeting also provides a versatile toolbox to design customized, next-generation biotherapeutics. A major strength of the Precision Targeting toolbox is its modular engineerability. The target-specific Affilin® molecules can be combined with a variety of carrier units for site-specific payload coupling as well as custom half-life extension moieties and varying function-conferring effector modules. Navigo has chosen to develop its Affilin® ligands in four different fields of use, protein-drug conjugates, radiotherapeutics, CAR-T cell therapy and targeted exosome therapy, to deliver best-in-class alternatives to conventional technologies. For more information visit www.navigo-proteins.com and follow Navigo Proteins on LinkedIn.

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