ITM to Present Trial Design of Ongoing Phase III COMPOSE Study in Advanced Neuroendocrine Tumors at ESMO 2022

Garching / Munich, September 6, 2022 – ITM Isotope Technologies Munich SE (ITM), a leading radiopharmaceutical biotech company, today announced that a scientific poster on the design of its second phase III clinical trial, COMPOSE, in advanced neuroendocrine tumors (GEP-NETs) will be presented at the upcoming ESMO Congress from September 9-13, 2022, in Paris. The start of patient treatment in the pivotal COMPOSE trial was announced in January this year.

The poster will be presented by Dr. Jaume Capdevila, Vall d'Hebron University Hospital, Barcelona, and Principal Investigator for the trial, on Sunday, September 11, 2022, from 12 to 1 pm CET in the poster area. COMPOSE (NCT04919226) is designed to evaluate the efficacy and safety of ITM's lead candidate, ITM-11 (n.c.a. ^{177}Lu-edotreotide), as first- or second-line treatment compared to best standard of care for patients with well-differentiated aggressive grade 2 and grade 3 somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors. ITM-11 is a Targeted Radionuclide Therapeutic consisting of the beta-emitting radioisotope, non-carrier-added lutetium-177 (n.c.a. ^{177}Lu) combined with the tumor-specific targeting molecule edotreotide, a somatostatin analogue.

Poster Information:

Poster-ID: 902TiP
Title: COMPOSE: Pivotal phase III trial to compare ^{177}Lu-edotreotide with best standard of care for well-differentiated aggressive grade 2 and 3 gastroenteropancreatic neuroendocrine tumours
Poster Session: EONS15
Date & Time: Sunday, September 11, from 12 to 1 pm CET

The poster will also be made available after presentation on the company's website in the "scientific publications" section.

COMPETE, ITM's second ongoing phase III clinical trial in neuroendocrine tumors (grade 1 and 2 GEP-NETS), completed patient recruitment in April this year.

About ITM-11 (n.c.a. ^{177}Lu-edotreotide)

ITM-11, ITM's therapeutic radiopharmaceutical candidate being investigated in the phase III clinical studies COMPETE and COMPOSE, consists of two components: the medical radioisotope non-carrier-added lutetium-177 (n.c.a. ^{177}Lu) and the targeting molecule edotreotide, a synthetic form of the peptide hormone somatostatin that targets neuroendocrine tumor-specific receptors. Edotreotide binds to these receptors and places the medical radioisotope n.c.a. lutetium-177 directly onto the diseased neuroendocrine cells so that it accumulates at the tumor site. N.c.a. lutetium-177 is internalized into the tumor cells and decays, releasing medical radiation (ionizing beta-radiation) with a maximum radius of 1.7 mm and destroying tumor tissue.

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.,

peptide, antibody, small molecule) that can precisely recognize tumor cells and bind to tumor-specific characteristics, like receptors on the tumor cell surface. As a result, the radioisotope accumulates at the tumor site and decays, releasing a small amount of ionizing radiation, thereby destroying tumor tissue. The highly precise localization enables targeted treatment with minimal impact to healthy surrounding tissue.

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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