Garching near Munich, Germany, September 26 2019

Mona M Wahba joins ITM as Deputy Chief Medical Officer

ITM Isotopen Technologien München AG (ITM), a biotechnology and radiopharmaceutical group of companies, announced today the appointment of Mona M Wahba, MD, MSM to the position of Deputy Chief Medical Officer. Dr Wahba joined ITM on September 15, 2019 and will primarily be responsible for the development and implementation of ITM's clinical strategy and presence in the United States (US), where Dr Wahba will be based. In this capacity Dr Wahba will also oversee the clinical conduct of the COMPETE phase III clinical trial in North America. This pivotal study is central to ITM's global strategy of providing cutting edge radiotheranostic care to patients with neuroendocrine tumors.

Prior to joining ITM, Dr Wahba has held several senior executive positions with major pharmaceutical companies including Pfizer, Bristol-Myers Squibb, Novartis, and Bayer. With more than 20 years of experience in senior management roles in the industry, she has extensive knowledge in medical affairs, drug safety and clinical development. Dr Wahba was instrumental in leading US and global medical plans and launch readiness of Xofigo, a radiopharmaceutical drug designed to treat bone metastases in patients with castration-resistant prostate cancer (CRPC). At Ipsen Bioscience Dr Wahba served as Clinical Development Lead, advancing the vision and strategy for clinical development of radiotheranostics in various tumor types.

"We are delighted to welcome Mona at ITM. Given her extensive experience in the industry and her strong medical background in oncology, radiotheranostics and immunology, she will be a key member of the developing medical team and a key asset to our US presence," said Dr Philip E Harris, CMO of ITM. *"She will provide important clinical and medical input to our developing pipeline and commercial operations particularly in the United States, where our Phase III clinical trial is in an accelerated phase of actively recruiting patients."*

"I am excited to join ITM at this pivotal moment in the company's history, in which many interesting projects are underway," commented Dr Mona M Wahba, newly appointed Deputy CMO of ITM. *"I am looking forward to helping patients with new treatment options as appropriate, to growing the company's US footprint and to furthering the success of our phase III clinical trial COMPETE, which is currently investigating our lead candidate Solucin® for the treatment of gastroentero-pancreatic neuroendocrine tumors. Targeted Radionuclide Therapy is an extremely precise and promising field that has the potential to improve the lives of countless cancer patients worldwide. I am looking forward to participating in developing and executing ITM's promising pipeline to address unmet medical needs."*

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About COMPETE phase III clinical trial

The phase III clinical trial COMPETE is led as an international, prospective, randomized, controlled, open-label, multicenter phase III study to evaluate efficacy and safety of TRT with n.c.a. ^{177}Lu-Edotreotide (Solucin®) compared to targeted molecular therapy with Everolimus in patients with inoperable, progressive, somatostatin receptor-positive (SSTR^{+}) neuroendocrine tumors of gastroenteric or pancreatic origin (GEP-NET). The trial is conducted worldwide in 12 countries and 42 leading cancer centers, in Europe, North America, Australia and South Africa.

In total, 300 GEP-NET patients will be randomized 2:1 to receive either Targeted Radionuclide Therapy with Solucin® consisting of a maximum of four cycles (7.5 GBq ^{177}Lu-Edotreotide each), administered as i.v. infusion at 3-monthly intervals for 9 months, or until diagnosis of progression (200 patients), or 10 mg Everolimus daily, administered orally as a tablet until diagnosis of progression (100 patients). Study duration per patient will be 24 months.

Primary endpoint is PFS. Diagnosis of progression and liver tumor burden will be established based on radiological information from morphological imaging (MRI and/or CT) according to RECIST 1. Secondary endpoints include overall survival (OS), parameters of morphological and functional tumor response, safety and health-related quality of life (HRQL). Furthermore, patient and tumor characteristics, as well as the uptake of n.c.a. ^{177}Lu-Edotreotide will be analyzed for criteria predicting the efficacy and safety of Targeted Radionuclide Therapy.

About ITM Isotopen Technologien München

ITM Isotopen Technologien München AG is a privately held biotechnology and radiopharmaceutical group of companies dedicated to the development, production and global supply of targeted diagnostic and therapeutic radiopharmaceuticals and radionuclides for use in cancer treatment. Since its foundation in 2004, ITM and its subsidiaries have established GMP manufacturing and a robust global supply network of innovative, first-in-class medical radionuclides and generator platforms for a new generation of targeted cancer diagnostics and therapies. Furthermore, ITM is developing a proprietary portfolio and growing pipeline of targeted treatments in various stages of clinical development, which address a range of cancers such as neuroendocrine tumors and bone metastases. ITM's main objectives, together with its scientific, medical and industrial collaboration partners worldwide, are to significantly improve outcomes and quality of life for cancer patients while at the same time reducing side-effects and improving health economics through a new generation of Targeted Radionuclide Therapies in Precision Oncology. For more information about ITM, please visit: www.itm.ag

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