PRESS RELEASE

DEBIOPHARM ANNOUNCES LAUNCH OF THE PHASE 1/2 GaLuCi™ STUDY FOR ITS CAIX-TARGETED RADIOPHARMACEUTICAL PROGRAM

- *Debiopharm is developing personalized radiotherapy through a theranostic approach, combining diagnostic imaging (Debio 0328 a gallium-labelled imaging tool) and therapeutic components (Debio 0228, a lutetium-labelled radioligand), thus allowing the pre-identification and treatment of patients expressing CAIX.*
- *The GaLuCi™ trial is the first-in-human, multicenter, non-randomized phase 1/2 clinical trial assessing safety and tolerability, imaging characteristics and the efficacy of the theranostic pair Debio 0228/0328 in patients with unresectable, locally advanced or metastatic solid tumors.*
- *Debiopharm's research is applying precision nuclear medicine to the promising target, Carbonic Anhydrase IX (CAIX), a surface protein overexpressed in many solid tumors and a well-known marker of tumor aggressiveness and resistance to treatment.*

Lausanne, Switzerland – March 21st, 2023 – Debiopharm (www.debiopharm.com), a Swiss-based, global biopharmaceutical company, aiming to establish tomorrow's standard-of-care to cure cancer and infectious diseases, today announced the first patient dosed of their first-in-human, phase 1/2 study, GaLuCi™. The first patient was screened and dosed at the Australian-based Peter MacCallum Cancer Centre. This multicenter international trial, evaluating a radioligand theranostic pair will be carried out in three stages: Part A to confirm the safety and reliability of Debio 0328 in detecting CAIX-expressing solid tumors, Part B to assess escalating doses of the therapeutic agent, Debio 0228 in patients, whose tumors show high uptake of Debio 0328 and finally, based on the recommended dose from part B, Part C will further assess safety and preliminary efficacy in selected tumor types.

Currently, Debio 0228/0328 is the only peptide-based theranostic pair targeting CAIX in clinical development, with pan-tumor potential, and developed first for patients with advanced cancers such as renal, pancreatic, and colorectal. It leverages a theranostic approach to identify and deliver radiation to diseased tissues, allowing the imaging-based pre-identification of patients who have the target proteins necessary to respond to the targeted radioligand.

"The results of the GaLuCi™ trial are highly anticipated considering the therapeutic potential of Debio 0228 as observed in preclinical models. Using this theranostic pair could pave the way for personalized nuclear medicine, enabling administration of the lutetium coupled radioligand only to patients who are more likely to respond to the therapy." ***explained Angela Zubel, Chief Development Officer at Debiopharm***.

"We always have immense gratitude for our patients who participate in first time in human trials, but in this case, we are particularly thankful for our patient who agreed to be the first person in the world to have their kidney cancer imaged with Debio 0328 on the GaLuCi™ trial. We hope this is the beginning of the theranostics era in kidney cancer!" expressed **Dr. Ben Tran, Lead Genito-urinary medical oncologist, Peter MacCallum Cancer Centre.**

"We are excited about this first-in-human study as it is a novel approach for advanced kidney cancer patients," said **Darren R. Feldman, MD, Associate Attending Physician, Genitourinary Oncology Service at Memorial Sloan Kettering Cancer Center**. *"Precision nuclear medicine applied to CA9 could benefit advanced cancer patients who still experience a high unmet medical need. This theranostic pair allows targeted radiation delivery to the cancer cells bearing CAIX, which is largely expressed, over 85%, in clear cell renal cell carcinoma."*

The theranostic approach with Debio 0228/0328
Debio 0228 ([^{177}Lu]Lu-DPI-4452) and 0328 ([^{68}Ga]Ga-DPI-4452) is an investigational theranostic pair originally discovered by 3B Pharmaceutical GmbH and exclusively licensed to Debiopharm. ([^{68}Ga]Ga-DPI-4452 is a PET imaging agent, (Debio 0328) used to identify patients whose cancers overexpress CAIX. Once identified, these patients can be treated with the lutetium-labelled radioligand, Debio 0228, which delivers targeted radiation to the tumor, destroying it from the inside.

Debiopharm's commitment to patients
Debiopharm aims to develop innovative therapies that target high unmet medical needs in oncology and bacterial infections. Bridging the gap between disruptive discovery products and real-world patient reach, we identify high-potential compounds and technologies for in-licensing, clinically demonstrate their safety and efficacy, and then select large pharmaceutical commercialization partners to maximize patient access globally.

For more information, please visit www.debiopharm.com

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