



PRESS RELEASE

Blue Earth Diagnostics Ltd Collaborates with Sinotau Pharmaceutical Group to Bring Prostate Cancer PET Diagnostic Imaging Agent, Flotufolastat (¹⁸F) Injection, to China

– Agreement with Sinotau Pharmaceutical Group part of Company's global strategy to increase clinician and patient access to innovative diagnostic imaging agent –

OXFORD, UK, and MONROE TOWNSHIP, NJ, 17th October 2023 – Blue Earth Diagnostics Ltd, a Bracco company and recognised leader in the development and commercialisation of innovative PET radiopharmaceuticals, announced that it has signed an exclusive strategic agreement with Sinotau Pharmaceutical Group for the positron emission tomography (PET) imaging agent flutufolastat (¹⁸F) injection (formerly referred to as ¹⁸F-rhPSMA-7.3) in prostate cancer. Under the terms of the agreement this will be a close strategic partnership, with ongoing technology and regulatory support, aiming to support the use of flutufolastat (¹⁸F) for men with prostate cancer in China. It marks an important stage in the Blue Earth Diagnostics' strategy to make flutufolastat (¹⁸F) available to patients and clinicians globally.

The introduction of flutufolastat (¹⁸F) has the potential to fill a significant gap in the Chinese domestic market where there are currently no ¹⁸F-labeled PSMA-PET diagnostic radiopharmaceuticals available. This could provide new solutions and options for the diagnosis and treatment of prostate cancer in China, where there is a growing need for clinicians and patients to have access to the latest advancements.

In recent years, the incidence of prostate cancer in China has shown a significant upward trend. Although the incidence of prostate cancer is lower than in Western countries, the proportion of patients with advanced stage disease at diagnosis is higher. The "2022 Prostate Cancer Diagnosis and Treatment Guidelines" recommended by the Chinese Society of Clinical Oncology (CSCO) suggest that PSMA-PET can be used to assess prostate cancer patients undergoing definitive treatment, including surgery, diagnosis and location of biochemical recurrence after radical surgery or radiotherapy, and evaluation of systemic treatment efficacy and long-term follow-up.

Yanmin Tang, CEO of Sinotau Pharmaceutical Group, said, "Sinotau Pharmaceutical Group is dedicated to the field of new generation radiopharmaceuticals. We are pleased to form this strategic cooperation with Blue Earth Diagnostics and we look forward to making flutufolastat (¹⁸F) available to the clinical community in China. In the future, Sinotau Pharmaceutical Group will continue to make clinically valuable and excellent radiopharmaceuticals available to benefit more Chinese patients."

Matt Morrison, Ph.D., Head of Operations and Supply Chain, at Blue Earth Diagnostics said, "Partnering with experienced companies such as Sinotau supports our strategic focus on PET imaging in cancer, with the goal to provide global solutions for the informed treatment of prostate cancer patients, something that we could not accomplish alone. We look forward to working together with our colleagues at Sinotau with the aim to successfully bring flutufolastat (¹⁸F) to clinicians and their patients in China."

“We are delighted to have this new agreement in place with Sinotau, to make innovative flutufolastat (^{18}F) PET imaging available to the Chinese community,” said David E. Gauden, D.Phil., Chief Executive Officer of Blue Earth Diagnostics. “Flutufolastat (^{18}F) represents a new class of PSMA-targeted PET radiopharmaceuticals that are based on novel radiohybrid technology. It is engineered to advance clinical decision-making by providing useful information to guide treatment planning in men with prostate cancer. We believe that the demonstrated diagnostic performance of flutufolastat (^{18}F), with its high-affinity PSMA binding and low urinary bladder activity, make it a valuable diagnostic tool for markets around the world.”

About Flutufolastat (^{18}F)

Flutufolastat (^{18}F) (formerly referred to as ^{18}F -rhPSMA-7.3) is an optimised, targeted radiohybrid diagnostic imaging agent that is approved in the United States, where it is indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer with suspected metastasis who are candidates for initial definitive therapy or with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level. Precision PET imaging with flutufolastat (^{18}F) can help identify the location and extent of prostate cancer, providing clinically valuable information to guide patient management. Flutufolastat (^{18}F) represents a new class of high-affinity PSMA-targeted PET radiopharmaceuticals that are based on novel radiohybrid technology and is labeled with the radioisotope ^{18}F to provide readily available patient access and leverage the high image quality of ^{18}F -labeled PSMA PET imaging to facilitate effective detection of disease. Flutufolastat (^{18}F) was approved by the U.S. Food and Drug Administration in May 2023.

About Radiohybrid Prostate-Specific Membrane Antigen (rhPSMA)

Radiohybrid Prostate-Specific Membrane Antigen (rhPSMA) compounds consist of a radiohybrid (“rh”) Prostate-Specific Membrane Antigen-targeted receptor ligand which attaches to and is internalised by prostate cancer cells, and they may be radiolabeled with imaging isotopes for PET imaging, or with therapeutic isotopes for therapeutic use – providing the potential for creating a true theranostic technology. Radiohybrid technology and rhPSMA originated from the Technical University of Munich, Germany. Blue Earth Diagnostics acquired exclusive, worldwide rights to rhPSMA diagnostic imaging technology from Scintomics GmbH in 2018, and therapeutic rights in 2020, and sublicensed the therapeutic application to its sister company Blue Earth Therapeutics. Blue Earth Diagnostics received U.S. Food and Drug Administration approval for its radiohybrid PET diagnostic imaging product for use in prostate cancer in 2023. rhPSMA compounds for potential therapeutic use are investigational and have not received regulatory approval.

About Blue Earth Diagnostics

Blue Earth Diagnostics, an indirect subsidiary of Bracco Imaging S.p.A., is a growing international molecular imaging company focused on delivering innovative, well-differentiated diagnostic solutions that inform patient care. Formed in 2014, the Company’s success is driven by its management expertise and supported by a demonstrated track record of rapid development and commercialisation of positron emission tomography (PET) radiopharmaceuticals. Blue Earth Diagnostics’ expanding oncology portfolio encompasses a variety of disease states, including prostate cancer and neuro-oncology. Blue Earth Diagnostics is committed to the timely development and commercialisation of precision radiopharmaceuticals for potential use in imaging and therapy. For more information, please visit: www.blueearthdiagnostics.com.

About Bracco Imaging

Bracco Imaging S.p.A., part of the Bracco Group, is a world-leading diagnostic imaging provider. Headquartered in Milan, Italy, Bracco Imaging develops, manufactures and markets diagnostic

imaging agents and solutions. It offers a product and solution portfolio for all key diagnostic imaging modalities: X-ray imaging (including Computed Tomography-CT, Interventional Radiology, and Cardiac Catheterization), Magnetic Resonance Imaging (MRI), Contrast Enhanced Ultrasound (CEUS), and Nuclear Medicine through radioactive tracers and novel PET imaging agents to inform clinical management and guide care for cancer patients in areas of unmet medical need. Our continually evolving portfolio is completed by a range of medical devices, advanced administration systems and dose-management software. In 2019 Bracco Imaging enriched its product portfolio by expanding the range of oncology nuclear imaging solutions in the urology segment and other specialties with the acquisition of Blue Earth Diagnostics. In 2021, Bracco Imaging established Blue Earth Therapeutics as a separate, cutting-edge biotechnology vehicle to develop radiopharmaceutical therapies. Visit: www.braccoimaging.com.

About Sinotau

Sinotau is an innovative radiopharmaceutical company located in China and developing globally. Since 2014, Sinotau started the research and development of targeted radiopharmaceuticals. Headquartered in Beijing, China, Sinotau has modern radiopharmaceutical intelligent production sites in Jiangsu, Guangdong, and Sichuan, an early discovery center in Shanghai, and a branch in the United States. Sinotau has taken the lead in deploying a portfolio of targeted therapies and precision diagnostic radiopharmaceuticals in the fields of tumors, neurodegenerative diseases, and cardiovascular diseases. More than 20 novel product pipelines are in different development stages. Sinotau looks into the future following the company's mission "invent radiopharmaceuticals for lives", and through continued investments in R&D to help improve the quality of life of patients and to contribute to China's radiopharmaceutical sector.

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PP-UK-0668 October 2023

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