

BLUE EARTH DIAGNOSTICS ANNOUNCES FIRST PATIENT DOSES OF PET IMAGING AGENT RHPSMA-7.3 (18F) IN COLLABORATION WITH NUCLEIS RADIOPHARMACEUTICALS IN LIEGE, BELGIUM

November 24, 2020

Oxford, UK – 24 November 2020 – [Blue Earth Diagnostics](#), a leading molecular imaging diagnostics company, today announced that their manufacturing partner Nucleis (Liege, Belgium) has manufactured and shipped their first patient doses of rhPSMA-7.3 (¹⁸F), an investigational Prostate-Specific Membrane Antigen (PSMA)-targeted radiohybrid PET imaging agent, currently under evaluation in clinical trials in men with newly diagnosed prostate cancer and suspected prostate cancer recurrence.

Prostate cancer is a leading cause of cancer death in men. Accurate staging of newly diagnosed prostate cancer assists in directing appropriate initial treatment strategies. After initial treatment, recurrence occurs in up to one-third of patients, typically detected by a rise in prostate-specific antigen (PSA) levels. However, in both settings, conventional imaging is limited in detecting the location and extent of the disease. Of those who suffer biochemical recurrence, approximately one-third develop metastatic prostate cancer.

Blue Earth Diagnostics has been working closely with Nucleis Radiopharmaceuticals, formerly part of the Cyclotron Research Centre (University of Liege in Belgium), to establish them as a contract manufacturer able to supply clinical trial sites. Nucleis is now qualified to supply rhPSMA-7.3 (¹⁸F) as part of a clinical trials programme in the Netherlands where the first patients have been scanned.

Blue Earth Diagnostics has two Phase 3 studies underway to investigate the use of rhPSMA-7.3 (¹⁸F) PET imaging in prostate cancer. The SPOTLIGHT study is designed to evaluate its safety and diagnostic performance in men with suspected prostate cancer recurrence based on elevated PSA following prior therapy. The LIGHTHOUSE trial is designed to evaluate the safety and diagnostic performance of rhPSMA-7.3 (¹⁸F) PET imaging in men with newly diagnosed prostate cancer. Further information, including a current list of clinical trial sites, can be found on www.clinicaltrials.gov (LIGHTHOUSE at [NCT04186819](#), and SPOTLIGHT at [NCT04186845](#)).

Dr. Jonathan Allis, Chief Executive Officer of Blue Earth Diagnostics said, “Our collaboration with Nucleis Radiopharmaceuticals and supply of our first rhPSMA-7.3 (¹⁸F) doses from their site in Liege is a great development in our R&D programme. This will enable us to bring more

European sites into our clinical trials programme as part of our work to bring new products to clinicians and their patients.”

Fabrice Giacomelli, Chief Executive Officer of Nucleis Radiopharmaceuticals said, “We are pleased to have been chosen by a global leader in diagnostic imaging, Blue Earth Diagnostics, to manufacture and supply rhPSMA-7.3 (¹⁸F) doses for these two Phase 3 studies. This collaboration is fully aligned with the Nucleis mission of delivering innovative PET tracers and improving patient care.”

About rhPSMA

rhPSMA-7.3 (¹⁸F) is an investigational agent that consists of a radiohybrid Prostate-Specific Membrane Antigen (PSMA)-targeted receptor ligand which attaches to and is internalized by prostate cancer cells, and is labeled with the ¹⁸F radioisotope for PET imaging. rhPSMA compounds can also be labeled with radioisotopes such as ¹⁷⁷Lu and ²²⁵Ac for therapeutic use. Blue Earth Diagnostics acquired exclusive, worldwide rights to rhPSMA imaging technology from Scintomics in 2018, with an option to therapeutic rights. rhPSMA originated from the Technical University of Munich, Germany, and has been utilised clinically under German legislation at the Department of Nuclear Medicine there for the diagnostic imaging of men with both primary and recurrent prostate cancer. rhPSMA compounds have not received regulatory approval.

This press release is intended to provide information about Blue Earth Diagnostics’ business in Europe.

About Blue Earth Diagnostics

Blue Earth Diagnostics is a leading molecular imaging diagnostics company focused on the development and commercialization of novel PET imaging agents to inform clinical management and guide care for cancer patients in areas of unmet medical need. Formed in 2014, Blue Earth Diagnostics is led by recognized experts in the clinical development and commercialization of innovative nuclear medicine products. The company’s first approved and commercially available product is Axumin® (fluciclovine F 18), a novel molecular imaging agent approved in the United States and European Union for use in PET imaging to detect and localize prostate cancer in men with a diagnosis of biochemical recurrence. Fluciclovine F 18 has a broad range of other potential applications in cancer imaging and Blue Earth Diagnostics is investigating the molecule for other cancers including in neuro-oncology. The company’s pipeline includes innovative Prostate-Specific Membrane Antigen (PSMA)-targeted radiohybrid (“rh”) agents, which are a clinical-stage, investigational class of theranostic compounds, with potential applications in both the imaging and treatment of prostate cancer. Blue Earth Diagnostics is a subsidiary of Bracco Imaging S.p.A., a global leader in diagnostic imaging. For more information, visit: www.blueearthdiagnostics.com.

About Nucleis Radiopharmaceuticals

Nucleis Radiopharmaceuticals is a GMP manufacturer and distributor of PET imaging agents located in Liege, Belgium. The company commercialises several products with a Marketing Authorization and participates as CMO in several clinical trials. Nucleis aims at developing constantly a wide portfolio of new diagnostic tools and support innovative therapies. Through its strategic location within Europe, Nucleis is able to supply by road sites in Belgium, The Netherlands, Luxembourg, France and Germany. For more information, visit: www.nucleis.eu.

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