PRESS RELEASE

Blue Earth Diagnostics Completes Patient Accrual in Phase 3 REVELATE Clinical Trial of ^{18}F-Fluciclovine PET Imaging for Detection of Recurrent Brain Metastases

– Clinical utility of ^{18}F-fluciclovine being investigated in expanded areas of cancer imaging –

BURLINGTON, Mass. and OXFORD, UK, June 8, 2022 – Blue Earth Diagnostics, a Bracco company and recognized leader in the development and commercialization of innovative PET radiopharmaceuticals, today announced completion of patient accrual in its Phase 3 REVELATE clinical trial of ^{18}F-fluciclovine, a positron emission tomography (PET) imaging radiopharmaceutical being studied for potential use in detecting recurrent brain metastases after radiotherapy. The REVELATE study is a prospective Phase 3, multi-center, single-arm imaging study being conducted in the United States.

Note: ^{18}F-fluciclovine is an approved molecular imaging radiopharmaceutical for use in PET imaging in men with suspected prostate cancer recurrence based on elevated blood prostate specific antigen (PSA) levels following prior treatment. The safety and efficacy of ^{18}F-fluciclovine PET imaging for the detection of recurrent brain metastases has not been established.

"Expanding our ^{18}F-fluciclovine franchise into neuro-oncology is part of the overall growth strategy for Blue Earth Diagnostics, and completion of Phase 3 patient accrual sets a major milestone in our development plan," said David E. Gauden, D.Phil., Chief Executive Officer. "We look forward to receiving the clinical results from REVELATE, and to presenting results of the Phase 2 PURSUE study at upcoming scientific meetings later this year. Additionally, we wish to thank the patients, physicians and clinical trial sites who worked closely with us to complete enrollment despite the many challenges presented by the COVID-19 pandemic. In line with our mission to develop novel PET radiopharmaceuticals to inform the management and care of patients with cancer, we are hopeful that our efforts may help patients with recurrent metastatic brain cancer."

"Radiation therapy is a mainstay of treatment for brain metastases which provides effective tumor control but can result in radiation necrosis," said Samuel T. Chao, MD, Department of Radiation Oncology, Cleveland Clinic; Professor at the Cleveland Clinic Lerner College of Medicine of Case Western Reserve University, Cleveland, Ohio; and Coordinating Investigator on the REVELATE Phase 3 study. "Serial magnetic resonance imaging (MRI) is often used to monitor patients after treatment. However, physicians face challenges in diagnosing and managing suspicious lesions found upon post-treatment surveillance, as they may represent tumor recurrence or treatment-related changes such as radiation necrosis. Significant progress has been made in diagnostic imaging modalities to assist in differentiating these entities, among them the use of amino acid-based PET radiopharmaceuticals. The Phase 3 REVELATE trial is designed to investigate the diagnostic performance of amino acid ^{18}F-fluciclovine PET imaging as a potential decision-making aid in assessing the status of a patient's disease."

"Limitations of conventional MRI are recognized in guidelines and recommendations established by the Response Assessment in Neuro-Oncology (RANO) group. Recommendations from the RANO/PET working group in 2019 cite the potential utility of amino acid PET radiopharmaceuticals in distinguishing

brain tissue changes after radiation therapy from recurrent brain metastases. In noting that existing data have been derived mainly from single center, retrospective studies, a call for prospective multi-center studies has been re-iterated to validate these observations," said Eugene J. Teoh, MBBS, MRCP, FRCR, D.Phil., Chief Medical Officer of Blue Earth Diagnostics. "^{18}F-Fluciclovine holds potential clinical utility for the detection of other cancers besides recurrent prostate cancer. As an amino acid-based PET radiopharmaceutical, ^{18}F-fluciclovine is designed to visualize the increased amino acid transport that occurs in malignant tumors and we eagerly await the results of the REVELATE and PURSUE clinical trials."

About the REVELATE and PURSUE Clinical Trials in Brain Metastases

Blue Earth Diagnostics has two clinical studies investigating the use of ^{18}F-fluciclovine PET in the detection of recurrent brain metastases. The REVELATE study ("Study to Establish the Diagnostic Performance of ^{18}F-fluciclovine PET in Detecting Recurrent Brain Metastases") is an open-label, single-arm, single-dose, prospective, multi-center Phase 3 study designed to establish the diagnostic performance of ^{18}F-fluciclovine PET in detecting recurrent brain metastases after radiation therapy. The primary endpoint of the REVELATE study is to assess the Negative Percent Agreement (NPA, equivalent to specificity) and Positive Percent Agreement (PPA, equivalent to sensitivity) of ^{18}F-fluciclovine PET in detecting recurrent brain metastases on a patient level. Secondary endpoints will assess the Positive Predictive Value (PPV) and Negative Predictive Value (NPV) of ^{18}F-fluciclovine PET for detecting recurrent brain metastases, among others. The Phase 2 PURSUE trial is designed to establish image interpretation criteria for ^{18}F-fluciclovine PET in detecting recurrent brain metastases. Further information about these trials can be found on www.clinicaltrials.gov (REVELATE, NCT04410133, PURSUE, NCT04410367).

About ^{18}F-Flucivlovine PET and Recurrent Brain Metastases

^{18}F-flucivlovine PET is a novel diagnostic imaging radiopharmaceutical for PET imaging to visualize the increased amino transport that occurs in malignant tumors. It consists of a synthetic amino acid that is preferentially taken up by cancer cells compared with surrounding normal tissues and is labeled with the radioisotope ^{18}F for PET imaging. ^{18}F-flucivlovine is under investigation by Blue Earth Diagnostics for potential use in adults for the detection of recurrent brain metastases in patients who have previously undergone radiation therapy. ^{18}F-fluciclovine is approved by the U.S. Food and Drug Administration (FDA) and in the EU for PET imaging in men with recurrent prostate cancer. ^{18}F-fluciclovine was invented at Emory University, in Atlanta, Ga., with much of the fundamental clinical development carried out by physicians at Emory University's Department of Radiology and Imaging Sciences. Blue Earth Diagnostics licensed ^{18}F-fluciclovine from GE Healthcare and is investigating the molecule for other potential cancer indications, including in neuro-oncology.

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 commercialization 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 commercialization 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 also 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.

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