BLUE EARTH DIAGNOSTICS ANNOUNCES DOSING OF INITIAL PATIENTS IN PHASE 3 SPOTLIGHT CLINICAL TRIAL OF TARGETED PET IMAGING AGENT RHPSMA-7.3 (18F) IN BIOCHEMICALLY RECURRENT PROSTATE CANCER

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– Patient enrollment now underway in Phase 3 SPOTLIGHT as well as LIGHTHOUSE clinical trials in prostate cancer –

BURLINGTON, Mass. and OXFORD, UK, July 21, 2020 – Blue Earth Diagnostics, a Bracco company focused on molecular imaging diagnostics, today announced that the first patients have been dosed at clinical trial sites in its Phase 3 SPOTLIGHT clinical trial of rhPSMA-7.3 (^{18}F), an investigational Prostate-Specific Membrane Antigen-targeted radiohybrid PET imaging agent. The SPOTLIGHT study is a Phase 3, multi-center, single-arm imaging study being conducted in the United States and Europe to evaluate the safety and diagnostic performance of rhPSMA-7.3 (^{18}F) PET imaging in men with suspected prostate cancer recurrence based on elevated PSA following prior therapy. The primary endpoints of the SPOTLIGHT study are to assess the Correct Detection Rate (CDR) and Positive Predictive Value (PPV) of rhPSMA-7.3 (^{18}F) PET, using histopathology or confirmatory imaging as a standard of truth. U.S. clinical trial sites that have dosed patients, to date, include: Emory Healthcare, Atlanta, Ga.; John Wayne Cancer Institute, Santa Monica, Calif.; Urology San Antonio, San Antonio, Texas and Virginia Oncology Associates, Norfolk, Va. The first European patient was recently dosed at a clinical site in Finland.

Blue Earth Diagnostics has two Phase 3 studies underway to investigate the use of rhPSMA-7.3 (^{18}F) 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 (^{18}F) 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).

“We are excited that both of our Phase 3 studies for rhPSMA-7.3 (^{18}F) are well underway and enrolling patients, with the hope that our efforts can help inform more personalized clinical management to address the needs of men with prostate cancer,” said Jonathan Allis, D. Phil., CEO of Blue Earth Diagnostics. “Blue Earth Diagnostics continues to advance our comprehensive prostate cancer PET imaging portfolio that is built on approved, commercially available Axumin® (fluciclovine F 18), and on the investigational agent, rhPSMA-7.3 (^{18}F). Pending successful development and approval of rhPSMA-7.3 (^{18}F), we will be in the

unique position to offer complementary products to assist in the clinical management of men with known or suspected prostate cancer."

"Up to 40% of patients who undergo radical prostatectomy, and up to 50% of patients who undergo radiation therapy will develop local or distant recurrences within 10 years," said David M. Schuster, MD, FACR, Emory University School of Medicine, and Coordinating Investigator for the SPOTLIGHT study. "An important consideration for physicians and their patients is the ability to determine the extent and location of recurrent prostate cancer in order to inform appropriate clinical management for these men. The Phase 3 SPOTLIGHT clinical study is designed to investigate the diagnostic performance of rhPSMA-7.3 (^{18}F) PET imaging as a potential decision-making aid in assessing suspected biochemical recurrence of the disease. At Emory, we scanned our first patient in the SPOTLIGHT study in late June, and we are rapidly recruiting more patients in this exciting trial."

"The Investigational New Drug (IND) submission for the SPOTLIGHT trial included results from early clinical experience by the Technical University of Munich (TUM) with rhPSMA, including with rhPSMA-7.3 (^{18}F), in more than 1,000 patients with prostate cancer," said Peter Gardiner, MB ChB, MRCP, FFPM, Chief Medical Officer of Blue Earth Diagnostics. "Blue Earth Diagnostics has also completed a Phase 1 clinical study in Turku, Finland to assess the safety, biodistribution and dosimetry of rhPSMA-7.3 (^{18}F) in healthy volunteers and patients with prostate cancer."

"The investigational PET agent, rhPSMA-7.3 (^{18}F), is a single isomer product, part of a family of theranostic rhPSMA compounds that BED exclusively acquired from TUM, via Scintomics Gmbh," said David Gauden, D.Phil., Chief Scientific Officer of Blue Earth Diagnostics. "In developing these compounds, we are initially focused on diagnostic PET imaging applications. We selected F18 as the radiolabeling isotope of choice for rhPSMA-7.3 PET based on important attributes, including: a positron energy that enables high resolution PET scans; high yielding chemistry for large batch, centralized manufacturing; and a half-life that enables efficient distribution across broad geographies, to be readily available for patients, independent of select individual hospitals."

About the SPOTLIGHT Phase 3 Clinical Trial for rhPSMA-7.3 (^{18}F)

The SPOTLIGHT Phase 3 clinical trial is a prospective, Phase 3, multi-center, single-arm, imaging study investigating the safety and diagnostic performance of rhPSMA 7.3 (^{18}F) Positron Emission Tomography (PET) in men with suspected prostate cancer recurrence based on elevated Prostate-Specific Antigen (PSA) following prior therapy. The study will enroll approximately 300 evaluable patients at clinical sites in the United States and Europe. The primary endpoints of the SPOTLIGHT study are to assess the Correct Detection Rate (CDR) of rhPSMA-7.3 (18F) PET, on a patient level, and the Positive Predictive Value (PPV), on a region level, of rhPSMA-7.3 (^{18}F) PET using histopathology or confirmatory imaging as a Standard of Truth (SoT). Secondary endpoints will assess the safety rhPSMA-7.3 (^{18}F) and

determine inter- and intra-reader agreement of rhPSMA-7.3 (^{18}F) scan interpretations by blinded independent readers. Additional information about the Phase 3 SPOTLIGHT trial is available at www.clinicaltrials.gov (NCT04186845).

About rhPSMA

rhPSMA-7.3 (^{18}F) 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 ^{18}F radioisotope for PET imaging. rhPSMA compounds can also be labeled with radioisotopes such as ^{177}Lu and ^{225}Ac 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 utilized 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.

NOTE: Axumin® (fluciclovine F 18) injection is FDA-approved for positron emission tomography (PET) imaging in men with suspected prostate cancer recurrence based on elevated blood prostate specific antigen (PSA) levels following prior treatment.

This press release is intended to provide information about Blue Earth Diagnostics' business in the United States. Please be aware that the approval status and product label for Axumin varies by country worldwide. For EU Axumin product information refer to: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004197/human_med_002100.jsp&mid=WC0b01ac058001d124.

U.S. Indication and Important Safety Information About Axumin

INDICATION

Axumin® (fluciclovine F 18) injection is indicated for positron emission tomography (PET) imaging in men with suspected prostate cancer recurrence based on elevated blood prostate specific antigen (PSA) levels following prior treatment.

IMPORTANT SAFETY INFORMATION

- Image interpretation errors can occur with Axumin PET imaging. A negative image does not rule out recurrent prostate cancer and a positive image does not confirm its presence. The performance of Axumin seems to be affected by PSA levels. Axumin uptake may occur with other cancers and benign prostatic hypertrophy in primary prostate cancer. Clinical correlation, which may include histopathological evaluation, is recommended.

- Hypersensitivity reactions, including anaphylaxis, may occur in patients who receive Axumin. Emergency resuscitation equipment and personnel should be immediately available.
- Axumin use contributes to a patient's overall long-term cumulative radiation exposure, which is associated with an increased risk of cancer. Safe handling practices should be used to minimize radiation exposure to the patient and health care providers.
- Adverse reactions were reported in ≤ 1% of subjects during clinical studies with Axumin. The most common adverse reactions were injection site pain, injection site erythema and dysgeusia.

To report suspected adverse reactions to Axumin, call 1-855-AXUMIN1 (1-855-298-6461) or contact FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Full U.S. Axumin prescribing information is available at www.axumin.com.

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.

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