BLUE EARTH DIAGNOSTICS ANNOUNCES DOSING OF FIRST PATIENT IN PHASE 3 LIGHTHOUSE CLINICAL TRIAL OF TARGETED PET IMAGING AGENT RHPSMA-7.3 (18F) IN NEWLY DIAGNOSED PROSTATE CANCER

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– Rapid development of research program on investigational Prostate Specific Membrane Antigen-targeted radiohybrid PET imaging agent since company's 2018 acquisition –

BURLINGTON, Mass. and OXFORD, UK, March 17, 2020 – Blue Earth Diagnostics, a Bracco company focused on molecular imaging diagnostics, today announced that the first patient has been dosed in its Phase 3 LIGHTHOUSE clinical trial of rhPSMA-7.3 (^{18}F), an investigational Prostate Specific Membrane Antigen-targeted radiohybrid PET imaging agent. The LIGHTHOUSE 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 newly diagnosed prostate cancer (NCT04186819). The primary objectives of the LIGHTHOUSE study are to assess the sensitivity and specificity of rhPSMA-7.3 (^{18}F) PET for detecting pelvic lymph node metastases compared to surgical pathology on a patient level. The first patient in the LIGHTHOUSE study was dosed in Los Angeles, Calif. at RadNet's Liberty Pacific Advanced Imaging Center in conjunction with Tower Urology.

"We are excited to initiate this Phase 3 imaging trial of rhPSMA-7.3 (^{18}F), with the hope that it may help address the needs of men with newly diagnosed prostate cancer," said Jonathan Allis, D. Phil., CEO of Blue Earth Diagnostics. "LIGHTHOUSE is part of our strategy to expand and advance a world-leading prostate cancer imaging portfolio, alongside our planned Phase 3 clinical trial investigating the use of rhPSMA-7.3 (^{18}F) PET imaging in patients with an elevated Prostate-Specific Antigen (PSA) level after prior therapy. rhPSMA-7.3 (^{18}F) and approved, commercially available Axumin® (fluciclovine F 18) have unique and complementary mechanisms of action, and we believe both compounds may ultimately allow physicians and their patients flexibility in selecting the diagnostic agent most appropriate to each specific clinical situation."

"Effective staging of primary prostate cancer – determining its presence and whether it may have metastasized – is critical in assessing a patient's prognosis and informing individual clinical management strategies," said Gerald L. Andriole, MD, the Robert K. Royce Distinguished Professor and Chief of Urologic Surgery at Washington University School of Medicine. "Up to 25% of prostate cancer patients may have detectable lymph node metastases, which are correlated with a risk for recurrence and associated overall survival. Conventional imaging techniques, such as MRI and CT, are limited in the information they

may provide, particularly in high-risk primary prostate cancer, due to low sensitivity and specificity. Pelvic lymph node dissection (PLND), or pelvic lymphadenectomy, is considered the gold standard in assessing pelvic lesions, but its use is limited to the planned surgical area. An ideal staging technique for detecting metastatic disease should not only include the pelvic nodes but also more distant soft tissue and skeletal findings and be both sensitive and specific for identifying prostate cancer metastases. A number of investigational studies have reported promising diagnostic performance using PSMA-targeted PET agents, but none are approved and clinical use is limited to compassionate use and research protocols. The Phase 3 LIGHTHOUSE 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 newly diagnosed disease."

"Prostate cancer is a leading cause of male cancer-related death worldwide, and we anticipate that eventually a large proportion of patients with prostate cancer may be eligible to undergo PSMA PET imaging to help stage their disease and inform subsequent treatment choices," said David Gauden, D.Phil., Chief Scientific Officer of Blue Earth Diagnostics. "Blue Earth Diagnostics acquired an exclusive license to a broad family of theranostic rhPSMA agents in 2018, which includes an exclusive option for therapeutic applications. Since that time, we have worked closely with the Technical University of Munich (TUM) and Scintomics to identify a lead imaging candidate for further development. We selected rhPSMA-7.3 (^{18}F), a single isomer of rhPSMA-7 (^{18}F), as the candidate for our Phase 3 imaging studies. In anticipation of imaging performance, production capacity and quality needs, we selected F18 as the radiolabeling isotope of choice for rhPSMA-7.3 PET imaging. The 110-minute half-life and energy of the F18 radioisotope enable high resolution PET scans; large batch production; consistent, centralized manufacturing; and efficient distribution and broad geographic availability independent of select individual hospitals – all of which are important considerations in facilitating broad availability of this cutting edge technology for prostate cancer patients."

"Results from the early clinical experience by TUM, including with rhPSMA-7.3 (^{18}F) PET, in more than 1,000 prostate cancer patients were included in the Investigational New Drug (IND) submission for the LIGHTHOUSE trial," said Peter Gardiner, MB ChB, MRCP, FFPM, Chief Medical Officer of Blue Earth Diagnostics. "Some of that experience has recently been published online in the *Journal of Nuclear Medicine*. Retrospective analyses assessed the diagnostic performance, biodistribution and safety of rhPSMA-7 (^{18}F) in primary prostate cancer and in biochemical recurrence after both radical prostatectomy and radiation therapy. Blue Earth Diagnostics is also conducting a Phase 1 clinical study in Finland to assess the safety, biodistribution and dosimetry of rhPSMA-7.3 (^{18}F) in healthy volunteers and patients with prostate cancer."

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

The LIGHTHOUSE 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 newly diagnosed prostate cancer. The study will enroll approximately 375 evaluable patients at clinical sites in the United States and Europe. The primary endpoints of the LIGHTHOUSE study are to assess the sensitivity and specificity of rhPSMA-7.3 (^{18}F) PET for detecting pelvic lymph node metastases compared to surgical pathology on a patient level. Secondary endpoints will assess the safety of rhPSMA-7.3 (^{18}F) in patients 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 LIGHTHOUSE trial is available at www.clinicaltrials.gov (NC04186819).

About rhPSMA

rhPSMA-7.3 (^{18}F) 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 and Europe. 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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