BLUE EARTH DIAGNOSTICS HIGHLIGHTS PRESENTATIONS ON AXUMIN® (FLUCICLOVINE F 18), 18F-FLUCICLOVINE AND 18F-RHPSMA AT UPCOMING ASTRO ANNUAL MEETING

September 10, 2019

BURLINGTON, Mass. and OXFORD, UK, September 10, 2019 – Blue Earth Diagnostics, a Bracco company focused on molecular imaging diagnostics, today announced upcoming presentations at the 2019 American Society for Radiation Oncology (ASTRO) Annual Meeting, from September 15 – 18, 2019 in Chicago, Ill.

Highlighted presentations encompass the clinical use of Axumin® (fluciclovine F 18) injection, including full results of the FALCON clinical study, which investigated the impact of 18F-fluciclovine PET on the management of patients with recurrent prostate cancer. The initial clinical experience by the Technical University of Munich with 18F-rhPSMA-7, an investigational Prostate Specific Membrane Antigen-targeted radiohybrid PET imaging agent representative of the family of rhPSMA agents that Blue Earth Diagnostics exclusively licensed in 2018, will also be presented. Details of selected oral and poster presentations by Blue Earth Diagnostics and its collaborators are listed below.

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. Presentations noted by "*" discuss results of investigational studies of an approved product that is not approved by the FDA for the specific use or purpose noted, or "*" denotes experience with an investigational agent for which the safety and efficacy have not been established by the FDA.

HIGHLIGHTED SCIENTIFIC PRESENTATIONS

Axumin (fluciclovine F 18) presentations

Date: **Sunday, September 15, 2019**

Mini-Oral Title:

Impact of Positron Emission Tomography (PET) with 18F-fluciclovine on management of patients with Recurrence of Prostate Cancer: Results from the FALCON Trial

Session Title: M0 04 – GU 1– Prostate and Bladder mini-orals

Presenter: David Bottomley, MBBS, St. James Institute of Oncology, Leeds UK

Presentation Time: 5:30 – 5:35 PM CT

Location: Room W183

Presentation No.: 1048

Date: **Tuesday, September 17, 2019**

Poster Title:

Impact of Fluciclovine PET/CT on Management of Patients with Biochemically Recurrent Prostate Cancer

Session Title: PV 04 – Poster Viewing Q&A – Session 4 (Genitourinary Cancer)

Presenter: Ankur Patel, MD, University of Pittsburgh Medical Center, Pittsburgh, Pa.

Presentation Time: 2:45 – 4:00 PM CT

Location: ASTRO Innovation Hub

Presentation No.: TU_33_2689

Investigational 18F-fluciclovine presentations

Date: **Monday, September 16, 2019**

Poster Title:

Diagnostic value and reproducibility of positron emission tomography with 18F-fluciclovine in high- and low-grade glioma*

Session Title: PV 02 – Poster Viewing Q&A – Session 2 (Central Nervous System)

Presenter: Igor Yakushev, MD, Technical University of Munich (TUM), Munich, Germany

Presentation Time: 10:45 AM – 12:00 PM CT

Location: ASTRO Innovation Hub

Presentation No.: MO_13_2251

Presentation on initial clinical experience with 18F-rhPSMA-7 at Technical University of Munich

Date: **Tuesday, September 17, 2019**

Poster Title:

18F-rhPSMA-7 Positron Emission Tomography (PET) for the Detection of Biochemical Recurrence after Primary Radiation Therapy of Prostate Cancer*

Session Title: PV 04 – Poster Viewing Q&A – Session 4 (Genitourinary Cancer)

Presenter: Harun Ilhan, MD, Ludwig-Maximilian-University (LMU), Munich, Germany

Presentation Time: 2:45 – 4:00 PM CT

Location: ASTRO Innovation Hub

Presentation No.: TU_28_2645

Blue Earth Diagnostics invites participants at the 2019 ASTRO Annual Meeting to attend the presentations above and to visit the company at Exhibit Booth 1439. The company is also hosting an Industry-Expert Theater event, "Detecting and Localizing Recurrent Prostate Cancer with Axumin® (Fluciclovine F 18) Injection," with invited speaker Dr. Jonathan D. Tward, MD, PhD, Huntsman Cancer Institute, University of Utah, which will be held on Sunday, September 15, 2019, from 12:15 – 1:15 p.m. CT, in Theater 1, Innovation Hub.

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 Axumin prescribing information is available at www.axumin.com.

About Axumin® (fluciclovine F 18)

Axumin® (fluciclovine F 18) injection is a novel product indicated for use in positron emission tomography (PET) imaging to identify suspected sites of prostate cancer recurrence in men. Recurrence of prostate cancer is suspected by an increase in prostate specific antigen (PSA) levels following prior treatment. PET imaging with Axumin may identify the location and extent of such recurrence. Axumin was developed to enable visualization of the increased amino acid transport that occurs in many cancers, including prostate cancer. It consists of a synthetic amino acid that is preferentially taken up by prostate cancer cells compared with surrounding normal tissues and is labeled with the radioisotope F 18 for PET imaging. Fluciclovine F 18 was invented at Emory University in Atlanta, Ga., with much of the fundamental clinical development work carried out by physicians at Emory University's Department of Radiology and Imaging Sciences. Axumin was approved by the U.S. Food and Drug Administration in May 2016, following Priority Review, and is the first product commercialized by Blue Earth Diagnostics, which licensed the product from GE Healthcare. The molecule is being investigated by Blue Earth Diagnostics for other potential cancer indications including in neuro-oncology.

About rhPSMA

Blue Earth Diagnostics acquired exclusive, worldwide rights to radiohybrid Prostate Specific Membrane Antigen (PSMA)-targeted technology (rhPSMA) from Scintomics in 2018. rhPSMA originated from the Chair of Pharmaceutic Radiochemistry at the Technical University of Munich, Germany, by Alexander Wurzer and Hans Juergen Wester, and has been utilized

clinically under German legislation at the Department of Nuclear Medicine for the diagnostic imaging of men with both primary and recurrent prostate cancer. 18F-rhPSMA consists of a prostate-specific membrane antigen (PSMA) 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. 18F-rhPSMA, 177Lu-rhPSMA and 225Ac-rhPSMA have not received regulatory approval.

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.

Contact:

For Blue Earth Diagnostics (U.S.)

Priscilla Harlan

Vice President, Corporate Communications

(M) (781) 799-7917

p.harlan@blueearthdx.com

Media

Sam Brown Inc.

Mike Beyer

(M) (312) 961-2502

mikebeyer@sambrown.com

For Blue Earth Diagnostics (UK)

Georgina Mowatt

Communications Manager

Tel: +44 (0) 7810 355 912

g.mowatt@blueearthdx.com