PRESS RELEASE

Blue Earth Diagnostics Highlights Presentations on Axumin® (Fluciclovine F 18) and ^{18}F-Fluciclovine at Upcoming ASTRO Annual Meeting

BURLINGTON, Mass. and OXFORD, UK, October 20, 2020 – Blue Earth Diagnostics, a Bracco company focused on molecular imaging diagnostics, today announced upcoming presentations at the 2020 American Society for Radiation Oncology (ASTRO) Annual Meeting, from October 23 – 28, 2020, to be held in a virtual format.

Presentations encompass the clinical use of Axumin® (fluciclovine F 18) injection positron emission tomography (PET) in recurrent prostate cancer, including a Late-Breaking Abstract Plenary Session presentation by Emory University. Information about an independent investigational study of ^{18}F-fluciclovine PET in brain metastases will also be presented at the meeting. Details of selected oral and poster presentations by Blue Earth Diagnostics collaborators are listed below.

NOTE: Axumin® (fluciclovine F 18) injection is FDA-approved for 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.

HIGHLIGHTED SCIENTIFIC PRESENTATIONS

Monday, October 26, 2020
Axumin (fluciclovine F 18) presentations

Title:	**LBA 1 Initial Report of a Randomized Trial Comparing Conventional- vs Conventional plus Fluciclovine (18F) PET/CT Imaging-Guided Post-Prostatectomy Radiotherapy for Prostate Cancer**
Session Title:	PL 01 - Plenary Session
Presenter:	Ashesh Jani, MD, FASTRO, Emory University, Atlanta, Ga.
Presentation Time:	1:35 – 1:45 PM ET
Presentation No.:	LBA 1

Investigational ^{18}F-fluciclovine presentation

Poster Title:	**^{18}F-Fluciclovine PET/CT to Distinguish Radiation Necrosis from Tumor Progression in Brain Metastases Treated with Stereotactic Radiosurgery***
Session Title:	PV 05 – Poster Q&A – Session 5
Presenter:	Martin C. Tom, MD, Department of Radiation Oncology, Taussig Cancer Institute, Cleveland Clinic, Cleveland, Ohio
Presentation Time:	4:30 PM ET
Presentation No.:	3587

Wednesday, October 28, 2020
Axumin (fluciclovine F 18) presentations

Poster Title:	**Advanced Imaging Including the 18-F Fluciclovine PET-CT Is Instrumental In the Salvage Management of Prostate Cancer**
Session Title:	PV 07 – Poster Q&A – Session 7
Presenter:	Max Chiu, MD, Department of Radiation Oncology, University of Nebraska Medical Center, Omaha, Neb.
Presentation Time:	2:00 PM ET
Presentation No.:	4136

Poster Title:	**The Use of ^{18}F-fluciclovine PET/CT in Prostate Cancer Diagnosis and Therapeutic Decision Making**
Session Title:	PV 07 – Poster Q&A – Session 7
Presenter:	Alexandra Dreyfuss, MD, MS, Department of Radiation Oncology, Perelman School of Medicine at the University of Pennsylvania, Philadelphia, Pa.,
Presentation Time:	2:00 PM ET
Presentation No.:	4056

Blue Earth Diagnostics invites participants at the 2020 ASTRO Annual Meeting to attend the presentations above and to visit Blue Earth Diagnostics' Commercial Product Showcase for Axumin (fluciclovine F 18) Injection in the Virtual Exhibit Hall. The company also has a Medical Affairs information booth at ASTRO, where attendees can learn about ongoing clinical trials. For full session details and scientific presentation listings, please see the ASTRO2020 online program (https://www.astro.org/Meetings-and-Education/Micro-Sites/2020/Annual-Meeting/Learn/Abstracts).

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 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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