



## PRESS RELEASE

### **Blue Earth Diagnostics Highlights Presentations on Axumin® (Fluciclovine F 18) and <sup>18</sup>F-Fluciclovine at Upcoming ASTRO Annual Meeting**

**BURLINGTON, Mass. and OXFORD, UK, October 19, 2021** – Blue Earth Diagnostics, a Bracco company and recognized leader in the development and commercialization of innovative PET radiopharmaceuticals, today announced presentations on Axumin® (fluciclovine F 18) and <sup>18</sup>F-fluciclovine at the upcoming American Society for Radiation Oncology (ASTRO) 2021 Annual Meeting, to be held in Chicago, Ill., from October 24 to 27, 2021. Details of selected oral and moderated poster presentations 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 25, 2021**

##### **Axumin (fluciclovine F 18) presentations**

Category: Genitourinary Cancer  
Title: **Detectability Rates and Impact on Management From High-Sensitivity Total-Body <sup>18</sup>F-Fluciclovine PET/CT Scans in Patients With Prostate Cancer Biochemical Recurrence**  
Presenter: Soheila Fayeghi Azghadi, MD, Department of Radiation Oncology, Comprehensive Cancer Center, University of California Davis, Sacramento, Calif.  
Session Title: Poster Q&A 05 - Session 05 – Genitourinary Cancer, Hematology Malignancies, and Sarcoma and Cutaneous Tumors  
Presentation Time: 1:30 PM CT  
Location: McCormick Place West, Outside Room W375  
Presentation No.: 2532

Category: Genitourinary Cancer  
Title: **Randomized Trial of Conventional vs Conventional plus Fluciclovine (18F) PET/CT-Guided Post-Prostatectomy Radiotherapy for Prostate Cancer: Volumetric and Patient-Reported Toxicity Analyses**  
Presenter: Vishal Ramesh Dhere, MD, Winship Cancer Institute, Department of Radiation Oncology, Emory University, Atlanta, Ga.  
Session Title: Poster Q&A 05 - Session 05 – Genitourinary Cancer, Hematology Malignancies, and Sarcoma and Cutaneous Tumors  
Presentation Time: 1:30 PM CT  
Location: McCormick Place West, Outside Room W375

Presentation No.: 2547

**Investigational <sup>18</sup>F-fluciclovine presentation**

Category: Central Nervous System  
 Session Title: <sup>18</sup>F-Fluciclovine PET/CT to Distinguish Radiation Necrosis From Tumor Progression in Brain Metastases Treated With Stereotactic Radiosurgery: Results of a Prospective Pilot Study\*  
 Presenter: Martin C. Tom, MD, Department of Radiation Oncology, Taussig Cancer Institute, Cleveland Clinic, Cleveland, Ohio  
 Session Title: 51 Oral presentation  
 Presentation Time: 12:15 PM CT  
 Location: McCormick Place West, Room W194 a/b  
 Presentation No.: 51

Blue Earth Diagnostics invites participants at the 2021 ASTRO Annual Meeting to attend the presentations above and visit the company at Exhibit Booth 665. Blue Earth Diagnostics is hosting an Industry-Expert Theater event, “The Role of PET in Post-Prostatectomy Radiotherapy,” with invited speaker Dr. Ashesh Jani, MD, MSEE, FASTRO, James C. Kennedy Professor, Department of Radiation Oncology, Winship Cancer Institute of Emory University, Atlanta, Ga. The event will be held on Sunday, October 24, 2021, from 12:30 to 1:30 PM CT, in Theater 1, Exhibition Floor. For full session details and scientific presentation listings, please see the ASTRO online program [here](#).

**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](http://www.fda.gov/medwatch).

Full Axumin prescribing information is available at <https://www.axumin.com/prescribing-information.pdf>.

**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](http://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. Visit: [www.braccoimaging.com](http://www.braccoimaging.com).

**Contact:****For Blue Earth Diagnostics (U.S.)**

Priscilla Harlan  
Vice President, Corporate Communications  
(M) (781) 799-7917  
[priscilla.harlan@blueearthdx.com](mailto:priscilla.harlan@blueearthdx.com)

**For Blue Earth Diagnostics (UK)**

Georgina Mowatt  
Communications Manager  
Tel: +44 (0) 7810 355 912  
[georgina.mowatt@blueearthdx.com](mailto:georgina.mowatt@blueearthdx.com)

**Media**

Sam Brown Inc.  
Mike Beyer  
(M) (312) 961-2502  
[mikebeyer@sambrown.com](mailto:mikebeyer@sambrown.com)

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