



## PRESS RELEASE

### **Blue Earth Diagnostics Announces Axumin® (Fluciclovine F 18) Presentations at Upcoming 2021 American Society of Clinical Oncology (ASCO) Annual Meeting**

**BURLINGTON, Mass. and OXFORD, UK, June 2, 2021** – Blue Earth Diagnostics, a Bracco company and recognized leader in the development and commercialization of innovative PET radiopharmaceuticals, today highlighted presentations at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting, to be held in a virtual format from June 4 to 8, 2021. The two abstracts outlined the launch of studies investigating the use of Axumin® (fluciclovine F 18, also known as FACBC) PET in the management of oligometastatic, recurrent prostate cancer, and its role, as assessed by the impact on radiographic progression-free survival, in guiding radiotherapy planning for patients with recurrent disease. Details of the presentations to be given 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. Axumin is a registered trademark of Blue Earth Diagnostics, Ltd., or its related companies. All other marks are the property of their respective owners.

#### **Highlighted Axumin (Fluciclovine F 18) Scientific Presentation**

All ASCO presentations are available beginning Friday, June 4, 2021, at 9:00 a.m. ET.

Session: Genitourinary Cancer—Prostate, Testicular, and Penile  
Subtrack: Prostate Cancer – Local-Regional Disease  
Title: **The fluciclovine (FACBC) PET/CT site-directed therapy of oligometastatic prostate cancer (Flu-BLAST-PC) trial.**  
Author(s): Risa Liang Wong, Sarah K Holt, Jing Zeng, Laura Graham, Rachel Kang, Nathan Conrad, Andrea Toulouse, Zoya Bauer, Michael Lai, Todd Yezefski, Jonathan L. Wright, Emily Steinberger Weg, Andrew Caleb Hsieh, Heather H. Cheng, Jean H Lee, Delphine L. Chen, Daniel W. Lin, Evan Y. Yu

Session: Poster session  
Abstract: TPS5099

Session: Genitourinary Cancer—Prostate, Testicular, and Penile  
Subtrack: Prostate Cancer – Local-Regional Disease  
Title: **Phase III study of local or systemic therapy Intensification Directed by PET in prostate Cancer patients with post-prostaTEctomy biochemical recurrence (INDICATE): ECOGACRIN EA8191.**  
Author(s): Neha Vapiwala, Yu-Hui Chen, Steve Y. Cho, Fenghai Duan, Christos Kyriakopoulos, Daniel H. Shevrin, Rana R. McKay, Bridget F. Koontz, Evan Y. Yu, Volkan Beylergil, David A. Mankoff, Jonathan McConathy, Glenn Liu, Terence Z. Wong, Michael Anthony Carducci  
Session: Poster session

Abstract: TPS5098

Blue Earth Diagnostics invites participants at the 2021 ASCO Annual Meeting to attend the above presentations and to learn more about the Company at [www.blueearthdiagnostics.com](http://www.blueearthdiagnostics.com). For full session details and scientific presentation listings, please see the ASCO online program [here](#).

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

**Full U.S. Axumin prescribing information is available at:**

<https://www.axumin.com/prescribing-information.pdf>.

### **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, a subsidiary of Bracco Imaging S.p.A., is a recognized leader in the development and commercialization of novel PET radiopharmaceuticals 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 proven experts in nuclear medicine, who have expanded and advanced its robust oncology portfolio. 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 suspected recurrence, based on elevated Prostate-Specific Antigen (PSA) levels. <sup>18</sup>F-fluciclovine 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 radiohybrid Prostate-Specific Membrane Antigen (rhPSMA)-targeted agents, a clinical-stage, investigational class of theranostic compounds with potential applications in both the imaging and treatment of prostate cancer. For more information, 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).

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