



PRESS RELEASE

This press release is for U.S. audiences only

Blue Earth Diagnostics Highlights Presentations on Axumin® (Fluciclovine F 18) at Upcoming RSNA® 2022 Annual Meeting

MONROE TOWNSHIP, NJ, and OXFORD, UK, November 22, 2022 – 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) at the upcoming Radiological Society of North America (RSNA) 108th Scientific Assembly and Annual Meeting, to be held in Chicago, Ill., from November 27 to December 1, 2022. Details of selected oral and poster presentations are listed below.

Two presentations from Emory University will discuss additional analyses from EMPIRE-1, the first prospective, randomized controlled trial to demonstrate that ¹⁸F-fluciclovine PET/CT-guided radiation therapy improved event-free survival rates in men with biochemical recurrence of prostate cancer. Another presentation compares the diagnostic performance of bone scintigraphy with ¹⁸F-fluciclovine in detecting bone metastases in men with prostate cancer at various PSA levels. 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.

HIGHLIGHTED SCIENTIFIC PRESENTATIONS

Oral presentation

Thursday, December 1, 2022

Title: **Failure-free Survival of Prostate Cancer Patients After Conventional Imaging Versus ¹⁸F-fluciclovine PET-guided Salvage Radiotherapy Stratified by Serum PSA Level: A Secondary Sub-group Analysis of a Randomized Control Trial**

Presenter: Ismaheel Lawal, MD, Division of Nuclear Medicine and Molecular Imaging, Department of Radiology and Imaging Sciences, Emory University, Atlanta, Ga.

Session Type: Oral Scientific Session

Session Title: Science Session with Keynote: Nuclear Medicine/Molecular Imaging (Prostate Cancer Imaging)

Presentation Time: 1:30 – 2:30 PM CT

Location: S402, McCormick Place

Presentation No.: R-6-SNMMI 08-1

Poster presentations

Tuesday, November 29, 2022

Title:	Bone Scan versus F-18 Fluciclovine PET/CT at Different PSA Levels: A Single Center Comparison Study
Presenter:	Hatice Savas, MD, Associate Professor, Feinburg School of Medicine, Northwestern University, Chicago, Ill.
Session Type:	Scientific Poster Session
Session Title:	Nuclear Medicine/Molecular Imaging Tuesday Poster Discussion
Presentation Time:	9:00 – 9:30 AM CT
Location:	Learning Center NMMI-DPS, McCormick Place
Session No.:	T2-SPNMMI-1
Title:	Impact of ¹⁸F-fluciclovine PET/CT on Failure-free Survival in Biochemical Recurrence of Prostate Cancer Following Salvage Radiation Therapy
Presenter:	Charles Marcus, MBBS, Assistant Professor, Department of Imaging and Radiology Sciences, Emory University School of Medicine, Atlanta, Ga.
Session Type:	Scientific Poster Session
Session Title:	Nuclear Medicine/Molecular Imaging Tuesday Poster Discussion - A
Presentation Time:	12:15 – 12:45 PM CT
Location:	Learning Center NMMI-DPS, McCormick Place
Session No.:	T5A-SPNMMI-2

Axumin® (fluciclovine F 18) presentations

Blue Earth Diagnostics invites participants at RSNA 2022 to attend the presentations above. For full session details and scientific presentation listings, please see the RSNA 2022 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.

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.

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.

Contact:

For Blue Earth Diagnostics (U.S.)

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

For Blue Earth Diagnostics (UK)

Clare Gidley
Associate Director Marketing and Communications
Tel: +44 (0)1865 784186
clare.gidley@blueearthdx.com

Media

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

#