



PRESS RELEASE

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Blue Earth Diagnostics Highlights Presentations on Axumin® (Fluciclovine F 18) and Investigational ¹⁸F-rhPSMA-7.3 in Biochemically Recurrent Prostate Cancer at Upcoming ASTRO Annual Meeting

MONROE TOWNSHIP, NJ, and OXFORD, UK, October 19, 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) and investigational ¹⁸F-rhPSMA-7.3 at the upcoming American Society for Radiation Oncology (ASTRO) 2022 Annual Meeting, to be held in San Antonio, Texas, from October 23 to 26, 2022. Details of selected oral and moderated poster presentations are listed below.

An oral presentation on the investigational radiohybrid Prostate-Specific Membrane Antigen (rhPSMA) compound, ¹⁸F-rhPSMA-7.3, is being made at the conference. It includes additional results from the Company's Phase 3 SPOTLIGHT study ([NCT04186845](#)) evaluating the impact of clinical factors on the detection rate of ¹⁸F-rhPSMA-7.3 PET imaging in men with suspected prostate cancer recurrence based on elevated PSA following prior therapy. Presentations on studies of Axumin (fluciclovine F 18) include interim analyses from a randomized trial of ¹⁸F-fluciclovine and ⁶⁸Ga-PSMA PET/CT in post-prostatectomy radiotherapy, experience on the prognostic utility of ¹⁸F-fluciclovine PET after salvage radiotherapy, and timing and patterns of potentially salvageable recurrences after SBRT for localized prostate cancer. Additionally, the Company will host an Industry-Expert Theater event, "Emerging Data on the Impact of Axumin® (fluciclovine F 18) PET Imaging on Radiotherapy Decisions." 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 PET imaging in men with suspected prostate cancer recurrence based on elevated blood prostate-specific antigen (PSA) levels following prior treatment. Currently, ¹⁸F-rhPSMA-7.3 is investigational and has not received regulatory approval.

HIGHLIGHTED SCIENTIFIC PRESENTATIONS

Monday, October 24, 2022

Investigational ¹⁸F-rhPSMA-7.3 presentation

Category:	Genitourinary Cancer
Title:	1049 Impact of Clinical Factors on ¹⁸F-rhPSMA-7.3 Detection Rates in Men with Recurrent Prostate Cancer: Findings from the Phase 3 SPOTLIGHT Study
Presenter:	Benjamin Lowentritt, MD, Chesapeake Urology Associates, Towson, Md.
Session Type	Quick Pitch
Session Title:	QP 09 – GU 3 – Salvage, SABR and Protons for Prostate Cancer
Presentation Time:	5:05 PM CT
Location:	Henry B. Gonzalez Convention Center, Room 304
Presentation No.:	1049

Tuesday, October 25, 2022

Axumin® (fluciclovine F 18) presentations

Category: Genitourinary Cancer
 Title: **Prognostic Utility of (18)F-Fluciclovine Positron Emission Tomography (FACBC) in Biochemically Recurrent (BCR) Prostate Cancer (PCa) Treated with Salvage Radiotherapy**
 Presenter: Graham Campbell, MD, University of Wisconsin Hospital and Clinics, Madison, Wis.
 Session Title: PQ 06 – Poster Q&A 06 – Session 06 – Genitourinary Cancer, Patient Safety and Nursing
 Presentation Time: 2:30 PM CT
 Location: Henry B. Gonzalez Convention Center, Exhibit Hall 1
 Presentation No.: 2478

Category: Genitourinary Cancer
 Title: **Timing and Patterns of Potentially Salvageable Recurrences Following SBRT for Clinically Localized Prostate Cancer Assessed by Preferential Amino Acid Uptake**
 Presenter: Michael Carrasquilla, MD, Department of Radiation Medicine, Medstar Georgetown University Hospital, Washington, DC
 Session Title: Poster Q&A 06 – Session 06 – Genitourinary Cancer, Patient Safety and Nursing
 Presentation Time: 2:30 PM CT
 Location: Henry B. Gonzalez Convention Center, Exhibit Hall 1
 Presentation No.: 2479

Category: Genitourinary Cancer
 Title: **Randomized Trial of ¹⁸F-fluciclovine vs ⁶⁸Ga-PSMA PET/CT Guided Post-Prostatectomy Radiotherapy: Interim Volumetric and Patient-Reported Toxicity Analyses**
 Presenter: Vishal Ramesh Dhere, MD, Department of Radiation Oncology, Winship Cancer Institute of Emory University, Atlanta, Ga.
 Session Title: Poster Q&A 06 – Session 06 – Genitourinary Cancer, Patient Safety and Nursing
 Presentation Time: 2:30 PM CT
 Location: Henry B. Gonzalez Convention Center, Exhibit Hall 1
 Presentation No.: 2489

Blue Earth Diagnostics invites participants at the 2022 ASTRO Annual Meeting to attend the presentations above and visit the company at Exhibit Booth 4142. Blue Earth Diagnostics is hosting an Industry-Expert Theater event, “Emerging Data on the Impact of Axumin® (fluciclovine F 18) PET Imaging on Radiotherapy Decisions,” with invited speaker Dr. Edward Obedian, MD, Radiation Oncologist, St. Francis Hospital, Long Island, NY. The event will be held on Sunday, October 23, 2022, from 11:00 AM to 12:00 PM CT, in Room 216, Meeting Level, Henry B. Gonzalez Convention Center. 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 $\leq 1\%$ 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.

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