



## PRESS RELEASE

This press release is for U.S. audiences only

### **Blue Earth Diagnostics Highlights Upcoming Presentation of Results from Phase 3 LIGHTHOUSE Study of Investigational PET Imaging Agent <sup>18</sup>F-rhPSMA-7.3 in Newly Diagnosed Prostate Cancer**

*– First presentation of results to be made at 23rd Annual Scientific Meeting in Urologic Oncology (SUO) –*

**MONROE TOWNSHIP, NJ, and OXFORD, UK, November 21, 2022** – Blue Earth Diagnostics, a Bracco company and recognized leader in the development and commercialization of innovative PET radiopharmaceuticals, today announced presentations on investigational rhPSMA compounds and Axumin® (fluciclovine F 18) at the upcoming 23rd Annual Scientific Meeting in Urologic Oncology (SUO), to be held in San Diego, Calif., from November 30 to December 2, 2022. They include the first presentation of key results from Blue Earth Diagnostics' completed Phase 3 LIGHTHOUSE trial ([NCT04186819](#)) investigating the safety and diagnostic performance of <sup>18</sup>F-rhPSMA-7.3 PET in newly diagnosed prostate cancer. <sup>18</sup>F-rhPSMA-7.3 is an investigational Prostate-Specific Membrane Antigen-targeted radiohybrid (rh) PET imaging agent. An rhPSMA presentation from Blue Earth Diagnostics' sister company, Blue Earth Therapeutics, will report on its ongoing Phase 1/2 trial investigating the use of <sup>177</sup>Lu-rhPSMA-10.1 for treatment in metastatic castrate-resistant prostate cancer. In addition, a further presentation will report findings from experiments designed to better understand PSMA regulation in castrate-resistant and neuroendocrine prostate cancer and the potential role of <sup>18</sup>F-fluciclovine PET imaging when these tumors have low PSMA expression.

Details of selected 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, rhPSMA compounds are investigational and have not received regulatory approval.

#### **HIGHLIGHTED SCIENTIFIC PRESENTATIONS**

SUO has designed this year's meeting to feature all presentations in digital poster format, presented in scheduled blocks and available in the online poster gallery.

**Thursday, December 1, 2022**

#### **Investigational rhPSMA**

##### **<sup>18</sup>F-rhPSMA-7.3**

Title: **Diagnostic Performance and Safety of <sup>18</sup>F-rhPSMA-7.3 PET in Patients with Newly Diagnosed Prostate Cancer: Results from a Phase 3, Prospective, Multicenter Study (LIGHTHOUSE)**

Presenter: Brian Chapin, MD, Assistant Professor, Department of Urology, Division of Surgery, The University of Texas MD Anderson Cancer Center, on behalf of the LIGHTHOUSE Study Group  
Time: 2:00 –3:00 PM PT  
Number: 134

#### **<sup>177</sup>Lu-rhPSMA-10.1**

Title: **The Safety, Tolerability, Radiation Dosimetry and Efficacy of <sup>177</sup>Lu-rhPSMA-10.1 for Metastatic Castrate-resistant Prostate Cancer: A Phase 1/2 Trial in Progress**  
Presenter: Koby Amankwah, Weill Cornell Cancer Center, New York, NY  
Time: 9:00 – 10:00 AM PT  
Number: 73

#### **Axumin® (fluciclovine F 18)**

Title: **Detection of PSMA-Low Castration Resistant and Neuroendocrine Prostate Cancer with <sup>18</sup>F-Fluciclovine PET Imaging**  
Presenter: Himisha Beltran, MD, Associate Professor, Medical Oncology, Dana-Farber Cancer Institute, Boston, Mass.  
Time: 9:00 – 10:00 AM PT  
Number: 72

Blue Earth Diagnostics invites participants at the SUO 23rd Annual Meeting to attend the presentations above and to learn more about the company at its Medical Affairs educational booth. For session details and scientific presentation listings, please see the SUO online program [here](#).

#### **About Radiohybrid Prostate-Specific Membrane Antigen (rhPSMA)**

rhPSMA compounds consist of a radiohybrid (“rh”) Prostate-Specific Membrane Antigen-targeted receptor ligand which attaches to and is internalized by prostate cancer cells and they may be radiolabeled with <sup>18</sup>F for PET imaging, or with isotopes such as <sup>177</sup>Lu or <sup>225</sup>Ac for therapeutic use – creating a true theranostic technology. They may play an important role in patient management in the future, and offer the potential for precision medicine for men with prostate cancer. Radiohybrid technology and rhPSMA originated from the Technical University of Munich, Germany. Blue Earth Diagnostics acquired exclusive, worldwide rights to rhPSMA diagnostic imaging technology from Scintomics GmbH in 2018, and therapeutic rights in 2020, and has sublicensed the therapeutic application to its sister company Blue Earth Therapeutics. Blue Earth Diagnostics has completed two Phase 3 clinical studies evaluating the safety and diagnostic performance of <sup>18</sup>F-rhPSMA-7.3 PET imaging in prostate cancer: (“SPOTLIGHT,” [NCT04186845](#)), in men with recurrent disease and (“LIGHTHOUSE,” [NCT04186819](#)), in men with newly diagnosed prostate cancer. Currently, rhPSMA compounds are investigational and have not received regulatory approval.

#### **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](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)**

Clare Gidley

Associate Director Marketing and Communications

Tel: +44 (0)1865 784186

[clare.gidley@blueearthdx.com](mailto:clare.gidley@blueearthdx.com)

**Media**

Sam Brown Inc.

Mike Beyer

(M) (312) 961-2502

[mikebeyer@sambrown.com](mailto:mikebeyer@sambrown.com)

# # #