



PRESS RELEASE

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Blue Earth Diagnostics Highlights Presentations on Investigational rhPSMA Radiopharmaceuticals and ¹⁸F-Fluciclovine at Upcoming Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting

BURLINGTON, Mass. and OXFORD, UK, June 9, 2022 – Blue Earth Diagnostics, a Bracco company and recognized leader in the development and commercialization of innovative PET radiopharmaceuticals, today announced upcoming presentations at the Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting, to be held June 11 – 14, 2022 in Vancouver, British Columbia, Canada.

Presentations on investigational radiohybrid Prostate-Specific Membrane Antigen (rhPSMA) compounds are being made at the conference. They include additional results from the Company's Phase 3 SPOTLIGHT study ([NCT04186845](https://clinicaltrials.gov/ct2/show/study/NCT04186845)) evaluating the safety and diagnostic performance of ¹⁸F-rhPSMA-7.3 PET imaging in men with suspected prostate cancer recurrence based on elevated PSA following prior therapy, and preclinical evaluation of ¹⁷⁷Lu-rhPSMA-10.1, being investigated by Blue Earth Therapeutics as a therapeutic radiopharmaceutical candidate for prostate cancer. Presentations on investigational studies of ¹⁸F-fluciclovine include an interim report from an exploratory trial in lobular breast cancer, distinguishing pseudoprogression from tumor recurrence in glioblastoma, and amino acid transport mechanisms and staging in muscle invasive bladder cancer. Details of selected oral and poster presentations by Blue Earth Diagnostics and its collaborators are listed below.

NOTE: Currently, rhPSMA compounds are investigational and have not received regulatory approval. ¹⁸F-fluciclovine is an approved molecular imaging radiopharmaceutical for use in 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.

Investigational rhPSMA **Oral presentations**

¹⁸F-rhPSMA-7.3

Tuesday, June 14, 2022

Title: Inter- and intra-reader reproducibility of ¹⁸F-rhPSMA-7.3 PET image interpretation in patients with suspected prostate cancer recurrence: Results from a phase 3, prospective, multicenter study (SPOTLIGHT)

Presenter: Phillip Kuo, MD, Ph.D., Departments of Medical Imaging, Medicine, and Biomedical Engineering, University of Arizona, Tucson, Ariz. and Invicro, Boston, Mass., on behalf of the SPOTLIGHT study group

Session Title: SS 33 -PSMA-targeted imaging

Session Time: 10:00 – 11:30 AM PT

Presentation: 10:20 – 10:30 AM PT

Room: 118/119/120
 Program ID: 2539

¹⁷⁷Lu-rhPSMA-10.1

Monday, June 13, 2022

Title: Preclinical evaluation of a novel radioligand therapy for patients with prostate cancer: biodistribution and efficacy of ¹⁷⁷Lu-rhPSMA-10.1 in comparison with ¹⁷⁷Lu-PSMA-I&T
Presenter: Caroline Foxton, Ph.D., Blue Earth Therapeutics, Oxford, UK
Session Title: SS 16 Radiotherapy and Radiotheranostics
Session Time: 10:00 – 11:30 AM PT
Presentation: 10:50 AM – 11:00 AM PT
Room: 114/115
Program ID: 2567

Axumin® (fluciclovine F 18) and Investigational ¹⁸F-fluciclovine

Oral presentation

Sunday, June 12, 2022

Title: ¹⁸F-Fluciclovine and ⁶⁸Ga-PSMA-11 PET/CT for Detection of Invasive Lobular Breast Cancer: Interim Report from an Exploratory Trial*
Presenter: David M. Schuster, MD, FACR, Winship Cancer Institute of Emory University, Atlanta, Ga.
Session Type: Oral
Session Title: SS 09 - Thoracic Malignancies: Breast and Lung
Session Time: 12:30 – 2:00 PM PT
Presentation: 1:10 – 1:20 PM PT
Room: 114/115
Program ID: 2592

Poster Award Candidate Presentation

The poster, ¹⁸F-fluciclovine PET and multi-parametric MRI to distinguish pseudoprogression from tumor progression in post-treatment glioblastoma*, has been selected as a Poster Award Candidate by SNMMI and will be presented in an oral presentation on Monday, June 13, 2022 at 3:00 PM PT in the Poster Hall.

All SNMMI poster presentations are available beginning Saturday, June 11, 2022 at 6:00 PM PT in Exhibit Hall A.

Title: Detection rates from ¹⁸F-fluciclovine total-body PET/CT in prostate cancer patients with biochemical recurrence
Presenter: Yasser Abdelhafez, MD, Research Specialist, University of California Davis, Davis, Calif.
Program ID: 3042

Title: Fluciclovine-PET assessment of amino-acid transporter kinetics for primary staging of muscle-invasive bladder cancer*
Presenter: Arda Konik, Ph.D., Instructor in Radiology, Department of Radiology, Dana Farber Cancer Institute, Boston, Mass.
Program ID: 3053

Abstract ID: 634

Title: ¹⁸F-fluciclovine PET and multi-parametric MRI to distinguish pseudoprogression from tumor progression in post-treatment glioblastoma*

Presenter: Ali Nabavizadeh, MD, Assistant Professor of Radiology, University of Pennsylvania Health System, Philadelphia, Pa.

Program ID: 3108

Abstract ID: 809

Title: **Pilot Study of ¹⁸F-Fluciclovine PET/CT for Staging Muscle Invasive Bladder Cancer Before Radical Cystectomy: Preliminary Results***

Presenter: Thomas Ng, MD, Ph.D., Instructor, Radiology, Harvard Medical School, Boston, Mass.

Program ID: 3052

Abstract ID: 604

Blue Earth Diagnostics invites participants at the 2022 SNMMI Annual Meeting to attend the presentations above and to visit the Company at Exhibit Booth 1419. The Company is hosting a Satellite Symposium, “¹⁸F-rhPSMA-7.3, a Unique Investigational Prostate-specific Membrane Antigen (PSMA)-targeted PET Imaging Agent for Men with Prostate Cancer,” with invited speaker Dr. Andrei Purysko, MD, Department of Diagnostic Radiology, Cleveland Clinic, Cleveland, Ohio. Additional speakers include David Gauden, D.Phil., Chief Executive Officer, and Eugene M. Teoh, MBBS, MRCP, FRCR, D.Phil., Chief Medical Officer, of Blue Earth Diagnostics. The event will be held on Sunday, June 12, 2022, from 11:15 a.m. – 12:15 p.m. PT in Ballroom C (East Building) of the Vancouver Convention Center. For full session details and scientific presentation lists, please see the SNMMI 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 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. In 2021, Bracco Imaging established Blue Earth Therapeutics as a separate, cutting-edge biotechnology vehicle to develop radiopharmaceutical therapies. Visit: www.braccoimaging.com.

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