



PRESS RELEASE

Blue Earth Diagnostics Announces Upcoming ¹⁸F-Fluciclovine Presentations at 2021 Society of Neuro-Oncology (SNO) Conference on Brain Metastases

BURLINGTON, Mass. and OXFORD, UK, August 10, 2021 – Blue Earth Diagnostics, a Bracco company and recognized leader in the development and commercialization of innovative PET radiopharmaceuticals, today highlighted presentations at the upcoming 2021 Society of Neuro-Oncology (SNO) Conference on Brain Metastases, to be held in a virtual format from August 19 to 20, 2021. The conference, the Third Annual Conference on Brain Metastases, is conducted by SNO and the American Association of Neurological Surgeons (AANS)/CNS Section on Tumors. Details of the presentations to be given by Blue Earth Diagnostics and its collaborators are listed below.

Note: ¹⁸F-fluciclovine, under the tradename Axumin[®] (fluciclovine F 18) injection, is an FDA-approved and commercially available 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. The safety and efficacy of ¹⁸F-fluciclovine PET imaging for the detection of recurrent brain metastases has not been established.

Highlighted ¹⁸F-Fluciclovine Scientific Presentations

All 2021 SNO Conference on Brain Metastases presentations are available beginning 11:00 a.m. ET, Thursday, August 19, 2021.

Title: **Trial in Progress: A Prospective, Multicenter Phase 2b Study to Establish Image Interpretation Criteria for 18F-Fluciclovine PET in Detecting Recurrent Brain Metastases after Radiation Therapy (PURSUE)**

Presenter: Rupesh Kotecha, MD, Baptist Health South Florida, Miami, FL, USA

Abstract: TRLS-01

Title: **Trial in Progress: A Multicenter Phase 3 Study to Establish the Diagnostic Performance of 18F-Fluciclovine PET in Detecting Recurrent Brain Metastases after Radiation Therapy (REVELATE)**

Presenter: Alain Chaglassian, MD, Blue Earth Diagnostics Inc., Burlington, MA

Abstract: TRLS-02

Blue Earth Diagnostics invites participants at the SNO Conference on Brain Metastases 2021 to attend the presentations above. For more information about the meeting, please see the online program [here](#).

Blue Earth Diagnostics has two clinical studies underway to investigate the use of ¹⁸F-fluciclovine PET in the detection of recurrent brain metastases. The Phase 2 PURSUE trial is designed to establish image interpretation criteria for ¹⁸F-fluciclovine PET in detecting recurrent brain metastases. REVELATE is a

Phase 3 study designed to evaluate its diagnostic performance in the detection of recurrent brain metastases in patients previously treated with radiation therapy. Further information about these trials, including a current list of clinical trial sites, can be found on www.clinicaltrials.gov (PURSUE, [NCT04410367](https://clinicaltrials.gov/ct2/show/study/NCT04410367); REVELATE, [NCT04410133](https://clinicaltrials.gov/ct2/show/study/NCT04410133)).

About ¹⁸F-Fluciclovine PET

¹⁸F-Fluciclovine PET is a novel diagnostic imaging radiopharmaceutical for PET imaging to visualize the increased amino transport that occurs in malignant tumors. It consists of a synthetic amino acid that is preferentially taken up by cancer cells compared with surrounding normal tissues and is labeled with the radioisotope ¹⁸F for PET imaging. ¹⁸F-Fluciclovine is under investigation by Blue Earth Diagnostics for potential use for the detection of recurrent brain metastases in adult patients who have previously undergone radiation therapy. ¹⁸F-Fluciclovine was invented at Emory University, in Atlanta, Ga., with much of the fundamental clinical development carried out by physicians at Emory University's Department of Radiology and Imaging Sciences. Blue Earth Diagnostics licensed ¹⁸F-fluciclovine from GE Healthcare and is investigating the molecule for other potential cancer indications, including in neuro-oncology.

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.

Full U.S. 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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