



PRESS RELEASE

Blue Earth Diagnostics Highlights Presentations on Axumin® (Fluciclovine F 18) at Upcoming 2021 ASCO Genitourinary Cancers Symposium (ASCO GU)

BURLINGTON, Mass. and OXFORD, UK, February 8, 2021 – 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 ASCO 2021 Genitourinary Cancers Symposium (ASCO GU), from February 11 to 13, 2021, to be held in a virtual format. Details of selected oral poster presentations 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. Axumin is a registered trademark of Blue Earth Diagnostics, Ltd., or its related companies. All other marks are the property of their respective owners.

Highlighted Axumin (Fluciclovine F 18) Scientific Presentations

All ASCO GU presentations are available beginning Thursday, February 11, 2021, at 8 a.m. ET.

- Track: Prostate Cancer – Advanced
Title: **Diagnostic utility of (¹⁸F)-fluciclovine positron emission tomography (FACBC) in biochemically recurrent (BCR) prostate cancer (PCa) based on prior primary treatment modality for localized disease and the impact of FACBC findings on treatment selection.**
Author(s): Marina N. Sharifi, Petra Lovrec, Jens C. Eickhoff, Aria Kenarsary, David F. Jarrard, John Floberg, Steve Y. Cho, Christos Kyriakopoulos, Hamid Emamekhoo
Session: Poster session
Abstract: 34
- Track: Prostate Cancer – Advanced
Title: **Use of ¹⁸F-fluciclovine PET/CT (FluPET) for prostate cancer (PC): Initial results from a prospective registry at a tertiary academic center.**
Author(s): Risa L. Wong, Heather H. Cheng, Sarah K. Holt, Nathan Conrad, Hannah Loesch, Sara Fernandez, Rameen Sahoo, Zoya Bauer, Andrea Toulouse, Petros Grivas, Todd Yezefski, Kenneth J. Russell, Jonathan L. Wright, Michael T. Schweizer, Robert B. Montgomery, Jean H. Lee, Delphine L. Chen, Jing Zeng, Daniel W. Lin, Evan Y. Yu
Session: Poster session
Abstract: 29
- Track: Trials in Progress – Advanced Prostate Cancer
Title: **¹⁸F-fluciclovine positron emission tomography (PET) in metastatic castration-resistant prostate cancer (mCRPC) treated with abiraterone acetate.**

Author(s): Pedro C. Barata, Charlotte Manogue, Ellen Jaeger, Malcolm Light, Patrick Cotogno, Elisa M. Ledet, Janeiro Goffin, Jodi L. Layton, Brian E. Lewis, A. O. Sartor
Session: Poster session
Abstract: TPS171

Blue Earth Diagnostics invites participants at the ASCO 2021 Genitourinary Cancers Symposium (ASCO GU) to attend the presentations above and to visit Blue Earth Diagnostics' commercial exhibit in the Virtual Exhibit hall. For full session details and scientific presentation listings, please see the ASCO GU 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, a subsidiary of Bracco Imaging S.p.A., is a recognized leader in the development and commercialization of novel PET radiopharmaceuticals to inform clinical management and guide care for cancer patients in areas of unmet medical need. Formed in 2014, Blue Earth Diagnostics is led by proven experts in nuclear medicine, who have expanded and advanced its robust oncology portfolio. The company's first approved and commercially available product is Axumin® (fluciclovine F 18), a novel molecular imaging agent approved in the United States and European Union for use in PET imaging to detect and localize prostate cancer in men with suspected recurrence, based on elevated Prostate-Specific Antigen (PSA) levels. ¹⁸F-fluciclovine has a broad range of other potential applications in cancer imaging and Blue Earth Diagnostics is investigating the molecule for other cancers, including in neuro-oncology. The company's pipeline includes innovative radiohybrid Prostate-Specific Membrane Antigen (rhPSMA)-targeted agents, a clinical-stage, investigational class of theranostic compounds with potential

applications in both the imaging and treatment of prostate cancer. For more information, 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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