



PRESS RELEASE

Blue Earth Diagnostics Announces Presentations on Axumin® (Fluciclovine F 18), ¹⁸F-Fluciclovine and ¹⁸F-rhPSMA at Upcoming American Urological Association's 2019 Annual Meeting

BURLINGTON, Mass. and OXFORD, UK, April 24, 2019 – Blue Earth Diagnostics, a molecular imaging diagnostics company, today announced upcoming presentations at the American Urological Association's 2019 Annual Meeting, AUA2019, being held May 3 - 6, 2019, in Chicago, Ill. Presentations on Axumin® (fluciclovine F 18) Injection include additional analyses from the LOCATE clinical trial (NCT02680041), a prospective, U.S., multicenter, open-label study investigating the impact of ¹⁸F fluciclovine PET/CT imaging on patient management of biochemically recurrent prostate cancer after initial prostate cancer treatment and negative or equivocal findings on standard-of-care imaging.

Additional presentations include an investigational use of ¹⁸F-fluciclovine and initial clinical experience by the Technical University of Munich with ¹⁸F-rhPSMA-7, a Prostate Specific Membrane Antigen-targeted radiohybrid PET imaging agent representative of the family of rhPSMA agents that the company licensed in 2018. Details of the presentations to be made by Blue Earth Diagnostics collaborators are listed below.

Axumin (fluciclovine F 18) presentations

Date: Friday, May 3, 2019
Presentation: PET/CT with ¹⁸F-fluciclovine to predict recurrence in post-treatment prostate cancer and its role in altering treatment plans
Abstract Number: MP13-01
Presenter: Julio Chong, MD, Icahn School of Medicine at Mt Sinai, New York, NY
Session Title & Times: Prostate Cancer: Detection and Screening I
1:00 – 3:00 p.m. CT
Location: MCP: W180

Date: Saturday, May 4, 2019
Presentation: Localization of recurrence of prostate cancer with ¹⁸F-fluciclovine positron emission tomography in patients with and without prior prostatectomy: Results from LOCATE
Abstract Number: MP36-18
Presenter: Gerald Andriole, Jr., MD, Washington University, St. Louis, Mo. on behalf of the LOCATE study group
Session Title & Times: MP36: Prostate Cancer: Detection and Screening V
1:00 – 3:00 p.m. CT
Location: MCP: W180

Date: Monday, May 6, 2019

Presentation: **Sites of prostate cancer recurrence delineated with ¹⁸F-fluciclovine positron emission tomography in patients with negative or equivocal conventional imaging**

Abstract Number: PD60-12

Presenter: Gerald Andriole, Jr., MD, Washington University, St. Louis, Mo. on behalf of the LOCATE study group

Session Title & Times: PD60: Prostate Cancer: Detection and Screening VII, 7:00 – 9:00 a.m. CT

Presentation Time: 8:50 – 9:00 a.m. CT

Location: MCP: W185d

Investigational ¹⁸F-fluciclovine presentation

Date: Saturday, May 4, 2019

Presentation: **Evaluation of fluciclovine (FACBC) PET scan for staging high-risk prostate cancer before primary treatment***

Abstract Number: PD23-08

Presenter: Mehrdad Alemozaffar, MD, Emory University, Atlanta, Ga.

Session Title & Times: PD23: Imaging/Radiology: Uroradiology I, 7:00 – 9:00 a.m. CT

Presentation Time: 8:10 – 8:20 a.m. CT

Location: MCP: W184d

Presentations by the Technical University of Munich on initial clinical experience with ¹⁸F-rhPSMA

Date: Friday, May 3, 2019

Presentation: **¹⁸F-rhPSMA-7 positron emission tomography for the detection of biochemical recurrence of prostate cancer following radical prostatectomy***

Abstract Number: MP09-16

Presenter: Tobias Maurer, MD, University of Hamburg-Eppendorf (previously Technical University of Munich), Germany

Session Title & Times: MP09: Prostate Cancer: Staging I
9:30 – 11:30 a.m. CT

Location: MCP: 180

Date: Friday, May 3, 2019

Presentation: **Diagnostic efficacy of ¹⁸F-rhPSMA-7 positron emission tomography for N-staging of patients with high risk primary prostate cancer***

Abstract Number: PD17-04

Presenter: Tobias Maurer, MD, University of Hamburg-Eppendorf (previously Technical University of Munich), Germany

Session Title & Times: PD17: Prostate Cancer: Staging II, 3:30 – 5:30 p.m. CT

Presentation Time: 4:00 – 4:10 p.m. CT

Location: MCP: 185d

Blue Earth Diagnostics invites participants at AUA2019 to attend the above presentations and to learn more about the company at Booth 3040.

NOTE: Axumin® (fluciclovine F 18) injection is FDA-approved 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. Presentations noted by “*” discuss results of

investigational studies or experiences with an investigational agent for which the safety and efficacy have not been established by the FDA.

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 $\leq 1\%$ 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 www.axumin.com.

About Axumin® (fluciclovine F 18)

Axumin (fluciclovine F 18) injection is a novel product indicated for use in positron emission tomography (PET) imaging to identify suspected sites of prostate cancer recurrence in men. Recurrence of prostate cancer is suspected by an increase in prostate specific antigen (PSA) levels following prior treatment. PET imaging with Axumin may identify the location and extent of such recurrence. Axumin was developed to enable visualization of the increased amino acid transport that occurs in many cancers, including prostate cancer. It consists of a synthetic amino acid that is preferentially taken up by prostate cancer cells compared with surrounding normal tissues, and is labeled with the radioisotope F 18 for PET imaging. Fluciclovine F 18 was invented at Emory University in Atlanta, Ga., with much of the fundamental clinical development work carried out by physicians at Emory University's Department of Radiology and Imaging Sciences. Axumin was approved by the U.S. Food and Drug Administration in May 2016, following Priority Review, and is the first product commercialized by Blue Earth Diagnostics, which

licensed the product from GE Healthcare. The molecule is being investigated by Blue Earth Diagnostics for other potential cancer indications, such as glioma.

About Blue Earth Diagnostics

Blue Earth Diagnostics is a leading molecular imaging diagnostics company focused on the development and commercialization of novel PET imaging agents 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 recognized experts in the clinical development and commercialization of innovative nuclear medicine products. 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 a diagnosis of biochemical recurrence. The company's pipeline includes Prostate Specific Membrane Antigen (PSMA)-targeted radiohybrid ("rh") agents. rhPSMA is a clinical-stage, investigational class of theranostic compounds, with potential applications in both the imaging and treatment of prostate cancer. Blue Earth Diagnostics is backed by Syncona, an investment company listed on the London Stock Exchange (LON: SYNC). For more information, visit: www.blueearthdiagnostics.com.

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