



PRESS RELEASE

Blue Earth Diagnostics Announces Axumin® (Fluciclovine F 18) LOCATE Study Presentation at Upcoming ASCO 2019 Genitourinary Cancers Symposium on Impact on Clinical Management of Recurrent Prostate Cancer

BURLINGTON, Mass. and OXFORD, UK, February 6, 2019 – Blue Earth Diagnostics, a molecular imaging diagnostics company, today announced the upcoming presentation of additional analyses from the LOCATE clinical trial (NCT02680041). The LOCATE trial is 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. The presentation will be made at the ASCO 2019 Genitourinary Cancers Symposium (ASCO GU), from February 14-16, 2019 in San Francisco, Ca. Details of the presentation to be given by Blue Earth Diagnostics collaborators is listed below.

Date: Thursday, February 14, 2019
Presentation: **Identification of bone involvement in patients with prostate cancer recurrence using ¹⁸F-fluciclovine PET/CT and impact on subsequent management**
Abstract Number: 248
Presenter: Michael S Kipper, MD, Genesis Healthcare, on behalf of the LOCATE study group
Session Title & Times: Poster Session A: Prostate Cancer
11:30 AM-1:00 PM and 5:30 PM-6:30 PM PT
Location: Moscone West Building, San Francisco, Ca.

Blue Earth Diagnostics invites participants at the ASCO Genitourinary (GU) Cancers Symposium 2019 to attend the above presentation and to learn more about the company at Exhibit 36.

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 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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