



**Blue Earth Diagnostics Announces Presentation on Fluciclovine (<sup>18</sup>F) PET/CT Impact on Clinical Management of Recurrent Prostate Cancer at Upcoming AUA2018, Annual Meeting of the American Urological Association**

**BURLINGTON, Mass. and OXFORD, UK, May 14, 2018** – Blue Earth Diagnostics, a molecular imaging diagnostics company, today announced the upcoming presentation of initial results from the LOCATE clinical trial (NCT02680041), evaluating the impact of fluciclovine (<sup>18</sup>F) PET/CT on planned treatment for patients with biochemical recurrence (BCR) of prostate cancer after curative-intent primary therapy. The presentation includes a Moderated Poster at AUA2018, the American Urological Association Annual Meeting being held in San Francisco, Ca., from May 18 - 21, 2018. Details of the presentation to be given by Blue Earth Diagnostics and its collaborators are listed below.

Date: Monday, May 21, 2018  
Presentation: **Impact of positron emission tomography with <sup>18</sup>F-fluciclovine on management of patients with suspected recurrence of prostate cancer: results from the LOCATE trial**  
Abstract Number: 18-6136  
Session Title: Prostate Cancer: Detection & Screening VI  
Moderated Poster: MP77-11  
Session Time: 7 a.m. – 9 a.m. PT  
Presenter: Gerald L. Andriole, MD, Robert K. Royce Distinguished Professor and Chief of Urologic Surgery at Washington University School of Medicine, St. Louis, Mo., on behalf of the LOCATE study group  
Location: Moscone West Building, Room 3005, San Francisco, Ca.

Blue Earth Diagnostics invites participants at the AUA2018, Meeting of the American Urological Association, to learn more about the company at Exhibit Booth 5666. The company is also hosting a Luncheon Symposium event at the AUA 16th International Prostate Forum, with invited speakers Dr. Ashley Ross, MD, PhD, Texas Urology Specialists and Texas Oncology, Associate Chair, US Oncology Research Genito-Urinary Committee, Adjunct Associate Professor of Urology, Johns Hopkins School of Medicine, Dallas, Tex. and Dr. Rodney Ellis, MD FACRO, Vice Chairman, Strategic Affairs, Radiation Oncology, University Hospital Cleveland Medical Center, Associate Professor, Radiation Oncology and Urology, Case Western Reserve University School of Medicine, Cleveland, Ohio which will be held on Sunday, May 20, 2018, 12 p.m. – 1 p.m. PT, in MCC West, Room 3001.

**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](http://www.fda.gov/medwatch).

**Full Axumin prescribing information is available at [www.axumin.com](http://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 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 experiencing suspected biochemical recurrence. Blue Earth Diagnostics is backed by [Syncona](http://Syncona), an investment company listed on the London Stock Exchange (LON: SYNC). For more information, visit: [www.blueearthdiagnostics.com](http://www.blueearthdiagnostics.com).

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