

BLUE EARTH DIAGNOSTICS ANNOUNCES PRESENTATION AT UPCOMING ASCO 2018 GENITOURINARY CANCERS SYMPOSIUM ON FLUCICLOVINE (18F) PET/CT IMPACT ON CLINICAL MANAGEMENT OF RECURRENT PROSTATE CANCER

February 6, 2018

– Company updates that F-18 fluciclovine (Axumin®) PET/CT now listed in American College of Radiology Appropriateness Criteria® for the Post-Treatment Follow-up of Prostate Cancer –

BURLINGTON, Mass. and OXFORD, UK, February 5, 2018 – Blue Earth Diagnostics, a molecular imaging diagnostics company, today announced the upcoming presentation of initial results from the FALCON clinical trial (NCT02578940) of fluciclovine (¹⁸F) PET/CT, evaluating its impact on patient management in biochemically recurrent prostate cancer patients scheduled for salvage treatment with curative intent. The presentation includes a Rapid Fire Abstract Session and a poster display at the ASCO 2018 Genitourinary Cancers Symposium (ASCO GU), from February 8 – 10, 2018 in San Francisco, Ca. Details of the presentation to be given by Blue Earth Diagnostics and its collaborators is listed below.

Date: – Thursday, February 8, 2018

Presentation: – **The FALCON trial: Impact of 18F-fluciclovine PET/CT on clinical management choices for men with biochemically recurrent prostate cancer**

Abstract Number: – 165

Presenter: – Eugene Teoh, MD, Oxford University Hospitals NHS Trust

Session Title & Time: – Rapid-Fire Abstract Session: Prostate Cancer – 5:15 – 6:15 p.m. PT

Session Title & Times: – Poster Session A: Prostate Cancer – 11:30 a.m. – 1 p.m.; 5:15 – 6:15 p.m. PT

Location: – Moscone West Building, San Francisco, Ca.

Blue Earth Diagnostics invites participants at the ASCO Genitourinary (GU) Cancers Symposium 2018 to learn more about the company at Exhibit Booth 32.

American College of Radiology Appropriateness Criteria® Update

Blue Earth Diagnostics notes that F-18 fluciclovine (Axumin) PET/CT is now listed in the American College of Radiology (ACR) Appropriateness Criteria® for the Post-Treatment Follow-up of Prostate Cancer. The *ACR Appropriateness Criteria*® are evidence-based guidelines to assist referring physicians and other providers in making the most appropriate imaging or management decision for a specific clinical condition.

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 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](#), an investment company listed on the London Stock Exchange (LON: SYNC). For more information, visit: www.blueearthdiagnostics.com.

Contact:

For Blue Earth Diagnostics (U.S.)

Priscilla Harlan

Vice President, Corporate Communications

(M) (781) 799-7917

p.harlan@blueearthdx.com

For Blue Earth Diagnostics (UK)

Georgina Mowatt

Communications Manager

Tel: +44 (0) 7810 355 912

gmowatt@blueearthdx.com

Media

Sam Brown Inc.

Mike Beyer

(M) (312) 961-2502

mikebeyer@sambrown.com