

## **BLUE EARTH DIAGNOSTICS ANNOUNCES AXUMINTM (FLUCICLOVINE F 18) PRESENTATIONS AT UPCOMING SCIENTIFIC CONFERENCES**

September 8, 2016

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### ***- Axumin Recently FDA-approved to Detect Recurrent Prostate Cancer -***

**BURLINGTON, Mass. and OXFORD, England, September 8, 2016** – Blue Earth Diagnostics, a molecular imaging diagnostics company, today announced that it will present results from Axumin (fluciclovine F 18) injection studies in biochemically recurrent prostate cancer at several upcoming conferences, including the First Global Summit on Precision Diagnosis for Prostate Cancer in Boston, Mass., and the American Society for Radiation Oncology (ASTRO) in Boston, Mass. The Company will also participate in a panel presentation on industry innovation in new imaging agents. Details of presentations by Blue Earth Diagnostics and its collaborators are listed below.

### **First Global Summit on Precision Diagnosis for Prostate Cancer, September 16 – 18, 2016**

Date: Saturday, September 17, 2016

Poster Title: **Performance of Fluciclovine F 18 in Men with Biochemically Recurrent Prostate Cancer**

Presenter: Karen Linder, Ph.D.

Presentation Time: 7 p.m. ET

Date: Saturday, September 17, 2016

Presentation: **Panel Session on Industrial Innovation**

Presenter: Jonathan Allis, D. Phil.

Presentation Time: 7 p.m. ET

### **American Society for Radiation Oncology (ASTRO), September 25 – 28, 2016**

Date: Wednesday, September 28, 2016

Oral Presentation: **Staging Of Biochemically Relapsing Prostate Cancer Using The PET Tracer Fluciclovine F 18**

Session Title: GU – Prostate Cancer: Imaging and Biomarkers of Response and Recurrence

Presenter: Tore Bach-Gansmo, M.D., Ph.D.

Presentation Time: 7:45 a.m. – 9:00 a.m. ET

Presentation No.: 251

### **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 F18 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 on May 27, 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.

### **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 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 for use in PET imaging to detect and localize prostate cancer in men experiencing suspected biochemical recurrence. Blue Earth Diagnostics Inc. of Burlington, Mass., is the wholly-owned U.S. subsidiary of U.K.-based Blue Earth Diagnostics Ltd. The Company is funded by Syncona LLP, an independent subsidiary of the Wellcome Trust. For more information, visit [www.blueearthdx.com](http://www.blueearthdx.com).

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