

**BLUE EARTH DIAGNOSTICS AND NORTHERN CALIFORNIA PET IMAGING CENTER  
ANNOUNCE REGION'S FIRST COMMERCIAL AXUMIN™ (FLUCICLOVINE F 18)  
ADMINISTRATION**

November 29, 2016

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*– FDA-Approved F18 PET Imaging Agent for Men with Suspected Biochemically Recurrent Prostate Cancer Now Available to Patients in Northern California and Southern Oregon –*

**BURLINGTON, Mass., OXFORD, England and Sacramento, Ca. November 29, 2016** – Blue Earth Diagnostics, a molecular imaging diagnostics company, and Northern California PET Imaging Center today announced that the first commercial administration of Axumin™ (fluciclovine F 18) injection in the northern California region occurred recently at Northern California PET Imaging Center in Sacramento, Ca. Axumin is a novel molecular imaging agent indicated for use in positron emission tomography (PET) imaging in men with suspected prostate cancer recurrence based on elevated blood levels of prostate specific antigen (PSA) following prior treatment. It is the first FDA-approved F18 PET imaging agent indicated for use in patients with suspected recurrent prostate cancer.

“We are committed to providing cutting-edge molecular imaging to help improve the quality of patient care,” said Steven Falen, M.D., Ph.D., Medical Director of Northern California PET Imaging Center. “Axumin is a new PET imaging agent to help identify sites of disease in biochemically recurrent prostate cancer patients. Using current imaging methods, it is often difficult to detect early metastatic disease in men with biochemically recurrent prostate cancer. Axumin can help identify where disease has spread, demonstrating abnormal uptake in areas of potential prostate cancer. With this knowledge, referring physicians can direct appropriate patient management.”

“The Axumin PET scan now offers urologists the ability to accurately determine where prostate cancer has recurred,” said Matt Janiga, M.D., of Sutter Auburn Urology, Auburn, Ca. “This offers the potential to determine the appropriate management for our patients, without having to wait for the cancer to progress to the point that it can be picked up with older imaging techniques.”

Prostate cancer is the second leading cause of cancer death in men. While most primary prostate cancer can be successfully treated, recurrence occurs in up to one-third of patients. Recurrent disease is typically detected by a rise in PSA levels, but often the location and extent of the disease cannot be detected by conventional imaging. Of those patients who experience biochemical recurrence, approximately one-third go on to develop metastatic prostate cancer.

## 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 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 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 NORTHERN CALIFORNIA PET IMAGING CENTER**

Northern California PET Imaging Center (NCPIC) was established in 1992 as a not-for-profit, community benefit organization committed to providing Positron Emission Tomography and Molecular Imaging services to the Northern California region offering fixed site and mobile PET services. It was the nation's first freestanding PET Imaging Center. NCPIC most recently established Optimal Tracers, a radiochemistry service to supply PET radiopharmaceuticals to clinical trial sites. Information, visit [www.NorCalScans.org](http://www.NorCalScans.org) and [www.OptimalTracers.org](http://www.OptimalTracers.org) .

### **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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