

Blue Earth Diagnostics Named as Finalist in First Annual Xconomy Awards

BURLINGTON, Mass. and OXFORD, UK – Aug. 30, 2017 – Blue Earth Diagnostics, a molecular imaging diagnostics company, announced today that it has been named as a finalist as part of the first annual Xconomy Awards in the “Newcomer” category. The inaugural 2017 Xconomy Awards “honor people, companies, and organizations that make the Boston life sciences community one of the most vibrant innovation centers in the world,” with the Newcomer category recognizing the most influential newcomers and their achievements. Winners will be announced in a ceremony during *Boston Biotech Week*, on September 26, 2017.

In January 2016, Blue Earth Diagnostics established its U.S. operations in Burlington, Mass. and received FDA approval for Axumin® (fluciclovine F 18) injection in May. Axumin is the first fluorine-labelled molecular imaging agent for use in men with recurrent prostate cancer that is both FDA-approved and widely available. It is indicated for use in positron emission tomography (PET) imaging of recurrent prostate cancer in men who have elevated blood levels of prostate specific antigen (PSA) following prior treatment. Biochemically recurrent prostate cancer is often only detectable by a rise in blood levels of prostate specific antigen (PSA) after prior treatment. Up to one-third of men who develop a recurrence go on to develop metastatic prostate cancer. Physicians face complex challenges in determining appropriate patient management strategies, because current commercially available imaging techniques are limited in their ability to identify the location and extent of recurrent tumors. Axumin PET imaging provides potentially useful information to assist in guiding patient management decisions for men with recurrent disease.

“We are excited and honored that Blue Earth Diagnostics has been selected as a finalist from more than 250 candidates for the first Xconomy Awards,” said Michael W. Heslop, President of Blue Earth Diagnostics. “Our company is dedicated to developing and commercializing innovative PET imaging agents that address unmet needs in cancer. This recognition is a result of the ongoing passion, enthusiasm and commitment across the entire company to deliver results for men affected by recurrent prostate cancer. We thank Xconomy and the judges for recognizing Blue Earth Diagnostics and our achievements and we congratulate the other fine organizations that have been named.”

Blue Earth Diagnostics has been recognized by Xconomy on the basis of the significant number of critical milestones it has achieved throughout 2016-2017, including: FDA approval of Axumin; patient enrollment in a clinical study evaluating the impact of PET/CT imaging on patient treatment in recurrent prostate cancer was stopped based on successful results of a pre-planned interim analysis, with results to be presented at an upcoming scientific congress; broad and expanding availability of Axumin across the United States; Marketing Authorization being granted in Europe; and the publication of peer-reviewed manuscripts about Axumin, including Phase 3 clinical trial diagnostic performance and safety results in *The Journal of Urology* and image interpretation results in *The Journal of Nuclear Medicine*.

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 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 is backed by Syncona Limited, a leading FTSE250 company listed on the London Stock Exchange (LON:SYNC) focused on investing in and building global leaders in life sciences. For more information, visit www.blueearthdiagnostics.com.

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