U.S. FDA APPROVES BLUE EARTH DIAGNOSTICS' AXUMINTM (FLUCICLOVINE F 18) INJECTION AFTER PRIORITY REVIEW FOR PET IMAGING OF RECURRENT PROSTATE CANCER

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OXFORD, England and BURLINGTON, Mass., May 31, 2016 – Blue Earth Diagnostics Ltd., a molecular imaging diagnostics company, today announced that the U.S. Food and Drug Administration (FDA) has approved Axumin (fluciclovine F 18) injection, a novel molecular imaging agent indicated for use in positron emission tomography (PET) imaging to identify suspected sites of prostate cancer recurrence in men who have elevated blood levels of prostate specific antigen (PSA) following prior treatment. Axumin is the first FDA-approved F18 PET imaging agent indicated for use in patients with suspected recurrent prostate cancer.

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 who experience biochemical recurrence, approximately one-third develop metastatic prostate cancer. Axumin was developed to target the increased amino acid transport that occurs in many cancers, including prostate cancer. It is labeled with the radioisotope F18, enabling it to be visualized in the body with PET imaging.

"FDA approval of Axumin is a major milestone for Blue Earth Diagnostics, and we hope also for patients and their physicians," said Jonathan Allis, D. Phil., CEO of Blue Earth Diagnostics Ltd. "Axumin is our first approved product and we believe that it will benefit patients who are affected by biochemically recurrent prostate cancer. Axumin will be increasingly available in coming months through the national radiopharmacy network of our exclusive U.S. commercial manufacturer and distributor, Siemens' PETNET Solutions."

"Approximately 180,000 new cases of prostate cancer are expected to be diagnosed in the United States in 2016, and between 20 to 30 percent of patients receiving primary therapy will develop biochemically recurrent disease," said Brian F. Chapin, M.D., Assistant Professor, Department of Urology, The University of Texas MD Anderson Cancer Center. "There is a need for clinical imaging techniques that can detect and localize suspected recurrent prostate cancer to facilitate the most appropriate patient management decision. Current commercially available imaging techniques have some limitations in terms of identifying recurrent tumors, which may impact subsequent patient management decisions. Additionally, many patient care options for men with suspected recurrent prostate cancer have uncertain benefits that may not justify the risk of side effects. New imaging procedures

that can provide reliable information can be useful tools for effective patient management and care."

"An imaging agent with sufficient diagnostic performance to adequately detect and localize recurrent prostate cancer can provide referring physicians with actionable information to guide

biopsy and inform management decisions for their patients," said David M. Schuster, M.D., a Georgia Research Alliance Distinguished Cancer Scientist, Associate Professor of Radiology and Imaging Sciences, and Director of the Division of Nuclear Medicine and Molecular Imaging at Emory University School of Medicine. "The fluciclovine molecule in Axumin was originally developed at Emory by Mark Goodman, Ph.D., and detects the upregulation of amino acid transport that occurs in prostate cancer and can potentially identify recurrent prostate cancer more reliably than conventional imaging techniques. The product will be convenient for patients and imaging facilities, as it can be made widely available and the entire imaging procedure can typically be completed in less than 30 minutes."

The FDA-approved prescribing information provides summaries from two clinical studies of Axumin, including an evaluation of Axumin images from 105 patients by three independent readers who were unaware of the clinical details of each patient or whether the biopsy of the prostate gland was positive or negative for cancer. On average, a correct image finding was identified in 77% of patients (range: 75%-79%). For cancer outside the region of the prostate, a correct image finding for cancer was identified in an average of 90% of patients (range: 88%- 93%). The results seem to be affected by PSA levels with, in general, lower PSA levels in patients with negative scans than in those with positive scans. In patients with PSA levels ≤ 1.78 ng/mL, 15 of 25 had a positive scan, with 11 confirmed as positive by histology; 71 of 74 patients with PSA levels > 1.78 ng/mL had a positive scan, of which 58 were confirmed as positive (see full U.S. prescribing information at www.axumin.com).

Axumin will be commercially available through the national radiopharmacy network of our exclusive U.S. commercial manufacturer and distributor, Siemens' PETNET Solutions. Initial commercial production of Axumin is underway at certain regional radiopharmacies, and increasingly broader availability is planned in coming months.

Both Emory University and inventor Goodman, Professor of Radiology and Imaging Sciences and Director of the Radiopharmaceutical Discovery Lab at Emory, are eligible to receive royalties for this technology.

ABOUT AXUMINTM (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 initial therapy. 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. 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

AxuminTM (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 ≤ 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 PROSTATE / RECURRENT PROSTATE CANCER

Prostate cancer is the second leading cause of cancer death in men. While most primary prostate cancer can be successfully treated, the disease recurs in up to one-third of patients. In some patients recurrent disease is detectable only by a rise in prostate specific antigen (PSA) levels, yet the location of the recurrence cannot consistently be located by conventional imaging, severely limiting treatment guidance for these patients.

ABOUT POSITRON EMISSION TOMOGRAPHY (PET) IMAGING

Positron emission tomography (PET) is an imaging test that uses a special type of scanner in conjunction with a radiolabeled tracer (a molecular imaging agent) to visually examine biochemical processes in the body. PET scan images depict biological function and are complementary with technologies which show anatomical information, such as computed tomography (CT) scans or magnetic resonance imaging (MRI).

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.

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