BLUE EARTH DIAGNOSTICS ANNOUNCES FIRST COMMERCIAL ADMINISTRATIONS OF AXUMINTM (FLUCICLOVINE F 18) BY ATLANTA'S NORTHSIDE HOSPITAL

September 8, 2016

– Recently FDA-Approved F 18 PET Imaging Agent for Patients with Suspected Biochemically Recurrent Prostate Cancer Now Also in Use at Additional Medical Centers –

BURLINGTON, Mass. and OXFORD, England, September 6, 2016 – Blue Earth Diagnostics, a molecular imaging diagnostics company, today announced that the first post-FDA approval, commercial administrations of Axumin™ (fluciclovine F 18) injection occurred recently at Northside Hospital of Atlanta, Ga. 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 was recently approved by the U.S. Food and Drug Administration (FDA) and is the first FDA-approved F-18 PET imaging agent indicated for use in patients with suspected recurrent prostate cancer.

"To date, we have had few imaging tools available for the evaluation of men with biochemically recurrent prostate cancer," said William C. Lavely, M.D., Nuclear Medicine Specialist, Northside Radiology Associates. "The approval of F-18 fluciclovine (Axumin) gives us an effective molecular imaging tool to evaluate these patients and assist clinicians in directing further management. Our initial experience is positive, demonstrating abnormal uptake in locations of potential metastatic prostate cancer. In my opinion, this prostate cancer PET agent, its clinical use for the evaluation of recurrent prostate cancer, and the additional information it provides for developing patient management plans has the potential to lead to better outcomes in men with recurrent prostate cancer. Further studies are necessary to determine these potential benefits."

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.

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 ≤ 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 Northside Hospital (www.northside.com)

The Northside Hospital health care system is an 852-bed, not-for-profit health care provider with more than 150 locations across Georgia, including three acute care, state-of-the-art hospitals in Atlanta, Cherokee County and Forsyth County. Northside Hospital leads the U.S. in newborn deliveries, diagnoses and treats the most cancer cases in Georgia and performs the most robotic surgeries in Georgia. The only Georgia hospital on the *Forbes* list of America's Best Employers, Northside has more than 2,500 physicians and 14,200 employees who serve nearly 2 million patient visits annually across a full range of medical services.

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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