FOR IMMEDIATE RELEASE

Blue Earth Diagnostics Announces Addition of Axumin® (Fluciclovine F 18) to NCCN Guidelines® for PET Imaging for Suspected Recurrent Prostate Cancer

- NCCN Guidelines aim to improve quality, effectiveness and efficiency of cancer care –

BURLINGTON, Mass. and OXFORD, UK – February 20, 2018 – Blue Earth Diagnostics, a molecular imaging diagnostics company, today announced that Axumin (fluciclovine F 18) injection has been added to the National Comprehensive Cancer Network® ("NCCN") Clinical Practice Guidelines in Oncology for Prostate Cancer (Version 1.2018). These updated NCCN Guidelines state that F-18 fluciclovine PET/CT or PET/MRI should be considered in the clinical workup of patients with recurrence or progression of their prostate cancer. This recommendation is based on uniform NCCN consensus that the intervention is appropriate. Axumin is a novel molecular imaging agent indicated for use in 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. It is the first FDA-approved F-18 labeled PET imaging agent indicated in patients with suspected recurrent prostate cancer.

"We are very pleased that Axumin has been added to the NCCN Guidelines, as we believe it further validates its clinical usefulness in patients with recurrent prostate cancer," said Jonathan Allis, D. Phil., CEO of Blue Earth Diagnostics. "Inclusion in these decision-making standards can help facilitate patient access to Axumin, and, in conjunction with our continuing efforts to increase U.S. commercial supply, is part of Blue Earth's commitment to make Axumin widely available for patients and their physicians."

"The NCCN Guidelines are widely used by clinicians and healthcare providers as a benchmark to assess clinical utility, and this update recognizes the important diagnostic ability of PET imaging to detect and localize the sites of recurrence in men with biochemically recurrent prostate cancer," said Gerald L. Andriole, MD, the Robert K. Royce Distinguished Professor and Chief of Urologic Surgery at Washington University School of Medicine in St. Louis. "Many treatment options exist for these men and when PSA levels rise after primary treatment, knowing where the disease has recurred is essential to making appropriate patient management decisions. PET imaging can provide reliable information for these patients."

"Referring physicians need actionable information to guide patient management decisions," said Lale Kostakoglu, MD, MPH, Professor of Radiology and Chief of Nuclear Medicine and Molecular Imaging, Icahn School of Medicine at Mount Sinai, New York, NY. "A PET imaging agent such as Axumin that can reliably detect and localize recurrent prostate cancer is important, due to the limited ability of other currently used imaging procedures to identify the extent and localization of recurrent disease in these patients."

Axumin received Transitional Pass-Through Status in the Hospital Outpatient Prospective Payment System 2017 Final Rule from the Centers for Medicare & Medicaid Services (CMS), effective since January 1, 2017. This also provides a product-specific A-code (A9588) for use with Medicare and private insurer patient claims. Axumin is currently available from 18 radiopharmacies throughout the United States, with additional manufacturing sites planned for 2018.

Prostate cancer is the second leading cause of cancer death in men in the United States. 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.

The National Comprehensive Cancer Network® (NCCN®) is a not-for-profit alliance of 27 of the world's leading cancer centers, working together to development treatment guidelines for most cancers, and dedicated to research that improves the quality, effectiveness and efficiency of cancer care. NCCN offers a number of programs to give clinicians access to tools and knowledge that can help guide decision-making in the management of 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 ≤ 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.

This press release is intended to provide information about Blue Earth Diagnostics' business in the United States. Please be aware that the approval status and product label for Axumin varies by country worldwide. Refer to the individual country product label for complete information or contact Blue Earth Diagnostics.

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 F 18 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 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 approved in the United States and European Union for use in PET imaging to detect and localize prostate cancer in men experiencing suspected biochemical recurrence. Blue Earth Diagnostics is backed by Syncona, an investment company listed on the London Stock Exchange (LON: SYNC). For more information, visit: www.blueearthdiagnostics.com.

Contact:

For Blue Earth Diagnostics (U.S.)
Priscilla Harlan
Vice President, Corporate Communications
(M) (781) 799-7917
p.harlan@blueearthdx.com

Media
Sam Brown Inc.
Mike Beyer
(M) (312) 961-2502
mikebeyer@sambrown.com

For Blue Earth Diagnostics (UK)
Georgina Mowatt
Communications Manager
Tel: +44 (0) 7810 355 912
g.mowatt@blueearthdx.com

# # #