Blue Earth Diagnostics and Siemens' PETNET Solutions Increase Patient Access to Axumin™ (Fluciclovine F 18) Injection PET Imaging Agent for Suspected Recurrent Prostate Cancer

BURLINGTON, Mass. and OXFORD, England February 7, 2017 – Blue Earth Diagnostics, a molecular imaging diagnostics company, and Siemens' PETNET Solutions, a wholly owned subsidiary of Siemens Medical Solutions USA, Inc., announce the increasing number of radiopharmacies offering Blue Earth Diagnostics' Axumin (fluciclovine F 18) PET imaging agent through PETNET's national network. In June 2016, PETNET Solutions began exclusive commercial production and distribution of Axumin at 2 sites in the United States, and additional sites have been rolled out in subsequent months. There are now 12 metropolitan locations in the United States offering Axumin, including the recent addition of sites in Phoenix, Az. and Ft. Lauderdale, Fla., with more sites planned during 2017. Axumin is 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. It is the first FDA-approved F-18 PET imaging agent indicated for use in patients with suspected recurrent prostate cancer.

"Our commitment to increasing the availability of Axumin for patients with biochemically recurrent prostate cancer has been progressing well and according to plan since its FDA approval in May 2016," said Jonathan Allis, D. Phil., CEO of Blue Earth Diagnostics Ltd. "In addition to the scheduled radiopharmacy roll-out, Axumin reader training is available in collaboration with the Society of Nuclear Medicine and Molecular Imaging (SNMMI), and this recently included a live training event at its Mid-Winter Meeting. We are also very pleased that CMS has granted Axumin transitional pass-through payment reimbursement status using a product-specific HCPCS A code (A9588), which became effective January 1, 2017. In conjunction with our exclusive U.S. commercial manufacturer and distributor, PETNET Solutions, we intend to continue expansion of available radiopharmacies in the coming months so that physicians and patients may have more convenient geographic access to the product. Any physician or patient seeking information about where Axumin procedures are offered should call our Medical Information line at 1-855 AXUMIN1 (298-6461); Option 3."

"We are proud to expand the production and distribution of Axumin, increasing the availability of this important imaging agent to patients in the United States," said Barry Scott, head of PETNET Solutions. "Through our broad network of radiopharmacies we are able to increase access to PET tracers, like Axumin, helping healthcare providers to address society's most challenging diseases. Pending U.S. Food and Drug Administration site inspections and approvals, production of Axumin is anticipated to begin at additional PETNET Solutions facilities during 2017, with appropriate locations currently being evaluated to further increase geographic access to the product. We are proud to work with Blue Earth Diagnostics as the exclusive U.S. commercial supplier making Axumin available to imaging centers and their patients."

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 ≤ 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 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 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 Limited, an investment company listed on the London Stock Exchange. For more information, visit www.blueearthdx.com.

About Siemens Healthineers
Siemens Healthineers is the separately managed healthcare business of Siemens AG and enables healthcare providers around the world to meet their current challenges and to excel in their respective environments. A leader in medical technology, Siemens Healthineers is constantly innovating its portfolio of products and services in both its core areas in imaging for diagnostic and therapeutic purposes as well as in laboratory diagnostics and molecular medicine. Siemens Healthineers is also continuously developing its digital health services and hospital management offerings, working closely with operators to develop common fields of business and to help them to not only minimize their risks, but also to exploit new opportunities. In fiscal 2015, which ended on September 30, 2015, Siemens Healthineers generated revenue of €12.9 billion and net income of over €2.1 billion and has about 45,000 employees worldwide. Further information is available on the Internet at www.siemens.com/healthineers.

Contact:

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

Media
Sam Brown Inc.
Cory Tromblee
(M) (617) 571-7220
corytromblee@sambrown.com

For Blue Earth Diagnostics Ltd. (UK)
Dr. Val Jones
Val Jones PR Ltd
(M) +44 (0) 7917 175 192
v.jones@blueearthdx.com

For Siemens Healthineers
Jeff Bell
Sr. Manager, Media Relations
+1 610-448-6348
jeffrey.t.bell@siemens.com

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