BLUE EARTH DIAGNOSTICS AND SIEMENS' PETNET SOLUTIONS ANNOUNCE COMMERCIAL AVAILABILITY OF AXUMIN™ (FLUCICLOVINE F 18) INJECTION FOR PET IMAGING OF RECURRENT PROSTATE CANCER

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Blue Earth Diagnostics and Siemens' PETNET Solutions Announce Commercial Availability of Axumin™ (Fluciclovine F 18) Injection for PET Imaging of Recurrent Prostate Cancer

BURLINGTON, Mass., OXFORD, England & Malvern, Pa. June 7, 2016 – Blue Earth Diagnostics Ltd., a molecular imaging diagnostics company, and Siemens' PETNET Solutions, Inc., a wholly-owned subsidiary of Siemens Medical Solutions USA, Inc. today announced the commercial availability of Axumin (fluciclovine F 18) injection in the United States. 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. Axumin was approved by the U.S. Food and Drug Administration on May 27, 2016, and is the first FDAapproved F-18 PET imaging agent indicated for use in patients with suspected recurrent prostate cancer.

Axumin will be commercially available this month through Blue Earth Diagnostics' manufacturer and exclusive distributor in the United States, Siemens' PETNET Solutions. Initial commercial production of Axumin will be underway at certain Siemens' PETNET Solutions radiopharmacies, with increasingly broader availability planned in the coming months.

"We are tremendously pleased with FDA's recent approval of Axumin for suspected biochemically recurrent prostate cancer, and hope that this will make a real difference to patients and their physicians," said Jonathan Allis, D. Phil., CEO of Blue Earth Diagnostics Ltd. "Blue Earth Diagnostics is extremely pleased to be working with Siemens' PETNET Solutions, the leading supplier of PET radiopharmaceuticals in the United States; we both share a passion for PET molecular imaging, and for providing imaging tools to improve patient management."

"This is a significant milestone for the PET industry, as this is the first proprietary F-18 labeled agent for an oncology indication approved by the FDA. And, being F-18 labeled enables efficient distribution and wide patient access," said Barry Scott, head of Siemens' 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. We are proud to work with Blue Earth Diagnostics as the U.S. commercial supplier making Axumin available to imaging centers and their patients."

Blue Earth Diagnostics and Siemens' PETNET Solutions welcome visitors to the upcoming SNMMI meeting to visit their exhibit booths. Blue Earth Diagnostics is at Booth 337; Siemens' PETNET Solutions is at Booth 431.

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 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 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

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 <u>www.fda.gov/medwatch.</u>

Full Axumin prescribing information is available at: www.axumin.com.

About Prostate Cancer/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 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 F18), 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: <u>www.blueearthdx.com</u>.

About Siemens AG

Siemens AG (Berlin and Munich) is a global technology powerhouse that has stood for engineering excellence, innovation, quality, reliability and internationality for more than 165 years. The company is active in more than 200 countries, focusing on the areas of electrification, automation and digitalization. One of the world's largest producers of energyefficient, resource-saving technologies, Siemens is No. 1 in offshore wind turbine construction, a leading supplier of gas and steam turbines for power generation, a major provider of power transmission solutions and a pioneer in infrastructure solutions as well as automation, drive and software solutions for industry. The company is also a leading provider of medical imaging equipment – such as computed tomography and magnetic resonance imaging systems – and a leader in laboratory diagnostics as well as clinical IT. In fiscal 2015, which ended on September 30, 2015, Siemens generated revenue of €75.6 billion and net income of €7.4 billion. At the end of September 2015, the company had around 348,000 employees worldwide. Further information is available on the Internet at <u>www.siemens.com</u>.

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