BLUE EARTH DIAGNOSTICS AND GE HEALTHCARE SIGN UK MANUFACTURING AGREEMENT
October 2, 2017

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*Agreement marks first step towards full commercial availability of Axumin® (*fluciclovine*(18F)) in the UK*

Oxford, UK – October 2, 2017 – Blue Earth Diagnostics, a molecular imaging diagnostics company, and GE Healthcare (NYSE:GE) today announced that they have signed an agreement to establish the manufacturing of Blue Earth Diagnostics' positron emission tomography (PET) imaging product Axumin® (fluciclovine (18F)) in the UK.

Following receipt of marketing authorization for Axumin from the European Commission in May 2017, Blue Earth Diagnostics is working to build a network of authorized and approved manufacturing locations across Europe. The agreement with GE Healthcare marks the first step towards full commercial availability of Axumin to PET imaging centres in the UK. The company recently announced manufacturing and distribution agreements for Axumin in France, Germany, Ireland, Italy, Portugal and Spain.

Axumin is indicated in Europe for use in PET imaging to detect recurrence of prostate cancer in adult men with a suspected recurrence based on elevated prostate specific antigen (PSA) levels after primary curative treatment*. Prostate cancer is the most common cancer in the United Kingdom for men, with 46,690 new cases diagnosed each year1. 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 PSA levels, but often the location of the recurrence cannot consistently be located by conventional imaging, limiting treatment guidance. Axumin was developed to target the increased amino acid transport that occurs in many cancers, including prostate cancer. It is labelled with the radioisotope (18F), enabling it to be visualized in the body with PET imaging.

Jonathan Allis, Chief Executive Officer of Blue Earth Diagnostics said, "This agreement with GE Healthcare marks the first step towards full commercial availability of Axumin in the UK. Detection and localization of recurrent prostate cancer is a significant unmet medical need, and Blue Earth Diagnostics is committed to making Axumin accessible to clinicians and their patients across Europe. Today's announcement is another step towards that goal, and we look forward to working with the team at GE."

"We are thrilled to support Blue Earth Diagnostics in their mission to improve prostate cancer care for patients in the UK", said Kevin O'Neill, General Manager of Core Imaging for GE

Healthcare Life Sciences. “We are very excited to contribute to this project with the expertise, quality and reliability of GE Healthcare’s PET production capabilities in the UK.”

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

1. Data from Cancer Research UK [http://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/prostate-cancer/incidence#heading-Zero] downloaded 25 July 2017

*This press release is intended to provide information about Blue Earth Diagnostics’ business in Europe. 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.

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ABBREVIATED PRESCRIBING INFORMATION FOR AXUMIN IN EUROPE

Axumin 1600 MBq/ml solution for injection/ Axumin 3200 MBq/ml solution for injection (fluciclovine, ^{18}F)

Indication: Axumin is indicated for Positron Emission Tomography (PET) imaging to detect recurrence of prostate cancer in adult men with a suspected recurrence based on elevated blood prostate specific antigen (PSA) levels after primary curative treatment.

Dosage: 370 MBq fluciclovine (18F)

Method of use: Diagnostic use only. I.V. administration. Refer to SmPC for dilution instructions prior to dosing and information on image acquisition.

Contraindications: Patients with hypersensitivity to active substance or excipients.

Common Adverse Reactions (reported in ≥ 1/100 to < 1/10 patients): Injection site reactions, dysgeusia and parosmia.

Special Warnings and Precautions: Individual benefit/risk justification: Radiation exposure of patient must be justifiable by likely benefit. Consider possible increased radiation exposure risk in patients with renal impairment. PSA value may affect the diagnostic performance. Patient preparation: Patients should avoid exercise for at least a day before and not eat or drink for at least 4 hours prior to administration. Afterwards, encourage patients to drink water and void as often as possible during first hours to reduce radiation exposure of the bladder. Restrict close contact with infants and pregnant women for 12 hours after administration.
Interpretation of fluciclovine (18F) images and limitations of use: Images should be interpreted visually by appropriately trained personnel. Suspicion of cancer is based on fluciclovine (18F) uptake in comparison with tissue background. For small lesions (<1 cm diameter) focal uptake greater than blood pool should be considered suspicious for cancer. For larger lesions, uptake equal to or greater than bone marrow is considered suspicious for cancer. Image interpretation errors can occur; fluciclovine (18F) uptake is not specific for prostate cancer and may occur with other types of cancer, prostatitis and benign prostatic hyperplasia. False-positive cases have been described with inflammatory response after cryotherapy and radiation artefacts in patients previously treated with radiotherapy. Clinical correlation, which may include histopathological evaluation, should be considered where appropriate. Iodinated CT contrast or oral contrast media is not required to interpret images. Detection of prostate cancer recurrence in prostate/prostate bed, regional lymph nodes, bone, soft tissue and non-regional lymph nodes by fluciclovine (18F) PET has been reported.

Specific warnings: Contains up to 39 mg sodium per dose; to be taken into consideration by patients on a controlled sodium diet. Not indicated for use in women or children.

MA Number: EU/1/17/1186/001-002

MA Holder: Blue Earth Diagnostics Ltd, 215 Euston Road, London, NW1 2BE UK.

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