Blue Earth Diagnostics receives marketing authorisation for Axumin™ (Fluciclovine (^{18}F)) for PET imaging of recurrent prostate cancer

OXFORD, UK. - May 23, 2017 – Blue Earth Diagnostics, a molecular imaging diagnostics company, announced today that the European Commission has granted marketing authorisation for Axumin™ (fluciclovine (^{18}F)) use in 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. Axumin is the first and only PET imaging agent indicated for use in men with suspected recurrent prostate cancer in all European Union member states as well as in Iceland, Liechtenstein and Norway.

Dr Jonathan Allis, CEO, Blue Earth Diagnostics said, "We are delighted by the European Commission's marketing authorisation for Axumin, which is a major milestone for Blue Earth Diagnostics and underlines our commitment to develop innovative molecular imaging agents that inform and guide treatment decisions for physicians and their patients. Axumin is our first approved product in Europe and we believe that it will benefit men with biochemically recurrent prostate cancer. We are now in discussions with potential manufacturing and distribution associates to make Axumin commercially available across Europe."

Prostate cancer is the most common cancer in Europe for men, with around 343,000 new cases diagnosed each year[1]. 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 (^{18}F), enabling it to be visualized in the body with PET imaging.

Initially, Axumin will be commercially available in Europe in Norway, with roll-out to additional countries planned in 2018.

The Marketing Authorisation Application for Axumin was submitted to the EMA in December 2015 and was approved on 22 May 2017.

1. http://eco.iarc.fr/EUCAN/CancerOne.aspx?Cancer=29&Gender=1

ABOUT AXUMIN™ (FLUCICLOVINE (^{18}F))
Axumin (fluciclovine (^{18}F)) 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 labelled with the radioisotope (^{18}F) for PET imaging. Fluciclovine (^{18}F) was invented at Emory

University in Atlanta, Ga., USA, with much of the fundamental clinical development work carried out by physicians at Emory University's Department of Radiology and Imaging Sciences. Axumin is the first product commercialized by Blue Earth Diagnostics, which licensed the product from GE Healthcare.

ABOUT POSITRON EMISSION TOMOGRAPHY (PET) IMAGING
Positron emission tomography (PET) is an imaging test that uses a special type of scanner in conjunction with a radiolabeled tracer (a molecular imaging agent) to visually examine biochemical processes in the body. PET scan images depict biological function and are complementary with technologies which show anatomical information, such as computed tomography (CT) scans or magnetic resonance imaging (MRI).

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 funded by Syncona, an investment company listed on the London Stock Exchange (LON: SYNC). For more information, visit: www.blueearthdiagnostics.com.

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ABBREVIATED PRESCRIBING INFORMATION

▼**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 (^{18}F)

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 paraosmia.

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 (^{18}F) 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 (^{18}F) 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 (^{18}F) 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.

POM

Date of Preparation: **May 2017**