BLUE EARTH DIAGNOSTICS APPOINTS M2I TO MANUFACTURE AND DISTRIBUTE AXUMIN™ IN IRELAND

July 27, 2017

Oxford, UK –July 27, 2017 – Blue Earth Diagnostics, a molecular imaging diagnostics company and M2i, a manufacturer of Positron Emission Tomography (PET) imaging agents, today announced that they have entered into an exclusive manufacturing and distribution agreement for the supply of Blue Earth Diagnostics' PET imaging product Axumin™ (fluciclovine (^{18}F)) in Ireland. M2i, through their Dublin PET manufacturing site, will bring Axumin to market in the Republic of Ireland and in Northern Ireland.

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 blood prostate specific antigen (PSA) levels after primary curative treatment*. Prostate cancer is the second most common cancer in Ireland for men, with around 3,200 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.

Axumin is the first and only PET imaging agent approved by the European Commission for use in men with suspected recurrent prostate cancer in all European Union member states as well as in Iceland, Liechtenstein and Norway. Following receipt of marketing authorization for Axumin from the European Commission on May 22, 2017, Blue Earth Diagnostics is working to build a network of authorized and approved manufacturing locations across Europe. In June 2017, Blue Earth Diagnostics announced it had appointed AAA as a manufacturer and exclusive distributor for Axumin in France, Germany, Italy, Portugal and Spain.

Jonathan Allis, Chief Executive Officer of Blue Earth Diagnostics said, "Detection and localization of recurrent prostate cancer is a significant unmet medical need, and Blue Earth Diagnostics is committed to maximizing access to Axumin for clinicians and their patients across Europe. This agreement is a key milestone in building our European manufacturing and distribution network for Axumin, and we look forward to working with the team at M2i."

Ruairi O'Donnell, Managing Director of M2i said, "This is a very exciting development for the management of prostate cancer patients in Ireland and we look forward to growing the utilisation of PET in the Irish healthcare system".

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

About M2i

M2i, an independent privately owned Irish company, produces radiopharmaceuticals for use in Positron Emission Tomography (PET) imaging. Its manufacturing facility located in Dublin is fully licenced by the HPRA (Health Products Regulatory Authority) and has been supplying PET products to imaging centres across all geographical regions of Ireland since 2001. It is committed to the highest quality standards and strives to maintain an uptime performance that is second to none across Europe. For more information please go to www.m2i.ie.

1. Data from Irish Cancer Society [https://www.cancer.ie/about-us/media-centre/cancer-statistics/most-common-cancers#sthash.INweEQH5.JG3dLFpq.dpbs] downloaded 20 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 (^{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 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 (^{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.