

BLUE EARTH DIAGNOSTICS SHORTLISTED FOR “BEST EMERGING MEDTECH COMPANY” AWARD

August 11, 2017

Oxford, UK – August 11, 2017 – [Blue Earth Diagnostics](#), a molecular imaging diagnostics company, today announced that it has been shortlisted as a finalist in the 2017 [OBN](#) awards in the category “Best Emerging Medtech Company”. These prestigious awards, which are judged by a panel of leading industry entrepreneurs and experts, celebrate innovation and outstanding achievement across the UK’s Life Sciences industry. The OBN’s “Best Emerging Medtech Company” award goes to a company which is between two and five years old, which has raised significant growth capital and which is developing innovative, disruptive and novel products. The winner will show evidence of commercial planning and progress.

Blue Earth Diagnostics, which was formed in 2014, is focused on the development and commercialization of novel positron emission tomography (PET) imaging agents to inform clinical management and guide care for patients with cancer. The company, which has its headquarters in Oxford, UK, and a US office in Burlington, MA, is led by a team of recognized experts in the clinical development and commercialization of innovative nuclear medicine products. Blue Earth Diagnostics’ PET imaging product Axumin™ (fluciclovine (¹⁸F)) 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*. 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.

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 building a network of authorized and approved manufacturing locations across Europe.

Dr. Jonathan Allis, the founding CEO of Blue Earth Diagnostics commented, “We’re delighted to receive the industry-wide recognition that being shortlisted for this prestigious award brings. We’re on a mission to help improve the lives of people with cancer by developing and bringing to market innovative imaging agents that both inform and guide patient

care. Receiving this nomination is both an honour for our whole team and a great endorsement of Blue Earth's progress over the last three years."

Dr John Harris, CEO of OBN (UK) said, "We received a high number of entries in the Best Emerging Medtech category and the standard of entries was consistently high. Blue Earth Diagnostics and all of the finalists are proof of the excellent innovation we are seeing in the medtech industry at this time, and we look forward to celebrating with all our finalists on 5th October at the Oxford Town Hall."

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, a leading FTSE250 company listed on the London Stock Exchange (LON:SYNC) focused on investing in and building global leaders in life sciences. For more information, visit: www.blueearthdiagnostics.com.

About OBN

The OBN is the membership organisation supporting and bringing together the UK's emerging life sciences companies, corporate partners and investors. Our 360-plus Member companies are located across the Golden Triangle and beyond to Nottingham, Manchester and Scotland benefiting from our networking, partnering, purchasing, advising and advocacy activities. For more information please visit: www.obn.org.uk.

*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, (¹⁸F))

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 $\geq 1/100$ 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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