

Blue Earth Diagnostics receives positive CHMP opinion for Axumin™ (Fluciclovine (¹⁸F)) for PET imaging of recurrent prostate cancer

OXFORD, UK. - March 24, 2017 – [Blue Earth Diagnostics](#), a molecular imaging diagnostics company, today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency has adopted a positive opinion recommending that Axumin™ (fluciclovine (¹⁸F)) is granted marketing authorization in the European Union. The recommendation is for Axumin 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. The CHMP's positive opinion will now be reviewed by the European Commission. If approved, Axumin will be 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.

Prostate cancer is the most common cancer in Europe for men, with around 343,000 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.

“The CHMP's positive recommendation for Axumin is a major advance in Blue Earth's commitment to providing a readily available PET imaging agent to detect and localize suspected biochemically recurrent prostate cancer for the thousands of men in Europe affected by this disease,” said Dr. Jonathan Allis, CEO, Blue Earth Diagnostics. “Information provided by an Axumin PET scan can help physicians localize disease, which may assist treatment decisions. We now look forward to working with our commercial manufacturing and distribution associates to be ready to make Axumin widely available to doctors and their patients across Europe.”

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

ABOUT AXUMIN™ (FLUCICLOVINE (¹⁸F))

Axumin (fluciclovine (¹⁸F)) 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 (¹⁸F) for PET imaging. Fluciclovine (¹⁸F) 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. The molecule is being investigated by Blue Earth Diagnostics for other potential cancer indications, such as glioma.

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 (¹⁸F)), a novel molecular imaging agent approved in the United States 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.

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