

PRESS RELEASE

Axumin▼[®] (fluciclovine (¹⁸F)) receives positive recommendation from Transparency Committee of the French HAS, for use in PET imaging of suspected recurrent prostate cancer

Oxford, UK – October 2, 2018 – [Blue Earth Diagnostics](#), a leading molecular imaging diagnostics company, today announced that the Transparency Committee of the French Haute Autorité de Santé (HAS) has recommended that Axumin[®] (fluciclovine (¹⁸F)) is included on the list of medicines approved in France for hospital use, in line with its European indication. Axumin is a novel molecular imaging agent approved in the European Union for use in PET imaging to detect and localize prostate cancer in men experiencing suspected recurrence based on elevated blood prostate specific antigen (PSA) levels after primary curative treatment. The positive recommendation marks a further milestone in the roll-out of Axumin across Europe, following receipt of Marketing Authorisation from the European Commission in May 22, 2017.

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. Blue Earth Diagnostics is working to build a network of authorized and approved manufacturing locations across Europe. The company now has six European manufacturing and distribution agreements for Axumin in place, covering seventeen countries. Axumin is already commercially available in Norway, the Czech Republic, The Netherlands, United Kingdom and Austria with further European countries set to follow soon.

Jonathan Allis, Chief Executive Officer of Blue Earth Diagnostics said, “We’re delighted to announce another significant step towards our mission of making Axumin commercially available to clinicians and their patients across Europe. Detection and localization of recurrent prostate cancer is a significant unmet medical need, and Blue Earth Diagnostics is committed to maximizing access to Axumin across Europe.”

About Blue Earth Diagnostics

Blue Earth Diagnostics is a leading 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 with a diagnosis of biochemical recurrence. The company’s pipeline includes Prostate Specific Membrane Antigen (PSMA)-targeted radiohybrid (“rh”) agents. rhPSMA is a clinical-stage, investigational class of theranostic compounds, with potential applications in both the imaging and treatment of prostate cancer. Blue Earth Diagnostics is backed by Syncona, an investment company listed on the London Stock Exchange (LON: SYNC). For more information, visit: www.blueearthdiagnostics.com.

This press release is intended to provide information about Blue Earth Diagnostics' business in Europe. The approval status and product label for Axumin varies by country worldwide. Refer to the individual country product label at

www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004197/human_med_002100.jsp&mid=WC0b01ac058001d124 for complete information or contact [Blue Earth Diagnostics](#).

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