

### **PRESS RELEASE**

# Blue Earth Diagnostics continues to expand access to Axumin® (fluciclovine (18F)) in Europe

Oxford, UK – May 9, 2019 – <u>Blue Earth Diagnostics</u>, a leading molecular imaging diagnostics company, today announced expanded access to Axumin® (fluciclovine (<sup>18</sup>F)) in Europe. The first commercial production of Axumin in Belgium occurred recently, with the first Belgian patients being dosed. This follows the first administration of Axumin in Luxembourg earlier this year. Axumin is the first and only PET imaging agent approved in the European Union for use in in men with suspected recurrent prostate cancer. Axumin is commercially available in Belgium, Luxembourg, Italy, France, Norway, the Czech Republic, The Netherlands, United Kingdom and Austria with further European countries set to follow soon.

Prostate cancer is a leading cause of cancer death in men. While most primary prostate cancer can be successfully treated, recurrence occurs in up to one-third of patients. Recurrent disease is typically detected by a rise in PSA levels but often the location and extent of the disease cannot be detected by conventional imaging. Of those who suffer biochemical recurrence, approximately one-third develop metastatic prostate cancer. Axumin was developed to target the increased amino acid transport that occurs in many cancers, including prostate cancer. It is labelled with the radioisotope (<sup>18</sup>F), enabling it to be visualized in the body with PET imaging.

Dr. Jonathan Allis, Chief Executive Officer of Blue Earth Diagnostics said, "Detection and localization of recurrent prostate cancer is a significant unmet medical need, and we're delighted to announce another significant step in our mission of making Axumin commercially available to clinicians and their patients 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, a healthcare 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 <a href="https://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004197/human\_med\_002100.jsp&mid=WC0b01ac058001d124">www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004197/human\_med\_002100.jsp&mid=WC0b01ac058001d124</a> for complete information or contact <a href="https://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004197/human\_med\_002100.jsp&mid=WC0b01ac058001d124</a> for complete information or contact <a href="https://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/

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