First production and administration of Axumin® (fluciclovine (^{18}F)) in Italy.

Oxford, UK – February 12, 2019 – Blue Earth Diagnostics, a leading molecular imaging diagnostics company, today announced that the first commercial production of Axumin® (fluciclovine (^{18}F)) in Italy occurred recently, with the first Italian patients being dosed. 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. 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. Axumin is commercially available in 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 (^{18}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 Blue Earth is committed to maximizing access to Axumin to clinicians and their patients across Europe. Today’s announcement is key milestone towards our goal.”

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.

Contacts:

Blue Earth Diagnostics (Europe)
Georgina Mowatt
Communications Manager

Tel: +44 (0) 7810 355 912
g.mowatt@blueearthdx.com

Media inquiries:

Sam Brown Inc. (for Blue Earth Diagnostics)
Mike Beyer
Tel: +1 312-961-2502
mikebeyer@sambrown.com