

## **BLUE EARTH DIAGNOSTICS AND PETNET SOLUTIONS ANNOUNCE NEW COMMERCIAL SUPPLY AGREEMENT FOR AXUMIN® (FLUCICLOVINE F 18) AND INVESTIGATIONAL RHPSMA-7.3 (18F) PROSTATE CANCER IMAGING AGENT**

June 16, 2020

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**Oxford, UK, BURLINGTON, Mass., June 16, 2020** – Blue Earth Diagnostics, a Bracco company focused on molecular imaging diagnostics, and PETNET Solutions Inc., a Siemens Healthineers company specializing in the manufacturing and distribution of positron emission tomography (PET) radiopharmaceuticals, today announced the signing of a commercial manufacturing and distribution agreement. Under the new multi-year agreement, PETNET will expand production and continue distribution of Axumin as well as commercially manufacture and distribute Blue Earth Diagnostics' investigational radiohybrid Prostate-Specific Membrane Antigen-targeted agent, rhPSMA-7.3 (<sup>18</sup>F), pending its successful development and potential FDA approval. PETNET is currently a supplier of rhPSMA-7.3 (<sup>18</sup>F) for Blue Earth Diagnostics' Phase 3 rhPSMA-7.3 (<sup>18</sup>F) clinical trials in newly diagnosed and recurrent prostate cancer (LIGHTHOUSE [NCT04186819](#) and SPOTLIGHT [NCT04186845](#), respectively). Axumin is a novel molecular imaging agent indicated for use in positron emission tomography (PET) imaging to identify suspected sites of prostate cancer recurrence in men who have elevated blood levels of prostate specific antigen (PSA) following prior treatment.

“We are pleased to work in conjunction with PETNET Solutions, the leading supplier of PET radiopharmaceuticals in the United States, to continue to expand Axumin production and distribution in the United States,” said Jonathan Allis, D. Phil., CEO of Blue Earth Diagnostics. “Axumin launched as the first FDA-approved <sup>18</sup>F imaging agent for recurrent prostate cancer in 2016, and is now available at more than 1,100 imaging centers across the United States. Based on Blue Earth Diagnostics' success in using its extensive radiopharmacy network for U.S. Axumin production and distribution, we chose PETNET as a clinical trial manufacturer of rhPSMA-7.3 (<sup>18</sup>F) for our Phase 3 clinical trials. Under this new agreement, PETNET will also provide commercial production and distribution of rhPSMA-7.3 (<sup>18</sup>F) pending its successful development and potential FDA approval. We believe that the complementary mechanisms of action of Axumin and rhPSMA-7.3 (<sup>18</sup>F) may ultimately allow physicians and their patients flexibility in selecting the diagnostic agent most appropriate to each specific clinical situation. The new agreement expands Axumin production in 2021, so that physicians and patients may have more convenient access to the product.”

“We are proud to continue working with Blue Earth Diagnostics as the U.S. commercial supplier in making Axumin available to imaging centers and their patients, and we are pleased that PETNET Solutions has been selected to manufacture and distribute rhPSMA-7.3

(<sup>18</sup>F),” said Barry Scott, Head of PETNET Solutions Inc. “PETNET’s broad national network of radiopharmacies enables us to increase access to <sup>18</sup>F PET radiopharmaceuticals to help healthcare providers address society’s most challenging diseases.”

### **About Axumin® (fluciclovine F 18)**

Axumin® (fluciclovine F 18) 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 labeled with the radioisotope F 18 for PET imaging. Fluciclovine F 18 was invented at Emory University in Atlanta, Ga., with much of the fundamental clinical development work carried out by physicians at Emory University’s Department of Radiology and Imaging Sciences. Axumin was approved by the U.S. Food and Drug Administration in May 2016, following Priority Review, and 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 including neuro-oncology.

### **About rhPSMA**

rhPSMA-7.3 (<sup>18</sup>F) is an investigational imaging agent that consists of a radiohybrid Prostate-Specific Membrane Antigen (PSMA)-targeted receptor ligand which attaches to and is internalized by prostate cancer cells, and is labeled with the <sup>18</sup>F radioisotope for PET imaging. rhPSMA compounds can also be labeled with radioisotopes such as <sup>177</sup>Lu and <sup>225</sup>Ac for therapeutic use. Blue Earth Diagnostics acquired exclusive, worldwide rights to rhPSMA imaging technology from Scintomics in 2018, with an option to therapeutic rights. rhPSMA originated from the Technical University of Munich, Germany, and has been utilized clinically under German legislation at the Department of Nuclear Medicine there for the diagnostic imaging of men with both primary and recurrent prostate cancer. rhPSMA compounds have not received regulatory approval.

NOTE: Axumin® (fluciclovine F 18) injection is FDA-approved for positron emission tomography (PET) imaging in men with suspected prostate cancer recurrence based on elevated blood prostate specific antigen (PSA) levels following prior treatment.

This press release is intended to provide information about Blue Earth Diagnostics’ business in the United States and Europe. Please be aware that the approval status and product label for Axumin varies by country worldwide. For EU Axumin product information refer

to: [http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004197/human\\_med\\_002100.jsp&mid=WC0b01ac058001d124](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004197/human_med_002100.jsp&mid=WC0b01ac058001d124).

## **U.S. Indication and Important Safety Information about Axumin**

### **INDICATION**

Axumin® (fluciclovine F 18) injection is indicated for positron emission tomography (PET) imaging in men with suspected prostate cancer recurrence based on elevated blood prostate specific antigen (PSA) levels following prior treatment.

### **IMPORTANT SAFETY INFORMATION**

- Image interpretation errors can occur with Axumin PET imaging. A negative image does not rule out recurrent prostate cancer and a positive image does not confirm its presence. The performance of Axumin seems to be affected by PSA levels. Axumin uptake may occur with other cancers and benign prostatic hypertrophy in primary prostate cancer. Clinical correlation, which may include histopathological evaluation, is recommended.
- Hypersensitivity reactions, including anaphylaxis, may occur in patients who receive Axumin. Emergency resuscitation equipment and personnel should be immediately available.
- Axumin use contributes to a patient's overall long-term cumulative radiation exposure, which is associated with an increased risk of cancer. Safe handling practices should be used to minimize radiation exposure to the patient and health care providers.
- Adverse reactions were reported in  $\leq 1\%$  of subjects during clinical studies with Axumin. The most common adverse reactions were injection site pain, injection site erythema and dysgeusia.

To report suspected adverse reactions to Axumin, call 1-855-AXUMIN1 (1-855-298-6461) or contact FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

**Full U.S. Axumin prescribing information is available at [www.axumin.com](http://www.axumin.com).**

### **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. Fluciclovine F 18 has a broad range of other potential applications in cancer imaging and Blue Earth Diagnostics is investigating the molecule for other cancers including in neuro-oncology. The company's pipeline includes innovative Prostate-Specific Membrane Antigen (PSMA)-targeted radiohybrid ("rh") agents, which are a clinical-stage, investigational class of theranostic compounds, with potential applications in both the imaging and treatment of prostate cancer. Blue Earth Diagnostics is a subsidiary of Bracco Imaging S.p.A., a global leader in diagnostic imaging. For more information, visit: [www.blueearthdiagnostics.com](http://www.blueearthdiagnostics.com).

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