



Blue Earth Diagnostics to be Acquired by Global Leader Bracco Imaging

- Blue Earth Diagnostics to become a subsidiary of Bracco Imaging; retains name and management team –*
- Acquisition driven by lead product Axumin® (fluciclovine F 18), a novel molecular imaging agent for use with PET imaging to detect recurrent prostate cancer, and a robust pipeline –*
- Combined business will leverage Bracco’s diagnostic modalities, global competencies, portfolio and financial resources –*

BURLINGTON, Mass. and OXFORD, UK, June 27, 2019 – Blue Earth Diagnostics, a molecular imaging diagnostics company, today announced that a definitive agreement has been signed for Bracco Imaging S.p.A. to acquire all outstanding shares of privately-held Blue Earth Diagnostics from leading healthcare company Syncona for \$450 million (£354.3 million) plus closing adjustment estimated at \$25 million (£19.7 million)¹. Upon closing of the transaction, Blue Earth Diagnostics will be a subsidiary of Bracco Imaging, led by its current leadership team and will retain the well-established Blue Earth Diagnostics name. Bracco Imaging is a leader in the diagnostic imaging business with an integrated product offering from a diverse roster of subsidiary companies.

“The acquisition of Blue Earth Diagnostics by Bracco Imaging is a validation of the quality of our people, our pipeline of novel diagnostic agents such as rhPSMA and the proven success of Axumin for imaging in prostate cancer and potentially other future indications,” said Jonathan Allis, D.Phil., chief executive officer, Blue Earth Diagnostics. “We believe this acquisition is excellent for Blue Earth as Bracco Imaging’s global footprint and clinical research and marketing support will enable us to expand the reach of our high-value platform of innovative radiopharmaceuticals to inform clinical management and guide care for even more people with cancer around the world.”

Blue Earth Diagnostics’ first commercialized product, Axumin® (fluciclovine F 18) injection is a novel molecular imaging agent approved in the United States and the European Union for use in PET imaging for men with suspected recurrent prostate cancer. Axumin is widely available and used across the United States, with more than 50,000 doses administered to date. ¹⁸F-Fluciclovine has a broad range of other potential applications in cancer imaging and Blue Earth Diagnostics is investigating the molecule for utility in other cancers, including in neuro-oncology.

In April 2018, Blue Earth Diagnostics expanded its prostate cancer portfolio through the acquisition of exclusive, worldwide rights to a broad family of Prostate Specific Membrane Antigen (PSMA)-targeted radiohybrid (“rh”) agents for cancer. 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’ innovative products and pipeline will significantly enhance Bracco Imaging’s portfolio in precision medicine and personalized diagnostics, while expanding our range of nuclear oncology imaging solutions in the Urology segment and other specialties,” said Fulvio Renoldi Bracco, Chief Executive Officer, Bracco Imaging. “We are thrilled to welcome to Bracco this world class team with exceptional product development and commercialization expertise.”

“We are so proud of our exceptional, patient-focused team for building a successful radiopharmaceuticals business in only five years. This acquisition provides us the tremendous opportunity to grow and expand Axumin, and our innovative pipeline, geographically and into other therapeutic targets,” added Dr. Allis. “We also wish to acknowledge Syncona for its role in the foundation of the company, and its operational and financial acumen as we have built the business.”

About Bracco Imaging

Bracco Imaging S.p.A., part of the Bracco Group, is one of the world’s leading companies in the diagnostic imaging business with 2018 revenues exceeding 1B Euros. Headquartered in Milan, Italy, Bracco Imaging develops, manufactures and markets diagnostic imaging agents and solutions.

Bracco Imaging offers a product and solution portfolio for all key diagnostic imaging modalities: X-ray Imaging (including Computed Tomography-CT, Interventional Radiology, and Cardiac Catheterization), Magnetic Resonance Imaging (MRI), Contrast Enhanced Ultrasound (CEUS), and Nuclear Medicine through radioactive tracers. The diagnostic imaging portfolio is completed by a range of medical devices and advanced administration systems for contrast imaging products.

The Company operates in over 100 markets worldwide, either directly or indirectly, through subsidiaries, joint ventures, licenses and distribution partnership agreements. Bracco Imaging has a strong presence in key geographies: North America, China, Europe, Japan, Brazil, Mexico and South Korea.

Bracco Imaging’s manufacturing plants operate in full compliance with the best practices and with sustainable eco-friendly production processes. Manufacturing sites are located in Italy, Switzerland, Germany, Canada, China and Japan.

Bracco Imaging has a well skilled and an innovative Research and Development (R&D) organization with an efficient process-oriented approach and a track record in the diagnostic imaging industry. R&D activities are located in three centers based in Italy, Switzerland and USA.

To learn more about Bracco Imaging, visit www.braccoimaging.com.

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.

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 ≤ 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.

Full Axumin prescribing information is available at www.Axumin.com.

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, such as glioma.

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.

FOOTNOTE:

¹ Foreign exchange rates at 26 June 2019

Contact:

For Blue Earth Diagnostics (U.S.)

Priscilla Harlan
Vice President, Corporate Communications
(M) (781) 799-7917

Media

Sam Brown Inc.
Mike Beyer
(M) (312) 961-2502

p.harlan@blueearthdx.com

mikebeyer@sambrown.com

For Blue Earth Diagnostics (UK)

Georgina Mowatt

Communications Manager

Tel: +44 (0) 7810 355 912

g.mowatt@blueearthdx.com

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