

Blue Earth Diagnostics Acquires Exclusive, Worldwide Rights to Therapeutic Applications of Scintomics' Radiohybrid Prostate-Specific Membrane Antigen (rhPSMA) Technology for Prostate Cancer

- Expanded oncology portfolio includes comprehensive prostate cancer franchise to address patient management across the care continuum –*
- Agreement builds on Blue Earth Diagnostics' established leadership position in rapid development and commercialization of PET radiopharmaceuticals –*
- Theranostic rhPSMA radiopharmaceuticals have potential utility in both diagnostic imaging and therapy of prostate cancer –*

OXFORD, UK and BURLINGTON, Mass., January 5, 2021 – [Blue Earth Diagnostics](#), a Bracco company and recognized leader in the development and commercialization of innovative PET radiopharmaceuticals, today announced that it has signed an exclusive, worldwide agreement with [Scintomics GmbH](#), Germany, a specialist in radiopharmaceuticals and radiopharmaceutical technologies, and the Technical University of Munich (TUM). Under terms of the agreement, Blue Earth Diagnostics has exercised an option to acquire exclusive, worldwide rights to therapeutic applications of novel radiohybrid Prostate-Specific Membrane Antigen (rhPSMA) technology in prostate cancer. Blue Earth previously acquired exclusive rights to rhPSMA imaging technology in 2018 and now has two investigational Phase 3 clinical trials underway to investigate the use of lead candidate ¹⁸F-rhPSMA-7.3 for PET imaging in prostate cancer (“LIGHTHOUSE,” [NCT04186819](#) and “SPOTLIGHT,” [NCT04186845](#)).

“This agreement supports Blue Earth’s overall strategic focus and marks a significant step in advancing our mission to develop and deliver products that address significant unmet medical needs in prostate cancer,” said Jonathan Allis, D. Phil., Executive Chairman of Blue Earth Diagnostics. “Acquisition of this advanced therapeutic rhPSMA technology provides Blue Earth with a comprehensive, one-of-a-kind portfolio in prostate cancer. The company’s robust platform already includes two complementary and technologically advanced PET imaging agents, approved and commercially available Axumin® (fluciclovine F 18), and investigational ¹⁸F-rhPSMA-7.3, each having unique mechanisms of action. With access to therapeutic applications of the rhPSMA technology platform, Blue Earth has the potential to optimize and personalize treatment options for men with prostate cancer like no other company in the industry.”

The agreement further expands Blue Earth’s oncology portfolio and builds on the company’s proven track record and depth of expertise in the rapid development and global commercialization of PET radiopharmaceuticals for cancer. Blue Earth Diagnostics will drive development of a lead radiolabeled rhPSMA therapeutic compound and continue to collaborate with TUM to identify further optimized therapeutic candidates for future development.

Scintomics’ theranostic radiohybrid technology allows for the efficient labelling of PSMA-targeted agents with imaging radioisotopes such as ¹⁸F, or therapeutic radioisotopes such as ¹⁷⁷Lu or ²²⁵Ac, providing the

ability for potential use as a prostate cancer imaging agent or as a therapeutic agent. If approved, these innovative compounds offer the possibility of personalized medicine for men with prostate cancer, by effectively directing therapies using PSMA as the disease target.

“We are very pleased to enter into this therapeutic license agreement with Blue Earth Diagnostics, as their experience in the successful development and commercialization of radiopharmaceuticals will accelerate this first class of exciting “rh” technology based therapeutic agents towards use worldwide,” said Saskia Kropf, CEO of Scintomics GmbH. “Early clinical experience with ¹⁷⁷Lu-rhPSMA radioligand therapy at the Technical University of Munich has been very encouraging and justifies further development to advance a lead candidate into formal clinical studies,” added Dr. Matthias Eiber, Department of Nuclear Medicine, Klinikum rechts der Isar, TUM.

About Radiohybrid Prostate-Specific Membrane Antigen (rhPSMA)

rhPSMA compounds consist of a radiohybrid Prostate-Specific Membrane Antigen-targeted receptor ligand which attaches to and is internalized by prostate cancer cells and they may be radiolabeled with ¹⁸F for PET imaging, or with isotopes such as ¹⁷⁷Lu or ²²⁵Ac for therapeutic use – creating a true theranostic technology. The radiohybrid technology and rhPSMA originated from Prof. Hans J. Wester’s group at the Institute for Pharmaceutical Chemistry at Technical University of Munich, Germany. rhPSMA has been utilized clinically under German legislation at the Department of Nuclear Medicine for the diagnostic imaging of men with both primary and recurrent prostate cancer, and is in early evaluation for therapeutic use. Blue Earth Diagnostics acquired exclusive, worldwide rights to rhPSMA imaging technology from Scintomics in 2018, followed by acquisition of exclusive rights to therapeutic applications in 2020. Blue Earth Diagnostics has two Phase 3 clinical studies underway to evaluate the safety and diagnostic performance of ¹⁸F-rhPSMA-7.3 PET imaging in men with newly diagnosed prostate cancer (“LIGHTHOUSE,” [NCT04186819](https://clinicaltrials.gov/ct2/show/study/NCT04186819)) and in men with recurrent disease (“SPOTLIGHT,” [NCT04186845](https://clinicaltrials.gov/ct2/show/study/NCT04186845)). 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. 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 $\leq 1\%$ 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.

Full U.S. Axumin prescribing information is available at <https://www.axumin.com/prescribing-information.pdf>.

About Blue Earth Diagnostics

Blue Earth Diagnostics, a subsidiary of Bracco Imaging S.p.A., is a recognized leader in the development and commercialization of novel PET radiopharmaceuticals 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 proven experts in nuclear medicine, who have expanded and advanced its robust oncology portfolio. 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 suspected recurrence, based on elevated Prostate-Specific Antigen (PSA) levels. ^{18}F -fluciclovine 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 radiohybrid Prostate-Specific Membrane Antigen (rhPSMA)-targeted agents, a clinical-stage, investigational class of theranostic compounds with potential applications in both the imaging and treatment of prostate cancer. For more information, visit: www.blueearthdiagnostics.com.

About Bracco Imaging

Bracco Imaging S.p.A., part of the Bracco Group, is a world-leading diagnostic imaging provider. Headquartered in Milan, Italy, Bracco Imaging develops, manufactures and markets diagnostic imaging agents and solutions. It 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 and novel PET imaging agents to inform clinical management and guide care for cancer patients in areas of unmet medical need. Our continually evolving portfolio is completed by a range of medical devices, advanced administration systems and dose-management software. In 2019 Bracco Imaging also enriched its product portfolio by expanding the range of oncology nuclear imaging solutions in the urology segment and other specialties with the acquisition of Blue Earth Diagnostics. Visit: www.braccoimaging.com.

About Scintomics GmbH

Scintomics is a privately held company for innovative targeted theranostics and corresponding radiopharmaceutical technologies with a strong commitment towards personalized cancer care with an

exceptional pipeline of functional diagnostics and radiotherapeutics, such as Pentixafor and Pentixather for theranostics of lymphoproliferative diseases and Theridat for adrenocortical cancer. Scintomics' groundbreaking Radiohybrid technology and its first lead compound rhPSMA-7 allow the true bridging of functional imaging and therapy by labeling/activation of either the imaging or therapeutic option without affecting a drug's molecular structure. Scintomics considers the license agreement, the future collaboration with Blue Earth Diagnostics and the further adaption of the Radiohybrid technology to other targeted cancer theranostics as an important milestone towards its strong positioning as radiopharmaceutical development specialist.

Contact:**For Blue Earth Diagnostics (UK)**

Clare Gidley
Acting Communications Manager
Tel: +44 (0) 7917 536939
c.gidley@blueearthdx.com

Media

Sam Brown Inc.
Mike Beyer
(M) (312) 961-2502
mikebeyer@sambrown.com

For Blue Earth Diagnostics (U.S.)

Priscilla Harlan
Vice President, Corporate Communications
(M) (781) 799-7917
priscilla.harlan@blueearthdx.com

For Scintomics

Saskia Kropf
General Manager
(M) (+49) 8141 150 550
s.kropf@scintomics.com
www.scintomics.com

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