

**Blue Earth Diagnostics Expands Oncology Portfolio with Exclusive, Worldwide Licensing of Investigational Radiohybrid PSMA-targeted Agents for Prostate Cancer from Scintomics**

*– Unique attributes of rhPSMA and approved, commercially available Axumin® (fluciclovine F 18) for PET/CT together may provide expanded patient management options in biochemically recurrent prostate cancer –*

*– Agreement builds on Blue Earth Diagnostics' leadership position in rapid development and commercialization of radiopharmaceuticals –*

*– Theranostic radiohybrid (rh)PSMA pharmaceuticals have potential utility in both imaging and therapy of prostate cancer –*

**OXFORD, UK and BURLINGTON, Mass. – May 2, 2018** – Blue Earth Diagnostics, a leading molecular imaging diagnostics company, today announced that it has signed an exclusive, worldwide agreement with Scintomics GmbH, Germany, a specialist in radiopharmaceuticals and radiopharmaceutical technologies. Under the terms of the agreement, Blue Earth Diagnostics has acquired the exclusive worldwide rights to a broad family of Prostate Specific Membrane Antigen (PSMA)-targeted radiohybrid (“rh”) agents for cancer imaging, together with an exclusive option to explore therapeutic applications.

“This agreement supports our strategic focus and is the next step in advancing our mission to develop and deliver products that address unmet medical needs in prostate cancer,” said Jonathan Allis, D. Phil., CEO of Blue Earth Diagnostics. “Blue Earth Diagnostics is working to assemble a world-leading prostate cancer imaging portfolio. To that end, <sup>18</sup>F rhPSMA and Axumin® have unique mechanisms of action which we believe may ultimately allow physicians and their patients to select the diagnostic agent most appropriate to each specific clinical situation. <sup>18</sup>F rhPSMA is an ideal strategic expansion of our imaging portfolio that also enables us to broaden into therapeutic applications of this technology.”

The agreement expands Blue Earth Diagnostics' oncology portfolio and builds on the company's proven track record and depth of expertise in the rapid development and global commercialization of radiopharmaceuticals for cancer. Blue Earth Diagnostics will drive development of a lead <sup>18</sup>F rhPSMA imaging compound and collaborate with Scintomics to identify optimized therapeutic candidates for future development. Acquisition of the rights to this advanced technology provides strong synergies with Axumin® (fluciclovine F 18), Blue Earth Diagnostics' approved and commercially

available PET/CT imaging agent for use in patients with a rising PSA after prior prostate cancer treatment.

Scintomics' theranostic "radiohybrid" technology allows for the efficient labelling of PSMA-targeted agents with imaging radioisotopes, such as  $^{18}\text{F}$ , or therapeutic radioisotopes such as  $^{177}\text{Lu}$ , providing the ability to potentially be used either as a prostate cancer imaging agent or as a therapeutic agent. If approved, these innovative compounds offer the possibility of "precision medicine" for men with prostate cancer.

"We are very pleased to enter into this license agreement with Blue Earth Diagnostics, as their experience in the successful rapid development, approval and commercialization of Axumin will accelerate this first class of exciting "rh" technology based agents towards routine clinical use worldwide," said Prof. Hans-Jürgen Wester, PhD, Founder of Scintomics and Chair, for Pharmaceutical Radiochemistry at the Technical University of Munich (TUM), Germany. "Our early clinical experience with  $^{18}\text{F}$ -rhPSMA-7 has been very encouraging and justifies advancing an "rh" candidate into formal clinical development," added Matthias Eiber, MD, attending physician at the Department of Nuclear Medicine, Klinikum rechts der Isar, TUM.

"As evidenced by its recent inclusion in the National Comprehensive Cancer Network® guidelines,  $^{18}\text{F}$ -fluciclovine has become established as a standard-of-care PET imaging agent in the United States for men with recurrent prostate cancer," said Judd Moul, MD, Professor of Surgery and Director, Duke Prostate Center, Duke University Medical Center, Durham, NC. "It is clear that PSMA-targeted PET imaging agents will play an important role in the future management of prostate cancer patients. However, there is a wide array of these agents in development, and some have more promising attributes than others. Optimally, a PSMA-targeted diagnostic agent for routine clinical use should be labeled with the radioisotope  $^{18}\text{F}$  for its durability and possess favorable clinical attributes that facilitate broad applicability and utility in men with prostate cancer."

### **About rhPSMA**

rhPSMA was invented by Hans-J Wester and Alexander Wurzer at the Department of Pharmaceutical Radiochemistry of the Technical University of Munich, Germany, where it has been utilized clinically under German legislation by Matthias Eiber at the Department of Nuclear Medicine for the diagnostic imaging of men with both primary and recurrent prostate cancer. Bayerische Patentallianz (BayPAT), the technology transfer office of Bavarian Universities and Universities of Applied Sciences out-licensed the Radiohybrid ("rh") PSMA-targeted technology to Scintomics in 2017.  $^{18}\text{F}$  rhPSMA consists of a prostate-specific membrane antigen (PSMA) receptor ligand, which attaches to and is internalized by prostate cancer cells, and is labeled with the  $^{18}\text{F}$  radioisotope for PET imaging. rhPSMA compounds can also be labeled with the radioisotope  $^{177}\text{Lu}$  for therapeutic use.  $^{18}\text{F}$  rhPSMA and  $^{177}\text{Lu}$  rhPSMA have not received regulatory approval.

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 Prostate / Recurrent Prostate Cancer**

Prostate cancer is the second leading cause of cancer death in men in the United States and the most common cancer in men in Europe. While most primary prostate cancer can be successfully treated, the disease recurs in approximately one-third of patients. In some patients, recurrent disease is detectable only by a rise in prostate specific antigen

(PSA) levels, yet the location of the recurrence cannot consistently be located by conventional imaging, potentially impacting subsequent management of these patients.

### **About Blue Earth Diagnostics**

Blue Earth Diagnostics is a 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 experiencing suspected biochemical recurrence. 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](http://www.blueearthdiagnostics.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.

### **About BayPAT**

Bayerische Patentallianz GmbH (BayPAT) is the central patent and marketing agency to foster technology transfer of Bavarian Universities, University Hospitals and Universities of Applied Sciences. Having responsibility for 33 research institutes, BayPAT ([www.baypat.de](http://www.baypat.de)) is a full-service technology management provider offering services in the area of technology transfer, IP management and commercialization.

### **Contact:**

#### **For Blue Earth Diagnostics (UK)**

Georgina Mowatt  
Communications Manager  
Tel: +44 (0) 7810 355 912

#### **Media**

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

g.mowatt@blueearthdx.com

mikebeyer@sambrown.com

**For Blue Earth Diagnostics (U.S.)**

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

**For Scintomics**

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

**For BayPAT**

Dr. Robert Phelps, CEO  
Bayerische Patentallianz GmbH  
Destouchesstr. 68  
80796 Munich, Germany  
Tel: +49 (0)89 54801770  
www.baypat.de

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