



PRESS RELEASE

Blue Earth Diagnostics Highlights Presentations on Axumin® (Fluciclovine F 18), ¹⁸F-Fluciclovine and ¹⁸F-rhPSMA at Upcoming Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting

BURLINGTON, Mass. and OXFORD, UK, June 12, 2019 – Blue Earth Diagnostics, a molecular imaging diagnostics company, today announced upcoming presentations at the Society of Nuclear Medicine and Molecular Imaging Annual Meeting (SNMMI), from June 22 – 26, 2019 in Anaheim, Ca. Highlighted presentations encompass clinical use of Axumin® (fluciclovine F 18) injection; investigational use of ¹⁸F-fluciclovine; and initial clinical experience by the Technical University of Munich with ¹⁸F-rhPSMA-7, an investigational Prostate Specific Membrane Antigen-targeted radiohybrid PET imaging agent representative of the family of rhPSMA agents that Blue Earth Diagnostics exclusively licensed in 2018. Senior executives from Blue Earth Diagnostics will participate in sessions about advancing companies from concept to commercialization, and current and future approaches to molecular imaging and therapy. In addition, a special program led by SNMMI, “Fluciclovine Live Reader Training,” will be held immediately prior to the Annual Meeting. Details of selected oral and poster presentations by Blue Earth Diagnostics and its collaborators are listed below.

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. Presentations noted by “*” discuss results of investigational studies of an approved product that is not approved by the FDA for the specific use or purpose noted, or “*” denotes experience with an investigational agent for which the safety and efficacy have not been established by the FDA.

HIGHLIGHTED SCIENTIFIC PRESENTATIONS

Axumin (fluciclovine F 18) presentations

Date: Monday, June 24, 2019
Poster Title: [18F]-fluciclovine positivity rate is not affected by androgen deprivation therapy (ADT) in recurrent prostate cancer post-prostatectomy
Session Title: MTA I: Prostate/GU Imaging Posters
Presenter: Olayinka Abiodun-Ojo, MD, Emory University
Presentation Time: 3:00 – 4:30 PM PT
Location: Exhibit Hall C
Publication No.: 1576

Date: Monday, June 24, 2019
Poster Title: Comparison of ¹⁸F-Fluciclovine PET/CT and Technetium-99m MDP BS in Detection of Bone Metastasis in Prostate Cancer
Session Title: MTA I: Prostate/GU Imaging Posters
Presenter: Bo Chen, MD, MD Anderson Cancer Center

Presentation Time: 3:00 – 4:30 PM PT
 Location: Exhibit Hall C
 Publication No.: 1553

Investigational ¹⁸F-fluciclovine presentations

Date: Monday, June 24, 2019

Session Title: SS47: Brain PET/MRI

Presentation Title: **Evaluation of glioma tumor volume with 18F-fluciclovine positron emission tomography interpreted in combination with MRI, compared with MRI alone: Results from a prospective phase 3 blinded image evaluation***

Presenter: Matthew P. Miller, PhD, Blue Earth Diagnostics

Session Time: 4:45 – 6:15 PM PT

Presentation Time: 5:25 – 5:35 PM PT

Location: Room 204B

Publication No: 394

Date: Tuesday, June 25, 2019

Session Title: SS58: Brain Imaging Reloaded II

Presentation Title: **Safety and effectiveness of ¹⁸F-fluciclovine PET in adults with recurrent glioma: A retrospective observational study***

Presenter: Tore Bach-Gansmo, MD, PhD, Oslo University Hospital

Session Time: 10:00 – 11:30 AM PT

Presentation Time: 11:20 – 11:30 AM PT

Location: Room 201B

Publication No. 496

Date: Tuesday, June 25, 2019

Poster Title: **PET imaging of recurrent brain tumors using ¹⁸F-FACBC***

Session Title: MTA II: Neurology & Psychiatry Imaging Posters

Presenter: Laure Michaud, MD, Memorial Sloan-Kettering Cancer Center

Presentation Time: 3:00 – 4:30 PM PT

Location: Exhibit Hall C

Publication No.: 1506

Date: Monday, June 24, 2019

Poster Title: **[¹⁸F]-fluciclovine PET/CT is superior to conventional imaging in preoperative nodal staging in patients with high-risk prostate cancer***

Session Title: MTA I: Prostate/GU Imaging Posters

Presenter: Olayinka Abiodun-Ojo, MD, Emory University

Presentation Time: 3:00 – 4:30 PM PT

Location: Exhibit Hall C

Publication No.: 1580

Date: Monday, June 24, 2019

Poster Title: **Preoperative staging in high-risk prostate cancer patients using [¹⁸F] fluciclovine PET/CT***

Session Title: MTA I: Prostate/GU Imaging Posters

Presenter: Akinyemi A. Akintayo, MD, Emory University

Presentation Time: 3:00 – 4:30 PM PT
 Location: Exhibit Hall C
 Publication No.: 1554

Date: Monday, June 24, 2019
 Poster Title: **[18F] Fluciclovine PET/MRI for Initial Staging of High-Risk Prostate Cancer***
 Session Title: MTA I: Prostate/GU Imaging Posters
 Presenter: Samuel J. Galgano, MD, University of Alabama at Birmingham
 Presentation Time: 3:00 – 4:30 PM PT
 Location: Exhibit Hall C
 Publication No.: 1561

Date: Tuesday, June 25, 2019
 Poster Title: **Using dynamic PET/CT imaging to explore the kinetics of 18F-fluciclovine (anti-(18)F-FACBC) in invasive breast cancer***
 Session Title: MTA II: Data Analysis & Management Posters
 Presenter: Nathaniel P. Scott, MSc, MPhys, University of Oxford
 Presentation Time: 3:00 – 4:30 PM PT
 Location: Exhibit Hall C
 Publication No.: 1194

Date: Tuesday, June 25, 2019
 Session Title: SS65: Gynecological Cancers
 Presentation Title: **Feasibility of Fluciclovine PET-CT Imaging of Endometrial, Cervical and Ovarian Cancers: Preliminary Findings***
 Presenter: Funmilayo Tade, MD, MPH, Loyola University Medical Center
 Session Time: 12:30 – 2:00 PM PT
 Presentation Time: 1:50 – 2:00 PM PT
 Location: Room 202AB
 Publication No.: 558

Presentations on initial clinical experience with ¹⁸F-rhPSMA-7 at Technical University of Munich

Date: Monday, June 24, 2019
 Poster Title: **Preclinical dosimetry and human biodistribution of ¹⁸F-rhPSMA-7 and ¹⁸F-rhPSMA-7.3***
 Session Title: MTA I: Prostate/GU Imaging Posters
 Presenter: So Won Oh, MD, PhD, Seoul National University Boramae Hospital
 Presentation Time: 3:00 – 4:30 PM PT
 Location: Exhibit Hall C
 Publication No.: 1635

Date: Monday, June 24, 2019
 Poster Title: **Quantitative and qualitative analysis of biodistribution and PET image quality of novel radiohybrid PSMA ligand, ¹⁸F-rhPSMA-7, in patients with prostate cancer ***
 Session Title: MTA I: Prostate/GU Imaging Posters
 Presenter: So Won Oh, MD, PhD, Seoul National University Boramae Hospital
 Presentation Time: 3:00 – 4:30 PM PT

Location: Exhibit Hall C
 Publication No.: 1557

Date: Monday, June 24, 2019

Poster Title: **Histologically-confirmed diagnostic efficacy of ¹⁸F-rhPSMA-7 positron emission tomography for N-staging of patients with high risk primary prostate cancer***

Session Title: MTA I: Prostate/GU Imaging Posters
 Presenter: Markus Kroenke, Technical University of Munich
 Presentation Time: 3:00 – 4:30 PM PT
 Location: Exhibit Hall C
 Publication No.: 1567

Date: Tuesday, June 25, 2019

Session Title: SS69: Prostate Diagnosis I
 Presentation Title: **¹⁸F-rhPSMA-7 positron emission tomography (PET) for the detection of biochemical recurrence of prostate cancer following curative-intent radiation therapy***

Presenter: Harun Ilhan, MD, Ludwig-Maximilian-University (LMU), Munich
 Session Time: 12:30 – 2:00 PM PT
 Presentation Time: 1:30 – 1:40 PM PT
 Location: 204B
 Publication No.: 592

Date: Tuesday, June 25, 2019

Session Title: SS76: Prostate Cancer Diagnosis II
 Presentation Title: **¹⁸F-rhPSMA-7 positron emission tomography (PET) for the detection of biochemical recurrence of prostate cancer following radical prostatectomy***

Presenter: Matthias Eiber, MD, Technical University of Munich
 Session Time: 10:00 – 11:30 AM PT
 Presentation Time: 11:20 – 11:30 AM PT
 Location: Room 204B
 Publication No.: 649

PANEL PRESENTATIONS

Date: Saturday, June 22, 2019

Session Title: Concept to Commercialization and Funding Along the Way
 Panel Title: **Emerging Technologies, Funding, M&A**
 Panel Participant: Jonathan Allis, D.Phil., CEO, Blue Earth Diagnostics
 Session Time: Saturday 3:30 – 5
 Location: Room 303AB

Date: Sunday, June 23, 2019

Session Title: CMIIT Emerging Technologies – Emerging Technologies – A Look into the Future of Molecular Imaging and Therapy
 Presentation Title: **Molecular Imaging and Therapy – Current and Future Approaches***
 Presenter: David Gauden, D.Phil., CSO, Blue Earth Diagnostics
 Session Time: 4:30 – 6:00 PM PT

Presentation Time: 4:30 – 4:50 PM PT
 Location: Room 201D

In addition, the following presentations will be part of independent continuing education programs at SNMMI.

Date: Saturday, June 22, 2019
Session Title: SNMMI Special Programming
Presentation Title: Fluciclovine Live Training Session
Session Time: 9:00 AM PT – 12:00 PM PT
Location: Registration required:
<http://www.snmmi.org/AM/Registration/RegistrationAM.aspx>

Date: Saturday, June 22, 2019
Session Title: CE08: Prostate Cancer Nuts and Bolts: Diagnosis and Therapy
Presentation Title: Prostate Cancer Diagnostic: Fluciclovine F18 PET/CT
Presenter: David M. Schuster, MD, Emory University
Session Time: 3:15 – 4:45 PM PT
Presentation Time: 3:15 – 3:45 PM PT
Location: Room 211AB

Date: Sunday, June 23, 2019
Session Title: CE29: New PET Radiopharmaceuticals – Read with the Experts
Presentation Title: Fluciclovine F18 PET/CT
Presenter: David M. Schuster, MD, Emory University
Session Time: 4:45 – 6:15 PM PT
Presentation Time: 4:45 – 5:05 PM PT
Location: Room 212AB

Blue Earth Diagnostics invites participants at this year's SNMMI Annual Meeting to attend the presentations above and to visit the company at Exhibit Booth 720.

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 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 rhPSMA

Blue Earth Diagnostics acquired exclusive, worldwide rights to radiohybrid Prostate Specific Membrane Antigen (PSMA)-targeted technology (rhPSMA) from Scintomics in 2018. rhPSMA originated from the Chair of Pharmaceutical Radiochemistry at the Technical University of Munich, Germany, by Alexander Wurzer and Hans Juergen Wester, and 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. ^{18}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}F radioisotope for PET imaging. rhPSMA compounds can also be labeled with radioisotopes such as ^{177}Lu and ^{225}Ac for therapeutic use. ^{18}F -rhPSMA, ^{177}Lu -rhPSMA and ^{225}Ac -rhPSMA have not received regulatory approval.

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.

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