Blue Earth Diagnostics Announces Fluciclovine F 18 Research Presentations at Upcoming Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting

BURLINGTON, Mass. and OXFORD, UK, June 18, 2018 – Blue Earth Diagnostics, a molecular imaging diagnostics company, today announced that presentations related to the clinical use of fluciclovine F 18 injection will be occurring at the Society of Nuclear Medicine and Molecular Imaging Annual Meeting (SNMMI), from June 23 – 26, 2018 in Philadelphia, Pa. In addition, a special program led by SNMMI, "Fluciclovine Live Reader Training," will be held immediately prior to the Annual Meeting. The oral and poster presentations highlighting ongoing investigations with fluciclovine F 18 are listed below.

ORAL PRESENTATION

Tuesday, June 26, 2018

Session Title:	SS54: Prostate Cancer Imaging II
Presentation Title:	**^{18}F-Fluciclovine PET/CT in patients with biochemical recurrence of prostate cancer: Impact on management and associations of clinical variables with scan findings**
Presenter:	Austin R. Pantel, MD on behalf of the LOCATE study group, Hospital of the University of Pennsylvania
Session Time:	8:00 AM – 9:30 AM ET
Presentation Time:	9:00 – 9:10 AM ET
Location:	Room 107AB
Publication No:	457

POSTER PRESENTATIONS

Monday, June 25, 2018

Poster Title:	**The role of fluciclovine (^{18}F) PET/CT directed, 3D ultrasound-guided fusion targeted biopsy in the detection of biochemically recurrent prostate cancer***
Session Title:	MTA 1: Prostate Posters
Presenter:	Olayinka Abiodun-Ojo, MD, Emory University
Presentation Time:	3:00 – 4:30 PM ET
Location:	Exhibit Hall C
Publication No.:	1481

Poster Title:	**Think outside the box: tackling fluciclovine PET-CT with challenging extraprostatic findings**

Session Title: MTA 1: Educational Exhibits
Presenter: Yoram Baum, MD, Emory University
Presentation Time: 3:00 – 4:30 PM ET
Location: Exhibit Hall C
Publication No.: 1164

Poster Title: **Probability of a positive F-18 fluciclovine scan based on level of PSA**
Session Title: MTA 1: Prostate Posters
Presenter: William C. Lavely, MD, Northside Radiology Associates
Presentation Time: 3:00 – 4:30 PM ET
Location: Exhibit Hall C
Publication No.: 1447

Poster Title: **Utilization of F-18 fluciclovine PET/CT for initial staging of prostate carcinoma***
Session Title: MTA 1: Prostate Posters
Presenter: William C. Lavely, MD, Northside Radiology Associates
Presentation Time: 3:00 – 4:30 PM ET
Location: Exhibit Hall C
Publication No.: 1439

Poster Title: **Factors influencing the positivity rate of commercial ^{18}F-Fluciclovine PET/CT imaging in men with suspected recurrent prostate cancer**
Session Title: MTA 1: Prostate Posters
Presenter: Petra Lovrec, MD, Loyola University Medical Center
Presentation Time: 3:00 – 4:30 PM ET
Location: Exhibit Hall C
Publication No.: 1470

Poster Title: **Single academic center experience with 18F-fluciclovine PET/CT in prostate cancer management**
Session Title: MTA 1: Prostate Posters
Presenter: Hossein Jadvar, MD, PhD, MPH, MBA, FACNM, FSNMMI, University of Southern California
Presentation Time: 3:00 – 4:30 PM ET
Location: Exhibit Hall C
Publication No.: 1457

Poster Title: **Clinical experience with F-18-fluciclovine (Axumin®) in prostate cancer patients with a rising PSA after primary treatment**
Session Title: MTA 1: Prostate Posters
Presenter: Mitchel A. Muhleman, MD, Mount Sinai Medical Center
Presentation Time: 3:00 – 4:30 PM ET

Location:	Exhibit Hall C
Publication No.:	1487
Poster Title:	**^{18}F-Fluciclovine for the restaging of patients with biochemical recurrence of prostate cancer and the correlation with PSA values: Results from a single centre**
Session Title:	MTA 1: Prostate Posters
Presenter:	Dirk Wyndaele, MD, Catharina Hospital
Presentation Time:	3:00 – 4:30 PM ET
Location:	Exhibit Hall C
Publication No.:	1460

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 "" are investigational studies.

Blue Earth Diagnostics invites participants at this year's SNMMI Annual Meeting to visit the company at Exhibit Booth 607. Blue Earth Diagnostics is participating in SNMMI's Interactive Training Showcase events on the Exhibit floor, scheduled for Sunday, June 24, 2018, and Monday, June 25, 2018 from 2 – 2:30 p.m. ET.

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, an investment company listed on the London Stock Exchange (LON: SYNC). For more information, visit: www.blueearthdiagnostics.com.

Contact:

For Blue Earth Diagnostics (U.S.)
Priscilla Harlan
Vice President, Corporate Communications
(M) (781) 799-7917
p.harlan@blueearthdx.com

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

For Blue Earth Diagnostics (UK)
Georgina Mowatt
Communications Manager
Tel: +44 (0) 7810 355 912
gmowatt@blueearthdx.com

# # #