Blue Earth Diagnostics Announces Fluciclovine F 18 Research Presentations at Upcoming ASTRO Annual Meeting

BURLINGTON, Mass. and OXFORD, UK, October 17, 2018 – Blue Earth Diagnostics, a molecular imaging diagnostics company, today announced that oral and poster presentations related to the clinical use of fluciclovine F 18 injection will be occurring at the 2018 American Society for Radiation Oncology (ASTRO) Annual Meeting, from October 21 - 24, 2018 in San Antonio, Texas.

Some of the oral and poster presentations listed below highlight investigational uses of fluciclovine F 18. 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 "*" describe investigational uses of fluciclovine F 18 for which the safety and efficacy have not been established.

Sunday, October 21, 2018

ePoster Discussions

Session Title:	GU 1 – ePoster Discussion – New Data on PET, MRI and Protons for Treating Prostate Cancer
Presentation Title:	**Positive Findings on 18F-fluciclovine PET/CT in Patients with Suspected Recurrent Prostate Cancer and PSA levels ≤0.5 and ≤0.3 ng/ml**
Presenter:	Petra Lovec, MD, Loyola University Medical Center
Presentation Number:	1001
Presentation Time:	1:21 – 1:27 p.m. CT
Location:	Room 217 A/B

Session Title:	GU 1 – ePoster Discussion – New Data on PET, MRI and Protons for Treating Prostate Cancer
Presentation Title:	**The Impact of ^{18}F-Fluciclovine Positron Emission Tomography on Salvage Radiation Therapy Decisions for Patients with Post-Radical Prostatectomy Recurrence of Prostate Cancer: Results from LOCATE**
Presenter:	Abhishek Solanki, MD, MS, Loyola University Medical Center
Presentation Number:	1000
Presentation Time:	1:15 – 1:21 p.m. CT
Location:	Room 217 A/B

Poster Viewings

Session Title:	Poster Viewing Q&A 1

Presentation Title:	**Application of 18-F Fluciclovine PET/CT in Guiding Salvage Radiation Therapy for Recurrent Prostate Cancer***
Presenter:	Jalal Ahmed, MD, PhD, BS, Icahn School of Medicine at Mt Sinai
Session Time:	1:15 – 2:45 p.m. CT
Location:	Innovation Hub, Exhibit Hall 3
Presentation No.:	SU_22_2227

Tuesday, October 23, 2018

Poster Viewings

Session Title:	Poster Viewing Q&A 3
Title:	**Design and Evaluation of a Semi-Automated Algorithm for Segmentation of Anti-[18F]FACBC (Fluciclovine F18) PET Images for Post-Prostatectomy Radiation Therapy***
Presenter:	Eduard Schreibmann, PhD, DABR, Emory University
Presentation Time:	1:00 – 2:30 p.m. CT
Location:	Innovation Hub, Exhibit Hall 3
Presentation No.:	TU_20_3312

Blue Earth Diagnostics invites participants at the 2018 ASTRO Annual Meeting to visit the company at Exhibit Booth 2163. The company is also hosting an Industry-Expert Theater event, "Detecting and Localizing Recurrent Prostate Cancer with Axumin® (Fluciclovine F 18) Injection," with invited speaker Dr. Rodney Ellis, MD FACRO, Vice Chairman, Strategic Affairs, Radiation Oncology, University Hospital Cleveland Medical Center, Associate Professor, Radiation Oncology and Urology, Case Western Reserve University School of Medicine, Cleveland, Ohio, which will be held on Sunday, October 21, 2018, from 12:15 – 1:15 p.m. CT, in Theater 1, Innovation Hub.

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.

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