PRESS RELEASE

Blue Earth Diagnostics Announces ^{18}F-Fluciclovine Research Presentation at Upcoming Society for Neuro-Oncology (SNO) Annual Scientific Meeting

BURLINGTON, Mass. and OXFORD, UK, November 14, 2018 – Blue Earth Diagnostics, a molecular imaging diagnostics company, today announced that a presentation related to the clinical use of ^{18}F-fluciclovine in adults with glioma will be occurring at the upcoming Society for Neuro-Oncology (SNO) Annual Scientific Meeting, being held November 15 - 18, 2018 in New Orleans, La. Blue Earth Diagnostics is investigating the potential use of ^{18}F-fluciclovine in adults for the detection and continuing assessment of glioma.

The presentation listed below highlights the investigational use of ^{18}F-fluciclovine, as an adjunct to magnetic resonance imaging (MRI), in adults with glioma.

Friday, November 16, 2018

Session Type:	Poster Session
Session Title:	**A Blinded Image Evaluation Study to Determine the Diagnostic Efficacy of ^{18}F-fluciclovine PET, as an Adjunct to MRI Imaging, in Adults with Glioma**
Presenter:	Matthew P. Miller, PhD, Blue Earth Diagnostics
Poster Number:	NIMG-01
Abstract ID:	506064
Presentation Time:	7:30 – 9:30 p.m. CT

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. The safety and efficacy of ^{18}F-fluciclovine PET imaging in glioma have not been established.

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 ^{18}F-fluciclovine PET in Glioma

^{18}F-fluciclovine PET is a diagnostic imaging radiopharmaceutical for PET imaging that consists of a synthetic amino acid labeled with the radioisotope F 18, enabling the visualization of the increased amino acid transport that occurs in malignant tumors. ^{18}F-fluciclovine, under the trade name Axumin®, is approved by the U.S. Food and Drug Administration (FDA) for PET imaging in men with biochemically recurrent prostate cancer. It is also under investigation by Blue Earth Diagnostics for use in adults for the detection and continuing assessment of glioma. ^{18}F-fluciclovine has been granted Orphan Drug status by both the FDA and the European Medicines Agency for the diagnosis of glioma. The compound 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.

About Glioma

Glioma, the most commonly occurring type of primary brain tumor, is a serious and life-threatening condition. Cancer of the brain and central nervous system (CNS) is the twelfth most common cause of cancer death worldwide. Glioma accounts for about 25% of all brain tumors, and 80% of all malignant brain tumors. The most aggressive form of glioma, glioblastoma multiforme, is associated with significant morbidity and mortality with relatively low 5-year survival estimates after diagnosis. Current treatment options for patients with glioma include surgery, radiation and chemotherapy. Accurate evaluation of the location and extent of a glioma tumor is essential before or during surgery and radiotherapy and in assessing the continuing status of the disease. The detection and assessment of gliomas typically involves magnetic resonance imaging (MRI), which may be complemented by metabolic imaging using an appropriate amino acid-based PET radiopharmaceutical, as recommended in the Response Assessment in Neuro-Oncology (RANO) working group and European Association for Neuro-Oncology (EANO) guidelines.[1]

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.

References

[1]Albert NL, Weller M., Suchorska B, et al. Response Assessment in Neuro-Oncology working group and European Association for Neuro-Oncology recommendations for the clinical use of PET imaging in gliomas. Neuro-Oncology 2016;18(9):1199-1208.

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