NEWS RELEASE

PRESS RELEASE

Blue Earth Diagnostics Announces U.S. Food and Drug Administration (FDA) Filing Acceptance of Supplemental New Drug Application (sNDA) for ^{18}F-fluciclovine PET Imaging in Glioma

– sNDA seeks to expand Axumin® (fluciclovine F 18) label for use in detection and continuing assessment in adults with glioma –

BURLINGTON, Mass. and OXFORD, UK – December 10, 2018 – Blue Earth Diagnostics, a molecular imaging diagnostics company, today announced that the U.S. Food and Drug Administration (FDA) has accepted for review a supplemental New Drug Application (sNDA) for the expanded use of Axumin® (fluciclovine F 18) in adults for the detection and continuing assessment of glioma.

Fluciclovine is a synthetic amino acid labeled with the radioisotope F 18, enabling PET imaging to visualize the increased amino acid transport that occurs in malignant tumors such as glioma, which is a serious and life-threatening condition accounting for about 80% of all malignant brain tumors.

^{18}F-Fluciclovine, under the tradename Axumin® (fluciclovine F 18) injection, is FDA-approved for use in positron emission tomography (PET) imaging in men with suspected prostate cancer recurrence based on elevated blood levels of prostate specific antigen (PSA) following prior treatment. ^{18}F-Fluciclovine PET imaging is being investigated for the detection and continuing assessment of glioma. (For additional product information please see the end of this news release.) ^{18}F-Fluciclovine has previously been granted Orphan Drug status by both the FDA and the European Medicines Agency for the diagnosis of glioma.

“We are very pleased that the FDA has accepted for review our sNDA submission for the use of ^{18}F-fluciclovine PET imaging in glioma,” said Jonathan Allis, D. Phil., CEO of Blue Earth Diagnostics. “Expanding the label for Axumin is part of our mission to develop and commercialize innovative PET imaging products that address unmet medical needs for patients with cancer.”

“Glioma is the twelfth leading cause of death from cancer, and certain aggressive forms of the disease, such as glioblastoma multiforme, can progress rapidly,” said Peter Gardiner, MB ChB, MRCP, FFPM, CMO of Blue Earth Diagnostics. “Physicians need precise information about the location and extent of the tumor to help guide surgical procedures and radiation therapy, as well as for subsequent continued assessment and monitoring of the disease. We are exploring the potential utility of ^{18}F-fluciclovine PET to assist them in these efforts.”

Blue Earth Diagnostics recently announced results from one of the Phase 3 clinical trials supporting the sNDA submission to the FDA at the Society for Neuro-Oncology annual meeting

in November 2018. The study, BED006, was a prospective, blinded image evaluation that examined the diagnostic performance of ^{18}F-fluciclovine PET imaging, in conjunction with various types of MRI, for imaging of suspected glioma when interpreted by readers unfamiliar with ^{18}F-fluciclovine PET. Results indicated a Positive Predictive Value (PPV) of more than 90% for each of the three blinded readers and consistent image interpretation across these readers. In addition, ^{18}F-fluciclovine PET with MRI (CE-T_1W MRI) identified additional regions suspicious for glioma that MRI alone was unable to identify, which subsequent biopsies confirmed as malignant. To date, the safety profile of ^{18}F-fluciclovine PET imaging in patients with glioma appears to be consistent with that summarized in the current Axumin U.S. prescribing information.

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 recurrent prostate cancer. The clinical trial program to support the safety and efficacy, in terms of diagnostic performance, of ^{18}F-fluciclovine PET imaging in adults for the detection and continuing assessment of glioma encompasses four trials conducted in Japan by Nihon Medi-Physics Co., Ltd and two studies in Europe and the United States by Blue Earth Diagnostics. To date, the safety profile of ^{18}F-fluciclovine PET imaging in patients with glioma appears to be consistent with that summarized in the current Axumin prescribing information. ^{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]

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 U.S. Axumin prescribing information is available at www.axumin.com.

*This press release is intended to provide information about Blue Earth Diagnostics' business in the United States. Please be aware that the approval status and product label for Axumin varies by country worldwide. Refer to the individual country product label for complete information or contact Blue Earth Diagnostics.

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.

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
g.mowatt@blueearthdx.com

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