PRESS RELEASE

Blue Earth Diagnostics Announces Results from Investigational Clinical Study of Safety and Effectiveness of ^{18}F-Fluciclovine PET Imaging in Adult Glioma

– Presented at Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting –

Burlington, Mass. and OXFORD, UK, June 26, 2019 – Blue Earth Diagnostics, a molecular imaging diagnostics company, today announced results from a retrospective, observational analysis evaluating the safety and effectiveness of ^{18}F-fluciclovine in the detection of recurrent gliomas in adults, using data from multiple research sites. The primary aim was to determine the Positive Predictive Value (PPV) of ^{18}F-fluciclovine PET to detect glioma in comparison to a histopathological truth standard. Results demonstrated that among the patients with recurrent glioma (n=17), ^{18}F-fluciclovine PET demonstrated a PPV of 88.2%, a detection rate of 100% and sensitivity of 100%. No adverse events related to ^{18}F-fluciclovine were reported in the study. ^{18}F-fluciclovine is a synthetic amino acid labeled with the radioisotope F 18, enabling PET imaging which may help visualize the increased amino acid transport that occurs in malignant brain tumors such as glioma.

Results of the study were announced in an oral presentation, "Safety and effectiveness of ^{18}F-fluciclovine PET in adults with recurrent glioma: a retrospective observational study," by Tore Bach-Gansmo, MD, PhD, Oslo University Hospital, Oslo, Norway, at the Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting, June 22 – 26, 2019 in Anaheim, Ca.

"We are pleased to share results from this retrospective study of ^{18}F-fluciclovine PET imaging of recurrent adult glioma with the nuclear medicine community at SNMMI," said Jonathan Allis, D. Phil., CEO of Blue Earth Diagnostics. "Clinical investigations such as this can help to inform the development of innovative PET imaging agents to address important unmet medical needs."

"Glioma is a serious and potentially life-threatening disease, accounting for 80% of all malignant primary brain tumors," said Peter Gardiner, MB ChB, MRCP, FFPM, CMO of Blue Earth Diagnostics. "The ability to identify the location and extent of a tumor is important in planning appropriate treatment for patients, in both initial diagnosis and subsequent monitoring for recurrence."

In another oral presentation at SNMMI, "Evaluation of glioma tumor volume with ^{18}F-fluciclovine positron emission tomography interpreted in combination with MRI, compared with MRI alone: Results from a prospective phase 3 blinded image evaluation," Matthew Miller, PhD, of Blue Earth Diagnostics, presented results from another of the company's clinical trials. 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% (n=35) 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 CE-T_1W 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 current Axumin® U.S. prescribing information.

About the Retrospective Observational Study in Adults with Glioma (BED008)
Study BED008 was a retrospective observational study of ^{18}F-fluciclovine PET that was designed to evaluate the safety and efficacy of ^{18}F-fluciclovine PET in the detection or recurrent gliomas in adults. It analyzed results from three clinical sites (Emory University, Atlanta, Ga., Memorial Sloan Kettering Cancer Center, New York, NY; and under a compassionate use program at Oslo University Hospital, Oslo, Norway). The primary objective of the study was to determine the Positive Predictive Value (PPV) of ^{18}F-fluciclovine PET to detect glioma in comparison to a histopathological truth standard. Secondary objectives included determination of the detection rate, sensitivity, specificity, and negative predictive value (NPV). The study also aimed to evaluate adverse events in any patient who received ^{18}F-fluciclovine.

A total of 82 adult patients received at least one injection of ^{18}F-fluciclovine for the detection or primary or recurrent glioma and had had at least one histopathological report confirming the diagnosis of glioma. Only patients whose ^{18}F-fluciclovine PET scan, MRI and histopathology assessment (positive or negative) occurred within 30 days of one another were included in analyses of diagnostic performance. Eighteen of the 82 scans met these criteria (1 scan in a patient with primary glioma and 17 scans in patients with recurrent disease). Among the 17 patients with recurrent glioma, ^{18}F-fluciclovine showed a PPV of 88.2%, a detection rate of 100% and sensitivity of 100%. In patients with recurrent high-grade glioma (n = 12), the PPV, detection rate and sensitivity were 83.3%, 100% and 100%, respectively. In patients with recurrent low-grade glioma (n = 5) these were 100%, 100% and 100%, respectively. Specificity and NPV could not be calculated as no patients had a negative ^{18}F-fluciclovine PET scan. In total, 3.7% (3/82) patients experienced at least one treatment emergent adverse event during the safety monitoring, none of which were considered related to ^{18}F-fluciclovine.

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 compounds, with potential applications in the management of 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.

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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