PRESS RELEASE

Blue Earth Diagnostics Announces Results from Early Clinical Experience with Targeted PET Imaging Agent rhPSMA-7.3 (^{18}F) in Men with Intermediate and High-risk Prostate Cancer

– Results related to Company's investigational Phase 3 radiohybrid PSMA agent presented at the AUA2020 Virtual Meeting –

BURLINGTON, Mass. and OXFORD, UK, May 18, 2020 – Blue Earth Diagnostics, a Bracco company focused on molecular imaging diagnostics, today announced results from early clinical experience in Germany with positron emission tomography/computed tomography (PET/CT) imaging using rhPSMA-7.3 (^{18}F), a radiohybrid Prostate Specific Membrane Antigen-targeted compound. The results were presented by the Technical University of Munich (TUM) in an oral presentation at the American Urological Association's AUA2020 Virtual Meeting on May 15, 2020. Results of the retrospective analysis of 56 patients with intermediate or high-risk prostate cancer indicated that rhPSMA-7.3 (^{18}F) PET/CT demonstrated a patient-level sensitivity of 81%, specificity of 88% and diagnostic accuracy of 86%, when on-site image interpretations were compared to histopathological findings.

Blue Earth Diagnostics is conducting two Phase 3 clinical trials of rhPSMA-7.3 (^{18}F) PET imaging. The LIGHTHOUSE study (NCT04186819) will examine the potential use of rhPSMA-7.3 (^{18}F) in newly diagnosed prostate cancer, and the SPOTLIGHT study (NCT04186845) is focused on its potential use in biochemical recurrent prostate cancer. Results from the early clinical experience by TUM, including with rhPSMA-7.3 (^{18}F) PET, were included Blue Earth Diagnostics' Investigational New Drug (IND) submission.

"We are very pleased that TUM is able to share the results of this early clinical experience with the prestigious urology community through the Virtual Science platform at AUA2020," said Jonathan Allis, D. Phil., CEO of Blue Earth Diagnostics. "Blue Earth Diagnostics has rapidly advanced our rhPSMA-7.3 (^{18}F) research program since acquiring exclusive rights to theranostic rhPSMA technology in 2018, in line with our strategy to expand and advance a world-leading prostate cancer radiopharmaceutical portfolio. Both rhPSMA-7.3 (^{18}F) and approved, commercially available Axumin® (fluciclovine F 18) have unique and complementary mechanisms of action, and we believe that each may ultimately allow physicians and their patients flexibility in selecting the diagnostic agent most appropriate to each specific clinical situation."

"The ability to effectively stage primary prostate cancer is important in determining appropriate management for these patients," said Tobias Maurer, MD, of the Martini-Klinik and Department of Urology, University of Hamburg-Eppendorf, Germany (previously in the Department of Urology at TUM), who presented the results at AUA2020. "This retrospective analysis is the first report investigating the potential efficacy of the single isomer product rhPSMA-7.3 (^{18}F), in PET imaging for primary lymph node staging in patients with intermediate and high-risk prostate cancer. Our study results indicated that rhPSMA-7.3 (^{18}F) PET demonstrated 86% accuracy in men with primary prostate cancer. These preliminary data are encouraging and we are pleased that further research is ongoing."

"TUM's early experience with radiohybrid PSMA agents has allowed us to investigate the potential diagnostic performance of this new class of theranostic PSMA-targeting agents, which can be efficiently

labeled with imaging radioisotopes such as ^{18}F for PET imaging or with ^{177}Lu for therapeutic use," said Matthias Eiber, attending physician, Department of Nuclear Medicine, Klinikum rechts der Isar, TUM. "PSMA-targeted imaging agents labeled with ^{18}F offer potential advantages that are important considerations in detecting and localizing prostate cancer - broad availability, based on the radioisotope's 110-minute half-life; consistent, centralized manufacturing with high batch production and high resolution PET scans."

Diagnostic efficacy of F-18-rhPSMA-7.3 PET Imaging for N-staging in Intermediate and High-Risk Prostate Cancer Patients Validated by Histopathology

The oral presentation detailed a 56-patient retrospective analysis investigating the efficacy of rhPSMA-7.3 (^{18}F) PET/CT for primary lymph node staging in patients with intermediate and high-risk prostate cancer, spearheaded by Thomas Langbein, resident, Department of Nuclear Medicine, Klinikum rechts der Isar, TUM. Results from on-site reads were compared to morphological imaging and validated by histopathology. Patient-based analysis indicated that the sensitivity, specificity and diagnostic accuracy of rhPSMA-7.3 (^{18}F) PET imaging were 81.3% (95% CI, 54.4–96.0%), 87.5 (95% CI, 73.2–95.8%) and 85.7% (95% CI, 73.8–93.6%), respectively. Those for morphological imaging were 33.3% (95% CI, 13.3–59.0%), 89.5% (95% CI, 75.2–97.1%) and 71.4% (95% CI, 57.8–82.7%), respectively. On template-based analysis, the sensitivity, specificity and accuracy of rhPSMA-7.3 (^{18}F) PET were 63.6% (95% CI, 45.4-79.6%), 97.9% (95% CI, 95.5-99.2%) and 94.4% (95% CI, 91.2-96.6%), respectively, and those for morphological imaging were 15.2% (95% CI, 5.11-31.9%), 99.3%(95% CI, 97.5-99.9%) and 90.6% (95% CI, 86.9-93.6%), respectively. The mean PSA level of the patients in this primary prostate cancer study was 11.0 ng/mL.

About rhPSMA

rhPSMA-7.3 (^{18}F) consists of a radiohybrid Prostate-Specific Membrane Antigen (PSMA)-targeted receptor ligand which attaches to and is internalized by prostate cancer cells, and is labeled with the ^{18}F radioisotope for PET imaging. rhPSMA compounds can also be labeled with radioisotopes such as ^{177}Lu and ^{225}Ac for therapeutic use. Blue Earth Diagnostics acquired exclusive, worldwide rights to rhPSMA imaging technology from Scintomics in 2018, with an option to therapeutic rights. rhPSMA originated from the Technical University of Munich, Germany, and has been utilized clinically under German legislation at the Department of Nuclear Medicine there for the diagnostic imaging of men with both primary and recurrent prostate cancer. rhPSMA compounds have not received regulatory approval.

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.

This press release is intended to provide information about Blue Earth Diagnostics' business in the United States and Europe. Please be aware that the approval status and product label for Axumin varies by country worldwide. For EU Axumin product information refer to: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004197/human_med_002100.jsp&mid=WC0b01ac058001d124.

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.

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. Fluciclovine F 18 has a broad range of other potential applications in cancer imaging and Blue Earth Diagnostics is investigating the molecule for other cancers including in neuro-oncology. The company's pipeline includes innovative Prostate Specific Membrane Antigen (PSMA)-targeted radiohybrid ("rh") agents, which are a clinical-stage, investigational class of theranostic compounds, with potential applications in both the imaging and treatment of prostate cancer. Blue Earth Diagnostics is a subsidiary of Bracco Imaging S.p.A., a global leader in diagnostic imaging. For more information, visit: www.blueearthdiagnostics.com.

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