PRESS RELEASE

Blue Earth Diagnostics Announces Results from Initial Clinical Experience of ^{18}F-rhPSMA-7 PET Imaging in High-risk Primary and Biochemical Recurrent Prostate Cancer by Technical University of Munich

- Results related to Company's investigational radiohybrid PSMA acquisition presented at AUA2019 -

BURLINGTON, Mass. and OXFORD, UK, May 6, 2019 – Blue Earth Diagnostics, a molecular imaging diagnostics company, today announced results from early clinical experience in Germany with positron emission tomography/computed tomography (PET/CT) imaging using a lead radiohybrid Prostate Specific Membrane Antigen-targeted compound (^{18}F-rhPSMA-7) by the Technical University of Munich (TUM) in two presentations at AUA2019. Blue Earth Diagnostics acquired exclusive rights to a broad family of rhPSMA agents in 2018.

- In an oral presentation, results of a retrospective analysis of 58 patients with high risk primary prostate cancer indicated that ^{18}F-rhPSMA-7 PET/CT demonstrated sensitivity of 72% (13/18), specificity of 93% (37/40) and diagnostic accuracy 86% (50/58), when compared to histopathological findings.
- A poster presentation described results from another retrospective analysis of 261 patients with biochemically recurrent prostate cancer in which ^{18}F-rhPSMA-7 PET/CT demonstrated a detection rate of 81% (211/261) at a median PSA level of 0.96 ng/mL.

These retrospective analyses were presented at the American Urological Association's 2019 Annual Meeting, AUA2019, May 3-6, 2019 in Chicago, Ill.

NOTE: this early clinical experience with ^{18}F-rhPSMA-7 by TUM in Germany, consistent with the German Medicinal Products Act 13 (2b), reflects use of an investigational agent for which safety and efficacy have not been established by the U.S. Food and Drug Administration.

"We are very pleased that TUM is able to share the results of this initial clinical experience with the prestigious urology community at AUA2019," said Jonathan Allis, D. Phil., CEO of Blue Earth Diagnostics. "Blue Earth Diagnostics acquired rhPSMA last year as part of our mission to develop and commercialize innovative PET imaging agents for cancer. rhPSMA is a strategic expansion of our technologically advanced imaging portfolio, and a complement to approved, commercially available Axumin® (fluciclovine F 18). We believe that both agents may ultimately provide physicians and their patients living with recurrent prostate cancer the ability to select the diagnostic agent most appropriate to each specific clinical situation. We are currently progressing development of a lead ^{18}F-rhPSMA imaging candidate and collaborating with Scintomics to identify optimized therapeutic candidates for future development."

"Effective staging of primary prostate cancer and determining the extent and location of recurrent disease are important elements in determining appropriate management of 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 AUA2019. "The retrospective analyses of ^{18}F-rhPSMA-7 PET/CT demonstrated an accuracy of 86% (50/58) in men with primary prostate cancer and a detection rate of 81% (211/261) in men with biochemical recurrence, at a median PSA level of 0.96 ng/mL. These preliminary data are encouraging and support further research with rhPSMA."

"The TUM initial experience with ^{18}F-rhPSMA-7 has allowed us to investigate the potential diagnostic performance of a new class of theranostic PSMA-targeting agents that enable efficient labelling with imaging radioisotopes such as ^{18}F for PET imaging or ^{177}Lu for therapeutic use," said Matthias Eiber, MD, Department of Nuclear Medicine, Klinikum rechts der Isar, TUM. "PSMA-targeted imaging agents labeled with ^{18}F offer the advantages of broad availability, based on the radioisotope's half-life; consistent, centralized manufacturing and high resolution PET scans, all of which are important considerations in detecting and localizing prostate cancer."

About the TUM ^{18}F-rhPSMA-7 PET/CT Presentations at AUA2019

Diagnostic efficacy of ^{18}F-rhPSMA-7 positron emission tomography for lymph node staging in patients with high risk primary prostate cancer

The oral presentation detailed a 58-patient retrospective analysis investigating the efficacy of ^{18}F-rhPSMA-7 PET/CT for primary lymph node staging of prostate cancer compared with conventional imaging and histopathology. Patient-based analysis indicated that the sensitivity, specificity and accuracy of ^{18}F-rhPSMA-7 PET/CT were 72.2% (13/18), 92.5% (37/40) and 86.2% (50/58), respectively. Those for morphological imaging were 50.0% (9/18), 72.5% (29/40) and 65.5% (38/58), respectively. On template-based analysis, the sensitivity, specificity and accuracy of ^{18}F-rhPSMA-7 PET/CT were 51.9% (28/54), 96.6% (311/321) and 91.4% (339/371), respectively and those for morphological imaging were 11.1% (6/54), 95.3% (306/321) and 84.1% (312/371), respectively. The mean PSA level in the primary prostate cancer study was 12.4 ng/mL.

^{18}F-rhPSMA-7 positron emission tomography for the detection of biochemical recurrence of prostate cancer following radical prostatectomy

The poster presentation described results from a retrospective dataset analysis of 261 patients with non-castrate biochemical recurrence after radical prostatectomy who underwent ^{18}F-rhPSMA-7 PET/CT imaging. The detection rate of presumed recurrence sites was correlated with patients' PSA level, primary Gleason score and prior therapy. Results demonstrated that 211 patients (80.8%) (211/261) showed pathological findings on ^{18}F-rhPSMA-7 PET/CT. Detection rates were 71.2% (42/59) at PSA levels of 0.2 to <0.5 ng/mL; 86.3% (44/51) at PSA levels of 0.5 to <1 ng/mL; 85.7% (42/49) at PSA levels of 1 to <2 ng/mL and 95.0% (76/80) at PSA levels ≥ 2ng/mL. ^{18}F-rhPSMA-7 PET/CT revealed local recurrence in 43.3% (113) patients. Lymph node metastases were present in the pelvis in 42.2% (110), in the retroperitoneum in 17.2% (45) and in the supradiaphragmatic location in 8.0% (21) patients. Bone and visceral metastases were detected in 20.7% (54) and 3.8% (10) patients, respectively. In 31.8% (7/22) patients with a PSA < 0.2 ng/ml, suspicious lesions were present. Detection efficacy was not influenced by prior external beam radiation therapy (EBRT) (79.1% vs. 82.1%; p = 0.55), androgen deprivation

therapy (ADT) within the 6 months preceding imaging (80.6% vs. 80.9%; p = 0.54) or by primary Gleason score (77.9% for Gleason Score ≤ 7 vs. 82.6% for Gleason Score ≥ 8; p = 0.38).

About rhPSMA

Blue Earth Diagnostics acquired exclusive, worldwide rights to radiohybrid Prostate Specific Membrane Antigen (PSMA)-targeted technology (rhPSMA) from Scintomics in 2018. rhPSMA originated from the Chair of Pharmaceutic Radiochemistry at the Technical University of Munich, Germany, by Alexander Wurzer and Hans Juergen Wester, and has been utilized clinically under German legislation at the Department of Nuclear Medicine for the diagnostic imaging of men with both primary and recurrent prostate cancer. ^{18}F-rhPSMA consists of a prostate-specific membrane antigen (PSMA) 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. ^{18}F-rhPSMA, ^{177}Lu-rhPSMA and ^{225}Ac-rhPSMA 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. Presentations about ^{18}F-rhPSMA-7 discuss experiences with an investigational agent for which the safety and efficacy have not been established by the FDA.

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. 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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