PRESS RELEASE

Blue Earth Diagnostics Announces Results of Additional Analyses from LOCATE Trial Evaluating Change in Recurrent Prostate Cancer Management Following Axumin® (Fluciclovine F 18) PET/CT Imaging

- Presentations at AUA2019 explore Axumin detection rate and relationship to PSA levels, based on extent of recurrence and prior treatment -

BURLINGTON, Mass. and OXFORD, UK, May 6, 2019 – Blue Earth Diagnostics, a molecular imaging diagnostics company, today announced results of additional analyses from the LOCATE clinical trial (NCT02680041) in two presentations at the American Urological Association's 2019 Annual Meeting, AUA2019, May 3-6, 2019 in Chicago, Ill. The LOCATE trial was a prospective, U.S., multicenter, open-label study investigating the impact of ^{18}F-fluciclovine PET/CT imaging on patient management of biochemically recurrent prostate cancer after initial prostate cancer treatment and negative or equivocal findings on standard-of-care imaging.

- An oral presentation summarized LOCATE study results describing the sites of suspected recurrent prostate cancer in 213 patients, according to PSA levels, to investigate the potential for ^{18}F-fluciclovine PET/CT-to evaluate oligometastatic disease (evidence of limited recurrent disease potentially amenable to local treatment). Results indicated that patient level and pelvic region detection rates were broadly proportional to baseline PSA, with clinically important detection noted in pelvic nodes (9.3%), retroperitoneal nodes (5.6%) and bone (6.5%). In total, 25% (53/213) patients had oligometastatic disease. Twenty (38%) of the oligometastatic patients had PSA ≤ 1.0 ng/mL.
- A poster presentation detailed LOCATE study results which evaluated the detection rate (DR) of ^{18}F-fluciclovine PET/CT in men with prostate cancer recurrence with or without radical prostatectomy (RP). The overall DR for ^{18}F-fluciclovine PET/CT was 57% (122/213) and was broadly proportional to the pre-scan PSA level, ranging from 31% (25/81) to 95% (18/19) among patients with a PSA of more than 10ng/mL.

Axumin® (fluciclovine F 18 injection) is an FDA-approved molecular imaging agent 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. (For additional product information please see the end of this news release.)

"In line with our mission to develop and commercialize innovative PET imaging agents for cancer, Blue Earth Diagnostics conducted the U.S.-based LOCATE study to evaluate the utility of ^{18}F-fluciclovine PET/CT in providing physicians with actionable information for the management of men with recurrent prostate cancer," said Jonathan Allis, D. Phil., CEO of Blue Earth Diagnostics. "We are very pleased to share results from additional analyses of the LOCATE study with the prestigious urology community at AUA2019."

"The LOCATE study evaluated men with biochemically recurrent prostate cancer who had conventional imaging scans which were either negative or equivocal, and compared their treatment plans before and after ^{18}F-fluciclovine PET/CT to assess whether or not it impacted their management," said Gerald L. Andriole, MD, the Robert K. Royce Distinguished Professor and Chief of Urologic Surgery at Washington University School of Medicine in St. Louis and lead author on behalf of the LOCATE study group. "Results of the study indicated an overall detection rate of 57% (122/213) for ^{18}F-fluciclovine PET/CT in identifying lesions, that increases with increasing PSA and is higher among patients with intact prostate than those had previously undergone radical prostatectomy. As well, pelvic region detection rates were broadly proportional to baseline PSA."

Dr. Andriole continued, "Prostate cancer will recur in up to 30% of patients after initial treatment. In this study, for example, 25% (53/213) of patients had oligometastatic disease, with 38% (20/53) having PSA levels of less than or equal to 1.0 ng/mL. The ability to determine the extent and location of recurrent prostate cancer, in conjunction with other available clinical information, can inform the management plan for men with recurrent disease."

About the LOCATE ^{18}F-fluciclovine PET/CT Presentations at AUA2019

Sites of prostate cancer recurrence delineated with ^{18}F-fluciclovine positron emission tomography in patients with negative or equivocal conventional imaging

The oral presentation characterized sites of recurrence according to PSA using data from LOCATE, and explored the potential for ^{18}F-fluciclovine PET/CT to evaluate oligometastatic disease. Eligible men underwent ^{18}F-fluciclovine PET/CT according to standard protocols, with results for 213 patients stratified by baseline PSA levels. Oligometastatic disease was defined as 1–5 extraprostatic lesions (≤ 3 lesions in any single organ system) in men with negative prostate/bed imaging (as a surrogate for primary tumor control). ^{18}F-fluciclovine PET/CT detected lesions in 57% (122/213) of men. Patient level and pelvic region detection rates were broadly proportional to baseline PSA. At PSA < 1.0 ng/mL, substantial detection was noted in pelvic nodes at a rate of 9.3% (10/107), in retroperitoneal nodes at a rate of 5.6% (6/107) and in bone at a rate of 6.5% (7/107). In total, 53/213 (25%) had oligometastatic disease; 52 (24%) with 1–3 metastases and 1 (0.5%) with 5 metastases. Twenty (38%) of the oligometastatic patients had PSA ≤ 1.0 ng/mL.

Localization of recurrence of prostate cancer with ^{18}F-fluciclovine positron emission tomography in patients with and without prior prostatectomy: Results from LOCATE

The poster presentation described data from the LOCATE study to evaluate the detection rate (DR) of ^{18}F-fluciclovine PET/CT in men with prostate cancer recurrence with or without radical prostatectomy (RP). Eligible men underwent ^{18}F-fluciclovine PET/CT imaging according to standard protocol at one of 15 U.S. centers. Scan findings for 213 patients were stratified according to patients' prior therapy and baseline characteristics. In total, 164/213 (77%) men had RP prior to enrollment. PSA levels ranged more widely among the prior RP group compared with the intact prostate group, although the intact prostate group had a higher median PSA. ^{18}F-Fluciclovine-avid lesions were found in 122 (57%) men, with a DR of 49% (81/164) in men with prior RP and 84% (41/49) in the intact prostate group. The overall DR was

broadly proportional to the pre-scan PSA and ranged from 31% among those with a PSA < 0.5 ng/mL to 95% among patients with a PSA > 10 ng/mL. In the prior prostatectomy group, the DR ranged from 31% at PSA < 0.5 ng/mL to 95% at PSA > 10 ng/mL. In this cohort of men with PSA-recurrence but negative/equivocal standard imaging, the majority were shown to have one or more lesion by ^{18}F-fluciclovine PET/CT. The DR increased with increasing PSA and was higher among patients with intact prostate than those who had previously undergone RP.

About the LOCATE Trial

Blue Earth Diagnostics' investigational LOCATE study ("The Impact of ^{18}F Fluciclovine (FACBC) PET/CT (Positron Emission Computed Tomography) on Management of Patients with Rising PSA (Prostate-specific Antigen) After Initial Prostate Cancer Treatment"), was a U.S. multi-center study investigating the impact of ^{18}F fluciclovine PET/CT imaging on the management of patients with rising PSA after initial prostate cancer treatment. The clinical utility of ^{18}F fluciclovine PET/CT imaging was assessed by the change from initial management recommendation to the treatment plan after scanning with ^{18}F fluciclovine PET/CT. Additional information about the LOCATE trial is available at: www.clinicaltrials.gov (NCT02680041).

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 Axumin® (fluciclovine F 18)

Axumin (fluciclovine F 18) injection is a novel product indicated for use in positron emission tomography (PET) imaging to identify suspected sites of prostate cancer recurrence in men. Recurrence of prostate cancer is suspected by an increase in prostate specific antigen (PSA) levels following prior treatment. PET imaging with Axumin may identify the location and extent of such recurrence. Axumin was developed to enable visualization of the increased amino acid transport that occurs in many cancers, including prostate cancer. It consists of a synthetic amino acid that is preferentially taken up by prostate cancer cells compared with surrounding normal tissues, and is labeled with the radioisotope F 18 for PET imaging. Fluciclovine F 18 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. Axumin was approved by the U.S. Food and Drug Administration in May 2016, following Priority Review, and is the first product commercialized by Blue Earth Diagnostics, which licensed the product from GE Healthcare. The molecule is being investigated by Blue Earth Diagnostics for other potential cancer indications, such as glioma.

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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