NEWS RELEASE

The Journal of Urology Publishes Results from Blue Earth Diagnostics' LOCATE Trial of Role of ^{18}F Fluciclovine PET/CT Imaging in the Management of Men with Recurrent Prostate Cancer

- Results show that 59% of men with recurrent prostate cancer following prior treatment had a change in their management plan after ^{18}F fluciclovine PET/CT imaging -

BURLINGTON, Mass. and OXFORD, UK – September 11, 2018 – Blue Earth Diagnostics, a molecular imaging diagnostics company, announced the peer-reviewed publication of results from an investigational clinical trial ("LOCATE") evaluating 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. The LOCATE trial is a prospective, multi-center, open-label study (NCT02680041) conducted at 15 sites in the United States. Its primary endpoint measured the percentage of men with biochemical recurrence of prostate cancer following initial prior therapy whose treatment plan was changed following an ^{18}F fluciclovine PET/CT scan.

The manuscript, "The Impact of Positron Emission Tomography with ^{18}F-Fluciclovine on the Management of Patients with Biochemical Recurrence of Prostate Cancer: Results from the LOCATE Trial," was accepted by *The Journal of Urology* and is now available online: *The Journal of Urology®* (2018), doi:10.1016/j.juro.2018.08.050. The manuscript will also appear in an upcoming print issue. Lead authors are Gerald L. Andriole, Washington University School of Medicine, St. Louis, Mo.; Lale Kostakoglu, The Icahn School of Medicine at Mount Sinai, New York, NY; Albert Chau, Blue Earth Diagnostics, Oxford, UK; Fenghai Duan, Brown University, Providence, RI; Umar Mahmood, Massachusetts General Hospital, Boston, Mass.; David A. Mankoff, University of Pennsylvania, Philadelphia, Pa.; David M. Schuster, Emory University, Atlanta, Ga.; and Barry A. Siegel, Washington University School of Medicine, St. Louis, Mo. on behalf of the LOCATE Study Group.

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.)

The LOCATE trial prospectively evaluated 213 men with suspected recurrence of prostate cancer based on rising PSA levels (median PSA 1.00ng/mL) following previous curative-intent treatment, but with negative or equivocal findings on standard-of-care

imaging. Overall, ^{18}F fluciclovine PET/CT was positive in 57% of the evaluable patients. The study investigators used a questionnaire to document the patient's intended treatment plan prior to ^{18}F fluciclovine PET/CT and then to record if and how that plan was altered after reviewing the results of the scan with the patient. Results of the trial indicated that 59% (126/213) of patients had their clinical management changed when results of the ^{18}F fluciclovine PET/CT imaging were included in the diagnostic work-up. Of those changes, 78% (98/126) were classified as "major" (i.e., a change in treatment modality) and 22% (28/126) were classified as "other" (i.e., a change within a treatment modality).

Of 128 patients whose original treatment plan was salvage radiation therapy (with or without androgen deprivation therapy (ADT)), 51% (65/128) had their treatment changed after ^{18}F fluciclovine PET/CT. Of 60 patients originally planned to be treated with ADT, 75% (45/60) had their treatment changed to a non-systemic salvage treatment after ^{18}F fluciclovine PET/CT. The specific treatment plan selected after the^{18}F fluciclovine PET/CT imaging results were available was based on the independent judgment of the study investigators, who utilized any other available confirmatory information. The clinical utility of ^{18}F fluciclovine PET/CT to identify a particular course of treatment has not been established and clinical correlation, including potential histopathological evaluation of the suspected recurrence site, is recommended. Longer term follow-up is needed to confirm how incorporation of ^{18}F fluciclovine PET/CT into therapy planning will affect outcomes. The safety profile of ^{18}F fluciclovine in the LOCATE trial is consistent with that described in the approved U.S. Prescribing Information.

"We are extremely pleased that the results from the LOCATE study were so rapidly made available to the physician community through publication in the well-respected *Journal of Urology*," said Jonathan Allis, D. Phil., CEO of Blue Earth Diagnostics. "Blue Earth Diagnostics is focused on developing and commercializing innovative PET imaging agents for cancer. In line with that mission, the U.S.-based LOCATE study evaluated the utility of ^{18}F fluciclovine PET/CT in providing physicians with actionable information for the management of men with recurrent prostate cancer."

"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 showed that management plans were revised for 59% of patients, and that more than 75% of such revisions involved a change in treatment modality. The findings indicate that ^{18}F fluciclovine PET/CT provides beneficial information for treatment planning in men with suspected biochemical recurrence of prostate cancer and merits

further investigation of the long-term clinical outcomes following fluciclovine-guided patient management."

"The ability to determine the extent and location of recurrent prostate cancer can inform the clinical management plan for men with the disease. This is an important consideration for physicians and their patients, as up to 30% of patients with prostate cancer will develop local or distant recurrences within 10 years of radical prostatectomy or radiation therapy," said Lale Kostakoglu, MD, MPH, Professor of Radiology and Chief of Nuclear Medicine, Icahn School of Medicine at Mount Sinai, New York, NY and member of one of the LOCATE study group's leading enrollment sites. "The LOCATE study demonstrated that imaging with ^{18}F fluciclovine PET/CT can reveal the sites of disease recurrence in men with biochemically recurrent prostate cancer and, based on the pattern of recurrence together with the other available clinical information, this resulted in a change in management in 59% of the patients."

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"), is 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 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 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 Prostate / Recurrent Prostate Cancer
Prostate cancer is the second leading cause of cancer death in men in the United States. While most primary prostate cancer can be successfully treated, the disease recurs in approximately one-third of patients. In some patients, recurrent disease is detectable only by a rise in prostate specific antigen (PSA) levels, yet the location of the recurrence cannot consistently be located by conventional imaging, potentially impacting subsequent management of these patients.

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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