BLUE EARTH DIAGNOSTICS

NEWS RELEASE

Blue Earth Diagnostics' FALCON Trial of Fluciclovine (^{18}F) PET/CT Imaging in Recurrent Prostate Cancer Stops Recruitment after Successful Interim Analysis

- Study evaluates clinical utility of fluciclovine (^{18}F) PET/CT imaging in men with recurrent prostate cancer following prior treatment -

OXFORD, UK and BURLINGTON, Mass. – May 12, 2017 – Blue Earth Diagnostics, a molecular imaging diagnostics company, announced that the Trial Steering Committee recommended that further recruitment be stopped in the FALCON clinical study of fluciclovine (^{18}F) PET/CT imaging, based on successful results of a pre-planned interim analysis. The FALCON trial, announced in March 2016, is a U.K.-based, open-label study (NCT02578940) to evaluate the clinical impact of fluciclovine (^{18}F) PET/CT imaging on patient management decisions in men with biochemically recurrent prostate cancer.

In 2016, the U.S. Food and Drug Administration approved Axumin™ (fluciclovine F 18), a novel 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.

The primary endpoint of the FALCON study examines the percentage of men who have their management plan changed after a fluciclovine (^{18}F) scan. The single, pre-planned interim analysis of the primary endpoint was performed based on the first 85 evaluable patients. Based on the interim analysis results, recruitment in the trial was to be stopped due to efficacy.

The efficacy and safety of fluciclovine (^{18}F) to impact patient management decisions is currently under clinical investigation. Blue Earth Diagnostics plans to present results of this interim analysis of the FALCON trial at an upcoming medical congress and subsequently publish full results in a peer-reviewed publication.

"The primary aim of the UK multi-center FALCON trial of fluciclovine (^{18}F) PET/CT imaging was to assess its clinical impact on treatment decisions in men with recurrent prostate cancer being considered for radical potentially curative treatment," said Dr Fergus Gleeson, Professor of Radiology, University of Oxford, Oxford, UK, and Chief Investigator on the study. "Study recruitment has been stopped because of the significant numbers of changes to treatment made following the scan. In addition, we want to evaluate other criteria such as its diagnostic performance and the effect that PSA level may have on the probability of lesion detection by fluciclovine (^{18}F).

"We are pleased at the Trial Steering Committee's recommendation for the FALCON trial, and we look forward to sharing the results with the medical community at an upcoming scientific congress," said Jonathan Allis, D. Phil., CEO of Blue Earth Diagnostics. "Axumin can provide actionable information for physicians treating patients with suspected recurrent prostate cancer, and Blue Earth is committed to continuing efforts that may benefit men with recurrent disease."

"Biochemically recurrent prostate cancer poses an important medical challenge, as it occurs in up to one third of men who have been previously treated, and current commercially available anatomical imaging techniques are limited in the amount of information they provide," said Judd Moul, M.D., Professor of Surgery, Urology, at Duke University. "Information provided by an Axumin PET scan provides useful information about the location and extent of suspected recurrent disease and has the potential to provide information to facilitate the appropriate care of men with recurrent prostate cancer."

Blue Earth Diagnostics also announced that the 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"), has completed patient enrollment earlier than anticipated. The LOCATE trial is a U.S. multi-center study designed to assess the impact on patient management of ^{18}F fluciclovine PET imaging in patients with rising PSA after initial prostate cancer treatment. The clinical utility of ^{18}F fluciclovine PET/CT imaging will be assessed by the change from initial to revised treatment plan. Additional information about the LOCATE trial is available at: www.clinicaltrials.gov (NCT02680041).

About the FALCON Trial

The FALCON trial, "Fluciclovine (^{18}F) PET/CT in biochemicAL reCurrence Of prostate caNcer (FALCON)," is an open-label multi-center study in the U.K. designed to assess the clinical utility of fluciclovine (^{18}F) PET imaging in the management of patients with prostate cancer with biochemical recurrence after initial treatment. The primary endpoint is to evaluate the clinical impact of fluciclovine (^{18}F) in affecting treatment decision and is assessed by comparing records of the patient's treatment plan after a fluciclovine (^{18}F) PET scan with the treatment plan prior to the scan. Secondary endpoints include evaluation of the effect of treatment change in patients with positive fluciclovone (^{18}F) PET imaging findings who had a treatment change involving radical salvage therapy; diagnostic performance; PSA threshold; safety assessment and comparison with choline PET (if performed).

As stated in the protocol, a single, pre-planned interim analysis of the primary endpoint was to be performed based on the first 85 evaluable patients. If the number of treatment changes is greater than 45, the trial will stop recruitment early due to

efficacy. If the number of treatment changes is 8 or fewer, the trial will stop recruitment early due to futility.

The FALCON trial is jointly funded by Innovate UK and Blue Earth Diagnostics and is being conducted at six leading institutions in the UK: Oxford University Hospitals NHS Foundation Trust, University College London, Kings College London, The Royal Marsden NHS Foundation Trust, The Leeds Teaching Hospitals NHS Trust, East and North Hertfordshire NHS Trust and Greater Glasgow Health Board. Additional information about the FALCON trial is available at: www.clinicaltrials.gov (NCT02578940).

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 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 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 for use in PET imaging to detect and localize prostate cancer in men experiencing suspected biochemical recurrence. Blue Earth Diagnostics is funded by Syncona Limited, an investment company listed on the London Stock Exchange (LON: SYNC). For more information, visit www.blueearthdiagnostics.com.

Contact:

For Blue Earth Diagnostics (U.S.)
Priscilla Harlan
Vice President, Corporate Communications
(M) (781) 799-7917

Media
Sam Brown Inc.
Cory Tromblee
(M) (617) 571-7220

p.harlan@blueearthdx.com corytromblee@sambrown.com

For Blue Earth Diagnostics (UK)
Dr. Val Jones
Val Jones PR Ltd
(M) +44 (0) 7917 175 192
v.jones@blueearthdx.com

# # #