

RESULTS FROM BLUE EARTH DIAGNOSTICS' FALCON TRIAL SHOW 64% OF PATIENTS WITH SUSPECTED RECURRENT PROSTATE CANCER HAD CHANGE IN MANAGEMENT FOLLOWING AXUMIN® (FLUCICLOVINE F 18) PET/CT SCAN

September 16, 2019

– Results presented at ASTRO Annual Meeting evaluate clinical utility of ¹⁸F-fluciclovine PET/CT imaging in men with recurrent prostate cancer –

BURLINGTON, Mass. and OXFORD, UK, September 16, 2019 – Blue Earth Diagnostics, a Bracco company focused on molecular imaging diagnostics, today announced results from an investigational clinical trial (“FALCON”) evaluating the impact of ¹⁸F-fluciclovine PET/CT imaging on the clinical management of men with biochemically recurrent prostate cancer eligible for salvage therapy. The FALCON trial is a UK-based, prospective, multi-center, open-label study (NCT02578940). Its primary endpoint examined the percentage of men who had their management plan changed after an ¹⁸F-fluciclovine PET/CT scan.

Axumin® (fluciclovine F 18) injection is approved 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.)

Investigators in the FALCON trial recorded intended patient management plans prior to ¹⁸F-fluciclovine PET/CT imaging and then recorded how the plans were altered following review of the scan results. Results of the trial indicated that 64% (66/104) of patients had their clinical management plan changed when results of ¹⁸F-fluciclovine PET/CT imaging were added to the standard-of-care diagnostic work-up. Of those changes, 65% (43/66) were classified as “major,” denoting a change in treatment modality (e.g. salvage radiotherapy to androgen deprivation therapy (ADT)).

Results from the study were summarized in an oral presentation, “Impact of positron emission tomography (PET) with ¹⁸F-fluciclovine PET/CT on management of patients with recurrence of prostate cancer: results from the FALCON trial,” by David Bottomley, MBBS, St. James Institute of Oncology, Leeds UK, at the 2019 American Society for Radiology Oncology (ASTRO) Annual Meeting, September 15 – 18, 2019.

“We are very pleased to share results from the FALCON study with the radiation oncology community at ASTRO and look forward to publishing the results in an upcoming peer-reviewed journal,” said Jonathan Allis, D. Phil., CEO of Blue Earth Diagnostics. “As part of our mission to develop and commercialize innovative PET imaging agents for cancer, Blue Earth

Diagnostics conducted the FALCON and LOCATE studies to evaluate the utility of a ¹⁸F-fluciclovine PET/CT scan in providing physicians with actionable information for the management of men with recurrent prostate cancer. Each of these two independent, prospective studies arrived at similar conclusions – that ¹⁸F-fluciclovine PET/CT located recurrent disease in the majority of men in the study, which frequently resulted in major changes to their management plans for biochemical recurrence.”

“The FALCON study evaluated men with biochemically recurrent prostate cancer who were being considered for curative-intent salvage therapy, and compared their treatment plans before and after ¹⁸F-fluciclovine PET/CT imaging to assess whether or not it impacted their management,” said David Bottomley, MD, St. James Institute of Oncology, Leeds UK. “Results indicated that management plans were revised for the majority of patients, with 65% of revisions involving a major change in treatment modality. These results indicate that decisions based on ¹⁸F-fluciclovine PET/CT findings may facilitate more personalized management in men with biochemically recurrent prostate cancer. Investigation of the long-term clinical outcomes of these changes in management is warranted.”

The primary endpoint of the FALCON trial examined the percentage of men who had their management plan changed following an ¹⁸F-fluciclovine scan. Previously planned therapeutic management was revised after an ¹⁸F-fluciclovine PET/CT scan in 64% (66/104) of patients. Of the patients with revised treatment plans, major revisions (e.g., salvage radiotherapy to hormone deprivation or watchful waiting) were made for 65% (43/66) of patients. Salvage treatment was revised to watchful waiting for 24% (16/66) patients and to systemic therapy for 24% (16/66) patients, and 17% (11/66) experienced alternative changes to their treatment modality. Of the patients with revised treatment plans, 35% (23/66) had their intended radiotherapy/brachytherapy plans modified. The safety profile of ¹⁸F-fluciclovine in the FALCON trial is consistent with that described in the approved U.S. Prescribing Information.

“Between 30 – 40% of patients with prostate cancer will develop local or distant recurrences within 10 years of radical prostatectomy or radiation therapy, underscoring the need for accurate information on the extent and location of recurrent disease,” said Gerald L. Andriole, MD, the Robert K. Royce Distinguished Professor and Chief of Urologic Surgery at Washington University School of Medicine and lead author on behalf of the LOCATE study group. “Results of the FALCON study are consistent with those of the U.S., multi-center LOCATE study of 213 patients, which demonstrated that 59% of men with recurrent prostate cancer following prior treatment had a change in their management plan after ¹⁸F-fluciclovine PET/CT imaging.”

About the FALCON Trial

The FALCON trial, “Fluciclovine (¹⁸F) PET/CT in biochemicAL reCurrence Of prostate caNcer (FALCON),” was an open-label, multi-center study in the UK designed to assess the clinical utility of ¹⁸F-fluciclovine PET imaging in the management of patients with prostate cancer with biochemical recurrence after initial treatment. The primary endpoint was to evaluate the

clinical impact of ¹⁸F-fluciclovine in affecting treatment decisions and was assessed by comparing records of the patient's treatment plan after an ¹⁸F-fluciclovine PET scan with the treatment plan prior to the scan. Secondary endpoints included evaluation of the optimal PSA threshold for detection, salvage treatment outcome assessment based on ¹⁸F-fluciclovine involvement and safety.

The FALCON trial was jointly funded by Innovate UK and Blue Earth Diagnostics and was 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, Mount Vernon Cancer Centre and Greater Glasgow Health Board. Additional information about the FALCON trial is available at: www.clinicaltrials.gov (NCT02578940).

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 $\leq 1\%$ 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 including neuro-oncology.

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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