THE JOURNAL OF UROLOGY PUBLISHES BLUE EARTH DIAGNOSTICS' PHASE 3 STUDY RESULTS OF AXUMINTM (FLUCICLOVINE F 18) FOR PET IMAGING OF RECURRENT PROSTATE CANCER

October 25, 2016

– Data formed basis for FDA Priority Review and approval –

OXFORD, U.K. and BURLINGTON, Mass. – October 24, 2016 – Blue Earth Diagnostics, Ltd. a molecular imaging diagnostics company, announced the peer-reviewed publication of results from a Phase 3 clinical trial of Axumin (fluciclovine F 18) injection. Axumin is a novel molecular imaging agent indicated 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. Results of the multi-center study, conducted in Norway, Italy and the United States, demonstrated a 68% overall detection rate (DR) for Axumin, with the ability to detect local, as well as distant, prostate cancer recurrence across a wide range of PSA values. Axumin was well tolerated in the study.

The manuscript, "Multi-site experience of the safety, detection rate and diagnostic performance of fluciclovine (^{18}F) PET/CT imaging in the staging of biochemically recurrent prostate cancer," was accepted by *The Journal of Urology* and is now available online: *J Uro*l 2016; doi:10.1016/j.juro.2016.09.117. The manuscript will also appear in an upcoming print issue. The lead authors are T. Bach-Gansmo of Oslo University, Oslo, Norway; C. Nanni of the University of Bologna, Bologna, Italy and P.T. Nieh of Emory University, Atlanta, Ga.

"We are extremely pleased that the data from this Phase 3 study of fluciclovine F 18, or Axumin, can be 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 Ltd. "These data, together with results of a second Phase 3 study, formed the basis for the FDA's Priority Review and approval of Axumin, enabling it to be made available to patients with suspected biochemically recurrent prostate cancer in the United States."

"Axumin was designed and developed by Dr. Mark Goodman at Emory University to enable visualization with PET imaging of increased amino acid transport that occurs in many

cancers," said David M. Schuster, M.D., an investigator in the Axumin Phase 3 study and Associate Professor of Radiology and Imaging Sciences and Director of the Division of Nuclear Medicine and Molecular Imaging, Emory University. "While investigating this PET radiotracer we discovered its utility in detecting and localizing suspected biochemically recurrent prostate cancer. This study was designed to evaluate the diagnostic performance and safety of Axumin in this specific patient population."

"Biochemically recurrent prostate cancer occurs in up to one third of men who have been treated for prostate cancer, and is therefore a very important medical challenge," said Judd Moul, M.D., Professor of Surgery, Urology, at Duke University. "These patients are assumed to have disease present, and knowing the location and extent of suspected disease could profoundly impact patient management decisions. Effective detection and localization of recurrent disease is critical in order to select optimal management for these patients, yet the sensitivity of standard of care anatomical imaging tests is very limited for identifying sites of prostate cancer recurrence. In my opinion, information provided by Axumin PET imaging may provide information critical to developing effective patient management plans with the potential to lead to better outcomes for men with recurrent prostate cancer."

About the Axumin™ Phase 3 Study

This Phase 3 study assessed the diagnostic performance and safety of Axumin imaging of men with biochemical recurrence of prostate cancer. A total of 596 patients underwent Axumin PET/CT imaging at four clinical sites in Norway, Italy and the United States to determine the detection rate (DR) stratified by PSA values. Additionally, the diagnostic performance of Axumin was assessed against histopathology (biopsy) in 143 scans. Results indicated a detection rate (DR) for Axumin of 68% (403/595 patients). In the prostate/bed and pelvic lymph node regions, positive findings were detected in 39% (232/599) and 33% (194/596) of scans, respectively. Metastatic involvement outside the pelvis was detected in 26% (155/591) of Axumin scans. The DR for Axumin in patients in the lowest quartile of baseline PSA (<0.79 ng/mL) was 41% (53/128 patients). Of these patients, 13 had involvement in the prostate/bed only, 16 had pelvic lymph node involvement without distant disease and 24 had distant metastases. For the 143 patient scans, the positive predictive value (PPV) of Axumin PET/CT scanning was 82%. For tumors in the prostate/prostate bed the PPV was 72% and for extraprostatic tumors it was 92%. In this study population, adverse events were reported in 5.4% of patients, with none considered related to Axumin. The safety profile was not altered following repeat administration. The authors concluded that Axumin is well tolerated and able to detect local and distant prostate cancer recurrence across a wide range of PSA values.

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 F18 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. 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 Inc. of Burlington, Mass., is the wholly-owned U.S. subsidiary of U.K.-based Blue Earth Diagnostics Ltd. The Company is funded by Syncona LLP, an independent subsidiary of the Wellcome Trust. For more information, visit www.blueearthdx.com.

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