PRESS RELEASE

Blue Earth Diagnostics Announces Results of an Analysis of the Impact of Axumin® (Fluciclovine F 18) PET/CT Imaging on Androgen Deprivation Therapy (ADT) Planning in Recurrent Prostate Cancer

– 59% of patients with Axumin-informed change in management avoided or delayed ADT –

BURLINGTON, Mass. and OXFORD, UK, September 27, 2021 – Blue Earth Diagnostics, a Bracco company and recognized leader in the development and commercialization of innovative PET radiopharmaceuticals, today announced results of a secondary, post-hoc analysis of data from the prospective LOCATE and FALCON clinical trials that evaluated the impact of Axumin® (fluciclovine F 18) PET/CT imaging on management of patients with recurrent prostate cancer. This analysis characterized the impact of Axumin PET/CT on sites of disease recurrence and plans for androgen deprivation therapy (ADT) in patients with biochemical recurrence of prostate cancer. Of 146 patients who had a pre-scan plan for ADT, Axumin PET/CT detected lesions in 85 (58%) of patients. Detection rates in the prostate/bed, pelvic lymph nodes, extra-pelvic lymph nodes, soft tissue and bone were 30% (44/146), 25% (37/146), 13% (19/146), 2.1% (3/146) and 13% (19/146), respectively. Among the 146 patients with a pre-scan plan for ADT, 64% (93/146) had a change in their management plan following an Axumin scan. Of those whose management plan changed, 59% (55/93) avoided or delayed ADT. Of 60 patients originally planned for ADT monotherapy, only 25% (15) were still due to receive ADT monotherapy after Axumin PET/CT imaging. Axumin, a novel amino acid-based radiopharmaceutical, is FDA-approved for PET imaging in men with suspected prostate cancer recurrence based on elevated blood prostate specific antigen (PSA) levels following prior treatment. The secondary analysis is based on the Axumin LOCATE and FALCON trials, which have safety profiles consistent with that described in the approved U.S. Prescribing Information.

"Prostate cancer will recur in up to 30% of patients after initial treatment," said Gerald L. Andriole, MD, the Robert K. Royce Distinguished Professor and Chief of Urologic Surgery at Washington University School of Medicine. "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. Informed decision-making can facilitate personalized patient management. ADT is commonly used to treat recurrent prostate cancer, but may produce undesirable side effects for many patients, and may also lose effectiveness over time. This analysis of data from the LOCATE and FALCON trials indicated that ADT was avoided in approximately 40% (55/146) of the men originally intended for ADT, based on the information provided by ^{18}F-fluciclovine PET/CT imaging. Management plans were commonly amended to target salvage therapy to lesions identified with ^{18}F-fluciclovine PET/CT, and consequently likely spared these patients the potential systemic morbidity often associated with ADT."

"As the recognized leader in diagnostic PET prostate cancer imaging, Blue Earth Diagnostics continues to advance scientific knowledge about the proven clinical utility of Axumin," said David Gauden, D.Phil., President and Chief Scientific Officer of Blue Earth Diagnostics. "Blue Earth's independent, prospective FALCON and LOCATE studies demonstrated that Axumin PET/CT located recurrent disease in the majority of men in the study, which frequently resulted in significant changes to their management

plans for biochemical disease recurrence. Notably, Emory University's independent EMPIRE-1 study (NCT01666808), recently published in The Lancet, demonstrated that treatment informed by Axumin PET imaging significantly improved event-free-survival for men with recurrent prostate cancer at three and four years. These studies highlight the role that Axumin molecular imaging can have in guiding informed patient care."

Dr. Gauden continued, "In the United States, Axumin PET imaging has informed healthcare decisions for more than 125,000 men with recurrent prostate cancer across the country, where it is available at more than 1,300 imaging centers and widely reimbursed. Axumin availability and reimbursement continue to expand in Europe, with additional access anticipated this year. We are committed to helping patients through innovative diagnostic solutions that empower the evolution of care for men with recurrent prostate cancer, and we look forward to helping even more patients in the future."

Results from the secondary analysis were summarized in an oral presentation, "Impact of ^{18}F-Fluciclovine PET/CT on Plans for ADT in Patients with Biochemical Recurrence of Prostate Cancer; Analysis from Two Prospective Clinical Trials," by Gerald L. Andriole, MD, Division of Urologic Surgery, Department of Surgery and the Alvin J. Siteman Cancer Center, Washington University School of Medicine, St. Louis, Mo., at the Fifth Global Summit on Precision Diagnosis and Treatment of Prostate Cancer, on September 23, 2021.

About the LOCATE and FALCON Clinical Trials

The LOCATE trial (NCT02680041) was 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. Results 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).

The UK-based FALCON trial (NCT02578940) was a prospective, multi-center open-label multi-center study. Its primary endpoint evaluated the clinical impact of ^{18}F-fluciclovine in affecting treatment decisions as assessed by comparing records of the patient's treatment plan after an ^{18}F-fluciclovine PET scan with the treatment plan prior to the scan. Results indicated that 64% (66/104) of patients had their clinical management plan changed when results of ^{18}F-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.

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 https://www.axumin.com/prescribing-information.pdf.

About Blue Earth Diagnostics

Blue Earth Diagnostics, an indirect subsidiary of Bracco Imaging S.p.A., is a growing international molecular imaging company focused on delivering innovative, well-differentiated diagnostic solutions that inform patient care. Formed in 2014, the Company's success is driven by its management expertise and supported by a demonstrated track record of rapid development and commercialization of positron emission tomography (PET) radiopharmaceuticals. Blue Earth Diagnostics' expanding oncology portfolio encompasses a variety of disease states, including prostate cancer and neuro-oncology. Blue Earth Diagnostics is committed to the timely development and commercialization of precision radiopharmaceuticals for potential use in imaging and therapy. For more information, please visit: www.blueearthdiagnostics.com.

About Bracco Imaging

Bracco Imaging S.p.A., part of the Bracco Group, is a world-leading diagnostic imaging provider. Headquartered in Milan, Italy, Bracco Imaging develops, manufactures and markets diagnostic imaging agents and solutions. It offers a product and solution portfolio for all key diagnostic imaging modalities: X-ray imaging (including Computed Tomography-CT, Interventional Radiology, and Cardiac Catheterization), Magnetic Resonance Imaging (MRI), Contrast Enhanced Ultrasound (CEUS), and Nuclear Medicine through radioactive tracers and novel PET imaging agents to inform clinical management and guide care for cancer patients in areas of unmet medical need. Our continually evolving portfolio is completed by a range of medical devices, advanced administration systems and dose-management software. In 2019 Bracco Imaging also enriched its product portfolio by expanding the range of oncology nuclear imaging solutions in the urology segment and other specialties with the acquisition of Blue Earth Diagnostics. Visit: www.braccoimaging.com.

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