

BLUE EARTH DIAGNOSTICS ANNOUNCES UPCOMING PRESENTATIONS FROM FALCON STUDY OF AXUMIN® (FLUCICLOVINE F18) PET/CT IMPACT ON CLINICAL MANAGEMENT OF RECURRENT PROSTATE CANCER

February 12, 2020

– ASCO 2020 Genitourinary Cancers Symposium and Radiation Oncology Summit: ACRO 2020 –

BURLINGTON, Mass. and OXFORD, UK, February 11, 2020 – Blue Earth Diagnostics, a Bracco company focused on molecular imaging diagnostics, today announced upcoming presentations of additional analyses from the FALCON clinical trial (NCT02578940) of Axumin® (fluciclovine F18) injection), which evaluated its impact on the management of patients with recurrent prostate cancer. The presentations are part of the scientific programs for the ASCO 2020 Genitourinary Cancers Symposium (ASCO GU), February 13 – 15, 2020, in San Francisco, Calif., and the Radiation Oncology Summit: ACRO 2020, February 26 – 29, 2020, in Fort Lauderdale, Fla. Details of the presentations to be given by Blue Earth Diagnostics and its collaborators are listed below.

Blue Earth Diagnostics also provided an update that full results from the FALCON study will be published in an upcoming issue of the *International Journal of Radiation Oncology, Biology, Physics*.

ASCO 2020 Genitourinary Cancers Symposium (ASCO GU), February 13 – 15, 2020

Date: Thursday, February 13, 2020 11:30 a.m. – 1:00 p.m. and 5:30 – 6:30 p.m. PT

Presentation: **Impact of 18F-fluciclovine PET on salvage radiotherapy plans for men with post-radical prostatectomy recurrence of prostate cancer**

Abstract Number: 19

Presenter: Professor Heather Payne, FRCP, FRCR, University College Hospital, London

Session Title & Times: Prostate Cancer and Trials in Progress

Poster Session A: Prostate Cancer, Board A7

11:30 a.m. – 1 p.m., 5:15 – 6:15 p.m. PT

Location: Moscone West Building, San Francisco, Calif.

Blue Earth Diagnostics invites participants at the ASCO Genitourinary (GU) Cancers Symposium 2020 to attend the presentation above and to visit the company at Exhibit Booth 46.

Radiation Oncology Summit: ACRO 2020, February 26 – 29, 2020, Fort Lauderdale, Fla.

Date: Saturday, February 29, 2020

Presentation: **The impact of prior prostatectomy on the detection of prostate cancer recurrence with 18F-fluciclovine: Imaging results from the FALCON trial**

Abstract Number: 20

Presenter: Eugene Teoh, MD, Blue Earth Diagnostics (Oxford University Hospitals NHS Trust at time of study)

Session Title & Times: Poster Presentations

8:00 a.m. – 1:30 p.m. ET

Location: Westin Fort Lauderdale Beach Foyer, Las Olas ballrooms, Fort Lauderdale, Fla.

Blue Earth Diagnostics invites participants at ACRO 2020 to attend the presentation above and to visit the company at Exhibit Booth 27. The company is also hosting a satellite symposium event, “Detecting and Localizing Recurrent Prostate Cancer with Axumin® (fluciclovine F 18),” with invited speaker Dr. Steven Finkelstein, MD, DABR, FACRO, Florida Cancer Affiliates, US Oncology Network, which will be held on Thursday, February 27, 2020, from 12:00 – 1:00 p.m. ET, in the Rio Vista room.

NOTE: Axumin® (fluciclovine F 18) injection is FDA-approved 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

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 U.S. Axumin prescribing information is available at www.axumin.com.

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.

Contact:

For Blue Earth Diagnostics (U.S.) Media

Priscilla Harlan

Vice President, Corporate Communications

(M) (781) 799-7917

p.harlan@blueearthdx.com

For Blue Earth Diagnostics (UK)

Clare Gidley

Acting Communications Manager

Tel: +44 (0) 7917 536939

c.gidley@blueearthdx.com

Media

Sam Brown Inc.

Mike Beyer

(M) (312) 961-2502

mikebeyer@sambrown.com