# BLUE EARTH DIAGNOSTICS AND NORSK MEDISINSK SYKLOTRONSENTER AS ANNOUNCE MANUFACTURING AND DISTRIBUTION PARTNERSHIP FOR FLUCICLOVINE (18F)

March 24, 2016

Blue Earth Diagnostics Ltd. ("BED"), a private diagnostics company, announced that it agreed a new distribution partnership for fluciclovine (18F) with Norsk medisinsk syklotronsenter AS ("NMS") to cover the Norwegian territory.

BED has submitted an application to the European Medicines Agency (EMA) for an EU/EEA marketing authorisation for fluciclovine (18F) for lesion detection and localisation for prostate cancer patients experiencing biochemical recurrence. If granted, NMS, will be responsible for the manufacture, distribution and sale of the product to clinical imaging centers in Norway.

Fluciclovine (18F) is a synthetic amino acid investigational positron emission tomography (PET) radiopharmaceutical being investigated in the imaging of various cancers by BED, with its lead product being in prostate cancer.

# Jonathan Allis, CEO of Blue Earth Diagnostics Ltd., said:

"Blue Earth Diagnostics' mission is to transform the clinical management of cancer through the development of new molecular imaging technologies. It is an exciting time in the Company's development with this Norwegian distribution partnership with NMS coming soon after the U.S. Food and Drug Administration (FDA) acceptance of our New Drug Application (NDA) filing for fluciclovine (18F). The EU/EEA markets are large and attractive markets for us and this collaboration with NMS in Norway is the first step in setting up the distribution network in these important territories."

# **Thor Audun Saga, CEO of NMS, commented:**

"NMS is committed to expanding the range of PET products available to patients in Norway. We look forward to developing a strong partnership with BED and supporting them in the development and distribution of new PET tracers."

Prostate cancer is the second leading cause of cancer in men worldwide. Approximately one third of prostate cancer patients receiving radical first line treatment will subsequently experience recurring disease not detectable on conventional imaging, but accompanied by rising prostate specific antigen ("PSA") levels, which is known as biochemical recurrence.

Blue Earth Diagnostics Ltd. was formed in March 2014 and is funded by Syncona LLP. The Company licensed the PET imaging agent fluciclovine (18F), also known as FACBC, from GE Healthcare.

#### **Further information:**

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#### **Notes for Editors:**

## **About Blue Earth Diagnostics Ltd**

BED is a private, UK based, diagnostics company focused on the development and commercialisation of positron emission tomography (PET) agents. The BED team is made up of industry experts in the field of imaging, chemistry, clinical development, regulatory affairs and commercialisation of nuclear medicine products. For further information please visit: <a href="https://www.blueearthdiagnostics.com">www.blueearthdiagnostics.com</a>

### **About Norsk medisinsk syklotronsenter AS**

NMS has a strong pedigree in PET and was established in 2006 to develop and produce radiopharmaceuticals. It was the largest single investment in advanced medical research and diagnostics that has been implemented in Norway, and started as a joint venture between GE Healthcare AS, the Norwegian Research Council and the Ministry of Education. NMS is owned by Oslo University Hospital, Akershus University Hospital and the University of Oslo. NMS is located at Rikshospitalet in Gaustad, Oslo.

## **About Syncona LLP**

Syncona LLP was founded in 2012 and operates as a healthcare investment company, taking an active role in identifying, developing and funding technologies with the potential to significantly impact the healthcare market of the future. Syncona can take the long view when necessary, able to concentrate investment into opportunities as technology is validated. For further information please visit the Company's website at: www.synconallp.com

# **About positron emission tomography (PET)**

Positron emission tomography (PET) is a test that uses a special type of camera and a <u>tracer</u> (radioactive chemical) to examine biochemical processes in the body. During the test, the tracer liquid is injected into a vein (intravenous, or <u>IV</u>) in the arm. The tracer moves through the body, where much of it collects in the specific organ or tissue. The tracer gives off tiny positively charged particles (positrons). The camera records the emissions and turns the recording into pictures. PET scan pictures show biological function and are complimentary with <u>computed tomography (CT) scans</u> or <u>magnetic resonance imaging (MRI)</u>, which show anatomical information.

## **About Prostate / Recurrent Prostate Cancer**

Prostate cancer is the second leading cause of cancer in men worldwide. Most primary prostate cancer can be successfully treated, but the disease does recur in approximately 35% of patients. In some patients the recurrent disease is detectable only because their PSA rises, however the location of the recurrence cannot be located by conventional imaging. This severely limits making the correct choice for these patients.