

## **BLUE EARTH DIAGNOSTICS AND SIEMENS' PETNET SOLUTIONS ANNOUNCE FDA ACCEPTANCE OF NDA FILING FOR FLUCICLOVINE**

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Blue Earth Diagnostics Ltd. (“BED”), a private diagnostics company, announced that a New Drug Application (NDA) filing for fluciclovine has been accepted by the U.S. Food and Drug Administration (FDA) for priority review.

BED is seeking U.S. marketing approval of fluciclovine for lesion detection and localisation for prostate cancer patients experiencing biochemical recurrence. If approved, Siemens' PETNET Solutions, Inc., will be responsible for the manufacture, distribution and sale of the product to clinical imaging centers in the United States.

Fluciclovine (<sup>18</sup>F) 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. The NDA submission for fluciclovine is based on data from more than 700 prostate cancer patients, most with biochemical recurrence and some with high risk primary disease, imaged in the United States, Norway and Italy.

### **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 and the NDA filing of fluciclovine marks an important step forward for the future of this imaging agent. We are pleased that the FDA has recognised the high unmet medical need in prostate cancer patients and granted the product a priority review, setting the stage for us to bring this important imaging agent to market in the quickest possible time frame.”*

### **Barry Scott, Head of Siemens' PETNET Solutions, Inc., commented:**

*“As the nation’s largest commercial manufacturer and distributor of PET radiopharmaceuticals, we are delighted to work with Blue Earth Diagnostics to provide access to imaging agents for the evaluation of cancer. We are committed to offering PET radiopharmaceuticals that yield valuable clinical information to help physicians make effective treatment decisions. We look forward to the potential approval of fluciclovine and to supporting diagnostic imaging options for prostate cancer patients.”*

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 Partners LLP. The Company licensed the PET imaging agent fluciclovine (<sup>18</sup>F), 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: [www.blueearthdiagnostics.com](http://www.blueearthdiagnostics.com)

#### **About Siemens AG**

Siemens AG (Berlin and Munich) is a global technology powerhouse that has stood for engineering excellence, innovation, quality, reliability and internationality for more than 165 years. The company is active in more than 200 countries, focusing on the areas of electrification, automation and digitalization. One of the world’s largest producers of energy-efficient, resource-saving technologies, Siemens is No. 1 in offshore wind turbine construction, a leading supplier of gas and steam turbines for power generation, a major provider of power transmission solutions and a pioneer in infrastructure solutions as well as automation, drive and software solutions for industry. The company is also a leading provider of medical imaging equipment – such as computed tomography and magnetic resonance imaging systems – and a leader in laboratory diagnostics as well as clinical IT. In fiscal 2015, which ended on September 30, 2015, Siemens generated revenue of €75.6 billion and net

income of €7.4 billion. At the end of September 2015, the company had around 348,000 employees worldwide. Further information is available on the Internet at [www.siemens.com](http://www.siemens.com).

### **About Syncona Partners LLP**

Syncona was founded in 2012 and operates as an evergreen 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. Syncona is a subsidiary the Wellcome Trust who invested the initial £200m capitalisation. [www.synconapartners.com](http://www.synconapartners.com)

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

Positron emission tomography (PET) is a test that uses a special type of camera and a [tracer](#) (radioactive chemical) to examine biochemical processes in the body. During the test, the tracer liquid is injected into a vein (intravenous, or [IV](#)) 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 [computed tomography \(CT\) scans](#) or [magnetic resonance imaging \(MRI\)](#), 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.