

BLUE EARTH DIAGNOSTICS GRANTED US AND EUROPEAN ORPHAN DRUG DESIGNATION FOR FLUCICLOVINE (¹⁸F) IN THE DIAGNOSIS OF GLIOMA

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Blue Earth Diagnostics Ltd (“BED”), a private diagnostics company, announces today that it has received both U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) Orphan Drug Designation (ODD) for fluciclovine (¹⁸F) in the diagnosis of glioma. Fluciclovine (¹⁸F) is an investigational positron emission tomography (PET) radiopharmaceutical based on a synthetic amino acid, which appears to be preferentially taken up in a number of cancer indications, including in prostate cancer and brain tumours.

Gliomas make up about 30% of all brain and central nervous system tumours and 80% of all malignant brain tumours.* The symptoms, prognosis, and treatment of a malignant glioma depend on the person’s age, the exact type of tumour, and the location of the tumour – which often penetrates deep into the brain. PET scan pictures show biological function and are complimentary with [computed tomography \(CT\) scans](#) and [magnetic resonance imaging \(MRI\)](#). Blue Earth Diagnostics plans to investigate the role of fluciclovine (¹⁸F) PET in evaluating the spread of both high and low grade glioma within the brains of affected patients.

Jonathan Allis, CEO of Blue Earth Diagnostics said:

“We are pleased to receive Orphan Drug Designations for fluciclovine (¹⁸F) in the diagnosis of glioma from two of the leading regulatory agencies in the world. As well as occurring in adults, malignant gliomas are the most common type of primary brain tumour in children and are associated with disproportionate cancer-related morbidity and mortality. Published data suggests that we may provide treating neurologists with additional information enabling identification of the extent of malignant infiltration of brain tissue, potentially permitting more effective treatment.”

Dr. Jeffrey Olson, Neurosurgeon at Emory University, Atlanta, commented:

“Although diagnosis of tumors of the brain with standard surgical, histologic and imaging techniques, such as CT and MRI, is accurate and well established, definitive staging and management of these diseases later in their course is in need of improvement. Imaging based on alternative mechanisms, such as PET with fluciclovine, offer the possibility of accurate diagnosis with the possibility of faster evaluation of therapeutic response. The addition of novel PET data to MRI, for example, may give treating physicians the confidence to continue treatment or justification to move on to an alternative therapy.”

Orphan Drug Designation is a status granted to drugs or biological products that treat rare diseases or conditions. The designation qualifies the sponsor of the drug for various development incentives including a period of marketing exclusivity upon marketing approval for the designated indication, potential tax credits and the waiver of certain fees.

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. The Company's lead investor, Syncona LLP, an independent subsidiary of the Wellcome Trust, is an evergreen investment company, taking an active role in identifying, supporting and developing technologies with the potential to significantly impact the healthcare market of the future. For further information please visit: www.blueearthdiagnostics.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.