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EMA/COMP/212725/2015
Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

Fluciclovine (^{18}F) for the diagnosis of glioma

On 24 April 2015, orphan designation (EU/3/15/1472) was granted by the European Commission to Blue Earth Diagnostics Ltd, United Kingdom, for fluciclovine (^{18}F) for the diagnosis of glioma.

What is glioma?

Glioma is a type of brain tumour that affects the 'glial' cells (the cells that surround and support the nerve cells). Patients with glioma can have severe symptoms, but the types of symptoms experienced depend on where the tumour develops in the brain.

Symptoms can include headaches, nausea, loss of appetite, vomiting, and changes in personality, mood, mental capacity and concentration. About one fifth of patients with glioma have seizures (fits) for months or years before the disease is diagnosed.

Glioma is a long-term debilitating and life-threatening disease because of the severe damage to the brain, and is associated with poor long-term survival.

What is the estimated number of patients eligible for diagnosis of the condition?

At the time of designation, the number of patients eligible for diagnosis of glioma was estimated to be approximately 1.5 people in 10,000 in the European Union (EU). This was equivalent to a total of around 77,000 people*, and is below the ceiling for orphan designation. This is based on the information provided by the sponsor and the knowledge of the Committee for Orphan Medicinal Products (COMP).

What methods of diagnosis are available?

At the time of the application for orphan designation, 3 products are approved for the diagnosis of glioma: fludeoxyglucose (^{18}F), 6-[^{18}F]fluoro-L-3,4-dihydroxyphenylalanine and 5-aminolevulinic acid (Gliolan).

*Disclaimer: For the purpose of the designation, the number of patients eligible for diagnosis of the condition is estimated and assessed on the basis of data from the European Union (EU 28), Norway, Iceland and Liechtenstein. This represents a population of 512,900,000 (Eurostat 2015).

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The sponsor has provided sufficient information to show that fluciclovine (^{18}F) might be of significant benefit for patients with glioma because early studies suggest that it might be better than current methods at distinguishing gliomas from normal tissue. This assumption will need to be confirmed at the time of marketing authorisation, in order to maintain the orphan status.

How is this medicine expected to work?

Fluciclovine (^{18}F) is a radiopharmaceutical: it is made up of a substance similar to leucine (an amino acid), which has been labelled with a small amount of radioactivity. This medicine can enter cells through proteins called 'amino acid transporters' (AATs), and early studies have shown that it enters glioma cells more readily because AATs in these cells are more active.

When given as injection into patients with glioma, the medicine is therefore expected to build up in the glioma cancer cells. Its small radioactivity can then be picked up by a sensitive scanner (known as a PET scanner) and the images obtained will help show the extent of the cancer in the body, which may lead to more complete surgical removal of the cancer.

What is the stage of development of this medicine?

The effects of fluciclovine (^{18}F) have been evaluated in experimental models.

At the time of submission of the application for orphan designation, clinical trials with fluciclovine (^{18}F) in patients with glioma were ongoing.

At the time of submission, fluciclovine (^{18}F) was not authorised anywhere in the EU for glioma or designated as an orphan medicinal product elsewhere for this condition.

In accordance with Regulation (EC) No 141/2000 of 16 December 1999, the COMP adopted a positive opinion on 25 March 2015 recommending the granting of this designation.

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Opinions on orphan medicinal product designations are based on the following three criteria:

- the seriousness of the condition;
- the existence of alternative methods of diagnosis, prevention or treatment;
- either the rarity of the condition (affecting not more than 5 in 10,000 people in the EU) or insufficient returns on investment.

Designated orphan medicinal products are products that are still under investigation and are considered for orphan designation on the basis of potential activity. An orphan designation is not a marketing authorisation. As a consequence, demonstration of quality, safety and efficacy is necessary before a product can be granted a marketing authorisation.

For more information

Sponsor's contact details:

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For contact details of patients' organisations whose activities are targeted at rare diseases see:

- Orphanet, a database containing information on rare diseases, which includes a directory of patients' organisations registered in Europe;
- European Organisation for Rare Diseases (EURORDIS), a non-governmental alliance of patient organisations and individuals active in the field of rare diseases.

Translations of the active ingredient and indication in all official EU languages[1], Norwegian and Icelandic

Language	Active ingredient	Indication
English	Fluciclovine (^{18}F)	Diagnosis of glioma
Bulgarian	Флуцикловин (^{18}F)	Диагностика на глиома
Croatian	Fluciklovin (^{18}F)	Dijagnosticiranje glioma
Czech	Fluciklovin (^{18}F)	Diagnóza gliomu
Danish	Fluciclovin (^{18}F)	Diagnose af gliom
Dutch	Fluciclovine (^{18}F)	Diagnose van glioma
Estonian	Flutsikloviin (^{18}F)	Glioomi diagnoosimiseks
Finnish	Flusikloviini (^{18}F)	Gliooman diagnosointi
French	Fluciclovine (^{18}F)	Diagnostic des gliomes
German	Fluciclovin [^{18}F]	Diagnose des Glioms
Greek	Φθοριοκυκλοβίνη (^{18}F)	διάγνωση του γλοιώματος
Hungarian	Fluciklovin (^{18}F)	Glioma diagnosztizálása
Italian	Fluciclovina (^{18}F)	Diagnosi del glioma
Latvian	Fluciklovīns (^{18}F)	Gliomas diagnostika
Lithuanian	Fluciklovinas (^{18}F)	Gliomos diagnozė
Maltese	Fluciclovine (^{18}F)	Dijanjosi tal-glioma
Polish	Flucyklowina (^{18}F)	Rozpoznawanie glejaka
Portuguese	Fluciclovina (^{18}F)	Diagnóstico do glioma
Romanian	Fluciclovină (^{18}F)	Diagnosticul gliomului
Slovak	Fluciklovín (^{18}F)	Diagnóza gliómu
Slovenian	Fluciklovin (^{18}F)	Diagnosticiranje glioma
Spanish	Fluciclovina (^{18}F)	Diagnóstico del glioma
Swedish	Fluciklovin (^{18}F)	Diagnos av gliom
Norwegian	Fluciklovin (^{18}F)	Diagnose av gliom
Icelandic	Flúciklóvín (^{18}F)	Sjúkdómsgreining glioma

[1] At the time of designation