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Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

Talampanel for the treatment of glioma

Please note that this product was withdrawn from the Community Register of designated orphan medicinal products in March 2011 on request of the sponsor.

On 29 April 2009, orphan designation (EU/3/09/631) was granted by the European Commission to Teva Pharma GmbH, Germany, for talampanel for the treatment 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 symptom experienced depend on where the tumour develops in the brain. Symptoms can include headaches, nausea (feeling sick), loss of appetite, vomiting, and changes in personality, mood, mental capacity and concentration. About a fifth of patients with glioma have seizures (fits) for months or years before the disease is diagnosed.

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

What is the estimated number of patients?

At the time of designation, glioma affected approximately 1 in 10,000 people in the European Union (EU)*. This equivalent to a total of around 50,000 people, and is below the threshold for orphan designation, which is 5 people in 10,000. This is based on the information provided by the sponsor and knowledge of the Committee for Orphan Medicinal Products (COMP).

* Disclaimer: For the purpose of the designation, the number of patients affected by the condition is estimated and assessed on the basis of data from the European Union (EU 27), Norway, Iceland and Liechtenstein. This represents a population of 504,800,000 (Eurostat 2009).

What treatments are available?

At the time of designation, several medicines were authorised for the treatment of glioma in the Community. Treatments for glioma included surgery, radiotherapy (using radiation to kill the cancer cells) and chemotherapy (medicines used to kill cancer cells). Patients also received treatments for the symptoms of glioma, including corticosteroids to reduce pressure within the skull, and medicines to prevent fits.

The sponsor has provided sufficient information to show that talampanel might be of significant benefit for patients with glioma because it works in a different way to existing medicines. 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?

Although the cause of glioma is largely unknown, the growth of gliomas is believed to be stimulated by a neurotransmitter called glutamate. Neurotransmitters are naturally-occurring chemicals in the nervous system that allow nerve cells to communicate with each other. Glioma cells release large amounts of glutamate, which can lead to the over-activation of the receptors that glutamate normally attaches to. This results in the glioma cells stimulating their own growth and division. The over-activation of the receptors also leads to the death of the nerve cells surrounding the tumour.

Talampanel is expected to work by blocking a type of glutamate receptor on the surface of the glioma cells called AMPA receptor. This is expected to stop the signals that stimulate the glioma cells to grow and divide, slowing down the growth of the tumour and reducing the symptoms of the disease.

What is the stage of development of this medicine?

The effects of talampanel have been evaluated in experimental models.

At the time of submission of the application for orphan designation, a clinical trial in patients with glioma was ongoing.

At the time of submission, talampanel was not authorised anywhere in the EU for glioma or designated as 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 4 March 2009 recommending the granting of this designation.

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 languages¹, Norwegian and Icelandic

Language	Active ingredient	Indication
English	Talampanel	Treatment of glioma
Bulgarian	Талампанел	Лечение на глиома
Czech	Talampanel	Léčba gliomů
Danish	Talampanel	Behandling af gliom
Dutch	Talampanel	Behandeling van glioma
Estonian	Talampaneel	Glioomi ravi
Finnish	Talampaneeli	Gliooman hoito
French	Talampanel	Traitement des gliomes
German	Talampanel	Behandlung von Gliomen
Greek	Ταλαμπανέλη	Θεραπεία του γλοιώματος
Hungarian	Talampanel	Glioma kezelése
Italian	Talampanel	Trattamento del glioma
Latvian	Talampanels	Gliomas ārstēšana
Lithuanian	Talampanelis	Gliomos gydymas
Maltese	Talampanel	Kura tal-glioma
Polish	Talampanel	Leczenie glejaka
Portuguese	Talampanel	Tratamento do glioma
Romanian	Talampanel	Tratamentul gliomului
Slovak	Talampanel	Liečba gliómu
Slovenian	Talampanel	Zdravljenje glioma
Spanish	Talampanel	Tratamiento del glioma
Swedish	Talampanel	Behandling av gliom
Norwegian	Talampanel	Behandling av gliom
Icelandic	Talampanel	Meðferð á glíóma

¹ At the time of designation