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Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

Herpes simplex virus lacking infected cell protein 34.5 for the treatment of glioma

First publication	23 October 2003
Rev.1: sponsor's name change	17 November 2011
Rev.2: sponsor's change of address	10 March 2015
Disclaimer Please note that revisions to the Public Summary of Opinion are purely administrative updates. Therefore, the scientific content of the document reflects the outcome of the Committee for Orphan Medicinal Products (COMP) at the time of designation and is not updated after first publication.	

On 9 July 2003, orphan designation (EU/3/03/153) was granted by the European Commission to Crusade Laboratories Limited, United Kingdom, for herpes simplex virus lacking infected cell protein 34.5 for the treatment of glioma.

Crusade Laboratories Limited changed its name to Virttu Biologics Limited in September 2011.

What are gliomas?

Tumours that begin in brain tissue are known as primary brain tumours. Primary brain tumours are classified by the type of tissue from which they originate, the most common being gliomas, which begin in the glial (supportive) tissue.

Gliomas represent a potentially debilitating and life-threatening condition, with symptoms being influenced by which regions of the brain are affected. Patients affected by gliomas can suffer from medical problems to the nervous system, depending on where in the brain the tumour develops.

What is the estimated number of patients affected by the condition?

At the time of designation, glioma affected approximately 0.8 in 10,000 people in the European Union (EU). This was equivalent to a total of around 31,000 people^{*}, and is below the ceiling for orphan

^{*}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. At the time of designation, this represented a population of 382,800,000 (Eurostat 2003).



designation, which is 5 people in 10,000. This is based on the information provided by the sponsor and the knowledge of the Committee for Orphan Medicinal Products (COMP).

What treatments are available?

Treatment for gliomas depends on a number of factors and may include surgery, radiotherapy (using high-dose x-rays or other high-energy rays to kill cancer cells) or chemotherapy (using drugs to kill cancer cells), as well as symptomatic treatments. Symptomatic treatments include certain steroid hormones (corticosteroids) to control the effects of raised pressure within the skull, and medication to help control seizures, as required. Methods of treatment of glioma were authorised at the time of submission of the application for orphan designation.

Herpes simplex virus lacking infected cell protein 34.5 might be of potential significant benefit for the treatment of gliomas. The main reason is that herpes simplex virus lacking infected cell protein 34.5 may offer a new way of killing the cancer cells. The assumption will have to be confirmed at the time of marketing authorisation. This will be necessary to maintain the orphan status.

How is this medicine expected to work?

Herpes simplex is a virus that can infect human cells, and it requires these cells to replicate. Once a cell is infected, the virus is able to multiply and kill the cell. Herpes simplex virus lacking infected cell protein 34.5 is a modified virus that is lacking a vital part of its genetic material. Without this material, the virus cannot multiply and cannot kill the cells. However, if the infected cell is multiplying, then the virus can take advantage of this and multiply as well. This in turn kills the cell that is multiplying when the virus generates hundreds of daughter copies and makes burst the cell. In the brain of adult patients, normal cells do not multiply whilst cancer cells do. Thus, it is expected that Herpes simplex virus lacking infected cell protein 34.5 might be used to kill only the cancer cells, whilst preserving normal cells.

What is the stage of development of this medicine?

At the time of submission of the application for orphan designation, clinical trials in patients with gliomas were ongoing.

Herpes simplex virus lacking infected cell protein 34.5 was not marketed anywhere worldwide for the treatment of gliomas or designated as orphan medicinal product elsewhere for this condition, at the time of submission.

In accordance with Regulation (EC) No 141/2000 of 16 December 1999, the COMP adopted a positive opinion on 13 June 2003 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	Herpes simplex virus lacking infected cell protein 34.5	Treatment of glioma
Danish	Herpes simplex virus som mangler infiseret celleprotein 34.5	Behandling af gliom
Dutch	Herpes simplex virus met ontbrekend geïnfecteerd cel proteïne 34.5	Behandeling van glioma
Finnish	Herpes simplex virus, josta puuttuu infektoitunut solu-proteiini 34.5	Gliooman hoito
French	Herpes simplex virus dénué de la protéine 34.5 de la cellule infectée	Traitement des gliomes
German	Herpes simplex virus wo infizierte Zell Proteine 34.5 empfiehlt	Behandlung des Glioms
Greek	Ο ιός του απλού έρπητα άνευ προσβεβλημένης κυτταρικής προτεΐνης 34.5	Θεραπεία γλοιώματος
Italian	Virus Herpes simplex mancante di proteina cellulare 34.5	Trattamento dei gliomi
Portuguese	Vírus herpes simplex desprovido de proteína celular infectada 34.5	Tratamento de gliomas
Spanish	Virus herpes simplex deficitario de proteína de la célula infectada 34.5	Tratamiento de glioma
Swedish	Herpes simplex virus som saknar infekterat cellprotein 34.5	Behandling av gliom

¹ At the time of designation