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Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

Tecovirimat for the treatment of cowpox infection

On 1 October 2010, orphan designation (EU/3/10/799) was granted by the European Commission to SIGA Pharmaceuticals (Europe) Ltd, United Kingdom, for tecovirimat (also known as ST-246) for the treatment of cowpox infection.

Please note that this product was withdrawn from the Community Register of designated orphan medicinal products in March 2012 on request of the sponsor.

What is cowpox infection?

Cowpox is a viral infection that is most commonly transmitted to human by infected domestic cats. Symptoms of human infection are malaise (feeling unwell) and painful fluid-filled blisters usually on the hands. Cowpox infection can be debilitating as some patients develop widespread skin lesions or a lesion in the eye. The infection may be life threatening in patients with a weakened immune system (the body's natural defences).

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

At the time of designation, cowpox infection affected less than 0.001 in 10,000 people in the EU*. This is equivalent to a total of fewer than 50 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 the knowledge of the Committee for Orphan Medicinal Products (COMP).

What treatments are available?

At the time of designation, no satisfactory methods of treatment were authorised in the EU for cowpox infection.

*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 506,500,000 (Eurostat 2010).

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How is this medicine expected to work?

Tecovirimat is expected to work by interfering with a protein normally found on the surface of the cowpox virus particle. As a result, the virus cannot reproduce normally, slowing down the spread of infection.

What is the stage of development of this medicine?

The effects of tecovirimat have been evaluated in experimental models.

At the time of submission of the application for orphan designation, four clinical trials with tecovirimat in healthy volunteers had been completed.

At the time of submission, tecovirimat was not authorised anywhere in the EU for the treatment of cowpox infection 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 16 July 2010 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	Tecovirimat	Treatment of cowpox infection
Bulgarian	Тековиримат	Лечение на краварска шарка
Czech	Tecovirimat	Léčba kravských neštovic
Danish	tecovirimat	Behandling af ko koppe infektion
Dutch	Tecovirimat	Behandeling van koepokkeninfectie
Estonian	Tecovirimat	*Cowpox* infektsiooni ravi
Finnish	Tekovirimaatti	Lehmärokon hoito
French	Técovirimat	Traitement de l'infection par le cowpox
German	Tecovirimat	Behandlung von Kuhpocken Infektionen
Greek	Τεκοβιριμάτη	Θεραπεία της μόλυνσης από δαμαλίτιδα
Hungarian	Tecovirimat	Cowpox fertőzés kezelése
Italian	Tecovirimat	Trattamento delll'infezione da virus del vaiolo bovino
Latvian	Tekovirimats	Govju baku vīrusa infekcijas ārstēšana
Lithuanian	Tekovirimatas	Karvių raupų gydymas
Maltese	Tecovirimat	Kura ta' infezzjoni mill-virus tal-ġidri tal-baqar
Polish	Tekowirymat	Leczenie zakażeń wirusem krowianki
Portuguese	Tecovirimat	Tratamento da infecção por virus cowpox
Romanian	Tecovirimat	Tratamentul variolei bovine
Slovak	Tecovirimat	Liečba kravských kiahní
Slovenian	tekovirimat	Zdravljenje okužbe s kravjimi kozami
Spanish	Tecovirimat	Tratamiento de la infección por el virus de la viruela bovina
Swedish	Tekovirimat	Behandling av kokoppor
Norwegian	Tekovirimat	Behandling av kukoppeinfeksjon
Icelandic	Tecóvírimat	Meðferð kúabólu sýkingar

[1] At the time of designation