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Public summary of opinion on orphan designation

Ribavirin for the treatment of Crimean-Congo haemorrhagic fever

On 21 March 2018, orphan designation (EU/3/18/2002) was granted by the European Commission to Pharmadev Healthcare Ltd, Ireland, for ribavirin for the treatment of Crimean-Congo haemorrhagic fever.

What is Crimean-Congo haemorrhagic fever?

Crimean-Congo haemorrhagic fever is a viral infection that causes several symptoms, including high temperatures, muscle pain, vomiting and diarrhoea, and bleeding from the skin and internal membranes.

The disease is caused by a virus called nairovirus, which is passed on to humans by tick bites. People can also be infected by contact with blood or body parts of animals that have the virus.

Crimean-Congo haemorrhagic fever is debilitating and life-threatening, with around 13% of people who become infected dying from it.

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

At the time of designation, Crimean-Congo haemorrhagic fever affected less than 0.01 in 10,000 people in the European Union (EU). This was equivalent to a total of fewer than 500 people*, and is below the ceiling 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 the orphan designation there were no medicines or vaccines authorised for Crimean-Congo haemorrhagic fever in the EU. Treatment aimed at relieving the symptoms of the disease and included fluids and blood products.

*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 28), Norway, Iceland and Liechtenstein. This represents a population of 517,400,000 (Eurostat 2018).

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How is this medicine expected to work?

Ribavirin is an antiviral medicine that is already authorised for treating another viral infection, chronic hepatitis C. The medicine is known as a 'nucleoside analogue' and is thought to work by interfering with the virus genetic material, which viruses need to survive and multiply.

What is the stage of development of this medicine?

The effects of ribavirin have been evaluated in experimental models.

At the time of submission of the application for orphan designation, no clinical trials with ribavirin in patients with Crimean-Congo haemorrhagic fever were ongoing.

At the time of submission, ribavirin was not authorised anywhere in the EU for Crimean-Congo haemorrhagic fever 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 15 February 2018 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:

Contact details of the current sponsor for this orphan designation can be found on EMA website, on the medicine's rare disease designations page.

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	Ribavirin	Treatment of Crimean-Congo haemorrhagic fever
Bulgarian	Рибавирин	Лечение на Кримска-Конго хеморагична треска
Croatian	Ribavirin	Liječenje Krimsko-Kongoanske hemoragijske groznice
Czech	Ribavirin	Léčba krymsko-konžské hemoragické horečky
Danish	Ribavirin	Behandling af Krim-Congo hæmorragisk feber
Dutch	Ribavirine	Behandeling van Krim-Congo hemorragische koorts
Estonian	Ribaviriin	Krimmi-Kongo hemorraagilise palaviku ravi
Finnish	Ribaviriini	Krimin-Kongon verenvuotokuumeen hoito
French	Ribavirin	Traitement de la fièvre hémorragique de Crimée-Congo
German	Ribavirin	Behandlung von Krim-Kongo hämorrhagisches Fieber
Greek	Ριμπαβιρίνη	Θεραπεία αιμορραγικού πυρετού Κριμαίας-Κονγκό
Hungarian	Ribavirin	Krím-kongói vérzéses láz kezelése
Italian	Ribavirina	Trattamento della febbre emorragica Crimea-Congo
Latvian	Ribavirīns	Krimas-Kongo hemorāģiskā drudža ārstēšana
Lithuanian	Ribavirinas	Krymo-Kongo hemoraginės karštligės gydymas
Maltese	Ribavirin	Kura tad-deni emorraġiku Krimean-Kongo
Polish	Rybawiryna	Leczenie gorączki krwotocznej krymsko-kongijskiej
Portuguese	Ribavarina	Tratamento da febre hemorrágica da Crimeia-Congo
Romanian	Ribavirină	Tratamentul febrei hemoragice Crimeea-Congo
Slovak	Ribavirín	Liečba krymsko-konžskej hemoragickej horúčky
Slovenian	Ribavirin	Zdravljenje Krimsko-kongoške hemoragične vročice
Spanish	Ribavirina	Tratamiento de la fiebre Hemorrágica de Crimea-Congo
Swedish	Ribavirin	Behandling av Krim-Kongo blödarfeber
Norwegian	Ribavirin	Behandling av Krim-Kongo hemoragisk feber
Icelandic	Ríbavírín	Meðferð við Krímar-Kongó blæðingarhitasótt

[1] At the time of designation