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Public summary of opinion on orphan designation

Ribavirin for the treatment of Lassa fever

On 21 March 2018, orphan designation (EU/3/18/2003) was granted by the European Commission to Pharmadev Healthcare Ltd, Ireland, for ribavirin for the treatment of Lassa fever.

What is Lassa fever?

Lassa fever is a viral infection that causes symptoms such as fever, headache, sore throat, muscle, belly and chest pain, nausea, vomiting, diarrhoea, cough, face swelling, low blood pressure and bleeding.

The disease is caused by the Lassa virus and is transmitted to people mostly by contact with urine or blood of infected Mastomys rats.

Lassa fever is debilitating and life-threatening, with 1 to 2% of people who become infected dying from it.

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

At the time of designation, Lassa fever affected less than 0.001 in 10,000 people in the European Union (EU). This was equivalent to a total of fewer than 50 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 vaccine authorised for Lassa fever in the EU. Symptoms of the disease were managed with painkillers, transfusion with blood products and fluids.

*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).

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 Lassa fever were ongoing.

At the time of submission, ribavirin was not authorised anywhere in the EU for Lassa 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.

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 languages¹, Norwegian and Icelandic

Language	Active ingredient	Indication
English	Ribavirin	Treatment of Lassa fever
Bulgarian	Рибавирин	Лечение на Lassa треска
Croatian	Ribavirin	Liječenje Lassa groznice
Czech	Ribavirin	Léčba horečky Lassa
Danish	Ribavirin	Behandling af Lassa feber
Dutch	Ribavirine	Behandeling van Lassa-koorts
Estonian	Ribaviriin	Lassa palaviku ravi
Finnish	Ribaviriini	Lassa-kuumeen hoito
French	Ribavirin	Traitement de la fièvre de Lassa
German	Ribavirin	Behandlung von Lassa-Fieber
Greek	ΡΙΜΠΑΒΙΡΙΝΗ	Θεραπεία του πυρετού της Lassa
Hungarian	Ribavirin	Lassa-láz kezelése
Italian	Ribavirina	Trattamento della febbre di Lassa
Latvian	Ribavirīns	Lassa drudža ārstēšana
Lithuanian	Ribavirinas	Lasos karštligės gydymas
Maltese	Ribavirin	Kura tad-deni Lassa
Polish	Rybawiryna	Leczenie gorączki Lassa
Portuguese	Ribavarina	Tratamento da febre de Lassa
Romanian	Ribavirină	Tratamentul febrei Lassa
Slovak	Ribavirín	Liečba horúčky Lassa
Slovenian	Ribavirin	Zdravljenje Lassa mrzlice
Spanish	Ribavirina	Tratamiento de la fiebre de Lassa
Swedish	Ribavirin	Behandling av Lassafeber
Norwegian	Ríbavírín	Behandling av Lassa feber
Icelandic	Ríbavírín	Meðferð Lassa hitasóttar

¹ At the time of designation