



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Public summary of opinion on orphan designation

### Peginterferon lambda-1a for the treatment of hepatitis D virus infection

On 21 August 2019, orphan designation EU/3/19/2190 was granted by the European Commission to Eiger Biopharmaceuticals Europe Limited, United Kingdom, for peginterferon lambda-1a for the treatment of hepatitis D virus infection.

#### What is hepatitis D virus infection?

Hepatitis D virus infection is an infection of the liver with the hepatitis delta (D) virus. It spreads through contact with blood or other body fluids. The hepatitis D virus cannot replicate in cells without the help of another virus, the hepatitis B virus. Because of this, the virus is always present as an additional infection in patients with hepatitis B, and results in higher rates of liver failure and cirrhosis (scarring of the liver) than with hepatitis B infection alone.

Hepatitis D virus infection is life threatening and debilitating in the long term as it can lead to cirrhosis, liver failure, liver cancer and portal hypertension (high blood pressure in the vessels that connect the liver and the gut).

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

At the time of designation, hepatitis D virus infection affected approximately 3.8 in 10,000 people in the European Union (EU). This was equivalent to a total of around 197,000 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 application for orphan designation, there were no satisfactory treatments for hepatitis D virus infection in the EU.

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\*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 518,400,000 (Eurostat 2019).



## How is this medicine expected to work?

This medicine contains a substance called peginterferon lambda-1a. It belongs to a group of proteins called interferons, natural substances produced by the body that have a number of actions including helping fight off viruses. The exact way interferons work is not fully understood, but it is thought that they modify how the immune system (the body's defence system) works. The interferon in the medicine has been attached to a chemical called polyethylene glycol, which enables it to last longer in the body and so prolongs the interferon's effects.

## What is the stage of development of this medicine?

The effects of peginterferon lambda-1a have been evaluated in experimental models.

At the time of submission of the application for orphan designation, clinical trials with peginterferon lambda-1a in patients with hepatitis D virus infection were ongoing.

At the time of submission, peginterferon lambda-1a was not authorised anywhere in the EU for the treatment of hepatitis D virus infection. Orphan designation of peginterferon lambda-1a had been granted in the United States for this condition.

In accordance with Regulation (EC) No 141/2000, the COMP adopted a positive opinion on 18 July 2019, 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](#).

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<sup>1</sup>, Norwegian and Icelandic

Language	Active ingredient	Indication
English	Peginterferon lambda-1a	Treatment of hepatitis D virus infection
Bulgarian	Пегинтерферон ламбда-1a	Лечение на хепатит делта вирусна инфекция
Croatian	Peginterferon Lambda-1a	Liječenje infekcije virusom hepatitisa delta
Czech	Peginterferon lambda-1a	Léčba infekce způsobené virem hepatitidy D
Danish	Peginterferon lambda-1a	Behandling af infektion med hepatitis D virus
Dutch	Peginterferon lambda-1a	Behandeling van hepatitis D virus- infectie
Estonian	Peginterferoon lambda-1a	D-hepatiidi viiruse infektsiooni ravi
Finnish	Peginterferoni lambda-1a	Hepatiitti D -virusinfektion hoito
French	Peginterféron lambda-1a	Traitement de l'infection par le virus de l'hépatite delta
German	Peginterferon Lambda-1a	Behandlung der Hepatitis-Delta-Virus-Infektion
Greek	Πεγκιντερφερόνη Λάμδα-1a	Θεραπεία λοίμωξης από τον ιό της ηπατίτιδας δέλτα
Hungarian	Peginterferon lambda-1a	Hepatitis delta vírus fertőzős kezelése
Italian	Peginterferone lambda-1a	Trattamento dell'infezione da virus dell'epatite delta
Latvian	Peginterferons lambda-1a	Hepātīta delta vīrusa infekcijas ārstēšana
Lithuanian	Peginterferonas lambda-1a	epatito D viruso infekcijos gydymas
Maltese	Peginterferon lambda-1a	Kura ta' infezzjoni mill-Hepatitis Delta Virus (Virus Delta tal-Epatite)
Polish	Peginterferon lambda-1a	Leczenie wirusowego zapalenia wątroby typu D
Portuguese	Peginterferão lambda-1a	Tratamento da infeção pelo vírus da Hepatite D
Romanian	Peginterferon lambda-1a	Tratamentul infecției cu virusul hepatitic delta
Slovak	Peginterferón lambda-1a	Liečba infekcie zapríčinenej delta vírusom hepatitídy
Slovenian	Peginterferon lambda-1a	Zdravljenje okužbe z virusom hepatitisa delta
Spanish	Peginterferón lambda-1a	Tratamiento de la infección por el virus de la hepatitis delta
Swedish	Peginterferon lambda-1a	Behandling av hepatit D-virusinfektion
Norwegian	Peginterferon lambda-1a	Behandling av hepatitt D-virusinfeksjon
Icelandic	Peginterferón lambda-1a	Meðferð við sýkingu af völdum delta-lifrabólguveiru

<sup>1</sup> At the time of designation