

19 May 2015
EMA/COMP/212797/2015
Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

Human reovirus type 3 Dearing strain for the treatment of pancreatic cancer

On 24 April 2015, orphan designation (EU/3/15/1477) was granted by the European Commission to Oncolytics Biotech (UK) Limited, United Kingdom, for human reovirus type 3 Dearing strain for the treatment of pancreatic cancer.

What is pancreatic cancer?

Pancreatic cancer is cancer of the pancreas, a small organ that lies behind the stomach. The pancreas has two functions: to produce a juice that helps with the digestion of food, and to produce hormones such as insulin. Due to the absence of symptoms in the early stages of pancreatic cancer, the majority of patients are diagnosed when the cancer has spread locally or to other parts of the body.

Pancreatic cancer is a very severe and life-threatening disease that is associated with shortened life expectancy.

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

At the time of designation, pancreatic cancer affected less than 2 in 10,000 people in the European Union (EU). This was equivalent to a total fewer than 103,000 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 designation, several medicines were authorised in the EU for treating pancreatic cancer. The choice of treatment depended on several factors, including how far the disease had advanced. Treatments included surgery, radiotherapy (treatment with radiation) and chemotherapy (medicines to treat cancer).

The sponsor has provided sufficient information to show that human reovirus type 3 Dearing strain might be of significant benefit for patients with pancreatic cancer because early studies indicate that it

^{*}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 512,900,000 (Eurostat 2015).

may improve survival when used in combination with currently available medicines. This assumption will need to be confirmed at the time of marketing authorisation, in order to maintain the orphan status.

How is this medicine expected to work?

This medicine is made up of an 'oncolytic' virus called reovirus that it is able to target, infect and destroy cancer cells but does not infect normal cells. When inside a cancer cell, the virus is expected to take over the cell's replication apparatus and use it to make more copies of itself. This is expected to kill the cell, leaving the virus to spread to neighbouring cancer cells.

What is the stage of development of this medicine?

The effects of human reovirus type 3 Dearing strain have been evaluated in experimental models.

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

At the time of submission, the medicine was not authorised anywhere in the EU for pancreatic cancer 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 19 March 2015 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	Human reovirus type 3 Dearing strain	Treatment of pancreatic cancer
Bulgarian	Човешки реовирус, тип 3, щам Dearing	Лечение на рак на панкреаса
Croatian	Ljudski reovirus tipa III, soj Dearing	Liječenje raka gušterače
Czech	Lidský reovirus typu 3, kmen Dearing	Léčba karcinomu pankreatu
Danish	Human reovirus type 3 Dearing stamme	Behandling af pancreascancer
Dutch	Menselijk reovirus type 3 Dearing-stam	Behandeling van pancreaskanker
Estonian	Inimese reoviirus tüüp 3 Dearing'i tüvi	Pankreasevähi ravi
Finnish	Ihmisen reovirus tyyppi 3 Dearing-kanta	Haimasyövän hoito
French	Souche Dearing de type 3 de réovirus humain	Traitement du cancer pancréatique
German	Menschlicher Reovirus Typ 3 vom Dearing-Stamm	Behandlung des Pankreaskarzinoms
Greek	Στέλεχος Dearing ανθρώπινου ρεοϊού τύπου 3	Θεραπεία καρκίνου του παγκρέατος
Hungarian	Emberi reovírus, Dearing törzs, 3. típus	Hasnyálmirigyrák kezelése
Italian	Reovirus umano di tipo 3, ceppo Dearing	Trattamento del cancro pancreatico
Latvian	Cilvēka 3. tipa reovīrusa Dearinga celms	Aizkuņģa dziedzera vēža ārstēšana
Lithuanian	3 tipo "Dearing" padermės žmogaus reovirusas	Kasos vėžio gydymas
Maltese	Reovirus uman tat-tip 3 tar-razza Dearing	Kura tal-kanċer tal-frixa
Polish	Ludzki reowirus typu 3. Dearing	Leczenie raka trzustki
Portuguese	Reovírus humano da estirpe Dearing do tipo 3	Tratamento do carcinoma do pâncreas
Romanian	Reovirus uman de tip 3 – tulpina Dearing	Tratamentul cancerului pancreatic
Slovak	Ľudský reovírus typu 3, kmeň Dearing	Liečba rakoviny pankreasu
Slovenian	Človeški reovirus tipa 3 sev Dearing	Zdravljenje raka trebušne slinavke
Spanish	Cepa Dearing serotipo 3 del reovirus humano	Tratamiento del cáncer de páncreas
Swedish	Humant reovirus typ 3 Dearing-stam	Behandling av pancreascancer
Norwegian	Humant reovirus type 3 stamme Dearing	Behandling av pancreascancer
Icelandic	Manna reóveira af veirustofninum 3 Dearing	Meðferð briskrabbameins

¹ At the time of designation