



European Medicines Agency  
Pre-authorisation Evaluation of Medicines for Human Use

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*Please note that this product was withdrawn from the Community Register of designated Orphan Medicinal Products in May 2009 on request of the Sponsor.*

## **Committee for Orphan Medicinal Products**

### **Public summary of positive opinion for orphan designation of deuterium oxide for the treatment of pancreatic cancer**

On 20 October 2004, orphan designation (EU/3/04/239) was granted by the European Commission to BDD Berolina Drug Development GmbH, Germany, for deuterium oxide for the treatment of pancreatic cancer.

#### **What is pancreatic cancer?**

Cancer that begins in the pancreas is called pancreatic cancer. The pancreas is a small organ that lies behind the stomach and in front of the spine. The pancreas has two main functions in the body. It makes a juice that helps to digest (break down) food. It also produces hormones, such as insulin, that help to control blood sugar levels. About 95% of pancreatic cancers come from the cells that make the juice to digest. These cancers of the pancreas are called adenocarcinomas. Pancreatic cancer is life-threatening.

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

At the time of designation, pancreatic cancer affected approximately 1 in 10,000 people in the European Union (EU)\*. This is equivalent to a total of around 46,000 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 knowledge of the Committee for Orphan Medicinal Products (COMP).

#### **What treatments are available?**

The choice of the treatment of pancreatic cancer depends on several factors, including the stage of the disease. Treatments may include surgery, radiation therapy (using high-dose x-rays or other high energy rays to kill cancer cells), and chemotherapy (using drugs to kill cancer cells). There are anti-cancer drugs that have been authorised for treatment of pancreatic cancer.

Deuterium oxide might be of potential significant benefit for the treatment of pancreatic cancer because it may act in a different way than other available medicines. The assumption will have to be confirmed at the time of marketing authorisation. This will be necessary to maintain the orphan status.

#### **How is this medicine expected to work?**

Deuterium oxide is, in very small amounts, present in normal drinking water. In high amounts deuterium oxide might influence and block several processes in cancer cells necessary for tumour growth. Therefore it might prevent cancer cells from growing when given in higher concentrations.

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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 25), Norway, Iceland and Liechtenstein. This represents a population of 459,700,000 (Eurostat 2004).

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

At the time of submission of the application for orphan designation, the evaluation of the effects of deuterium oxide in experimental models was ongoing but no clinical trials in patients were initiated.

The medicinal product was not marketed anywhere worldwide, at the time of submission. Orphan designation of deuterium oxide has not been granted in other countries.

According to Regulation (EC) No 141/2000 of 16 December 1999, the Committee for Orphan Medicinal Products (COMP) adopted on 9 September 2004 a positive opinion recommending the grant of the above-mentioned 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 Community) 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.

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**Translations of the active ingredient and indication in all EU languages  
and Norwegian and Icelandic**

<b>Language</b>	<b>Active Ingredient</b>	<b>Indication</b>
English	Deuterium oxide	Treatment of pancreatic cancer
Czech	Deuteriumoxid	Léčba karcinomu pankreatu
Danish	Deuteriumoxid	Behandling af pancreascancer
Dutch	Deuterium oxide	Behandeling van pancreaskanker
Estonian	Deuteeriumoksiid	Pankreasevähi ravi
Finnish	Deuteriumoksidi	Haimasyövän hoito
French	Oxyde de deutérium	Traitement du cancer pancréatique
German	Deuteriumoxid	Behandlung von Pankreaskrebs
Greek	Οξειδίο του δευτερίου	Θεραπεία καρκίνου του παγκρέατος
Hungarian	Deuterium oxid	Hasnyalmirigyрак kezelse
Italian	Ossido di deuterio	Trattamento del cancro pancreatico
Latvian	Deitērija oksīds	Aizkuņģa dziedzera vēža ārstēšanai
Lithuanian	Deuterio oksidas	Kasos vėžio gydymas
Maltese	Deuterium oxide	Treatment of pancreatic cancer
Polish	Tlenek deuteru	Leczenie raka trzustki
Portuguese	Óxido de deutério	Tratamento do cancro do pâncreas
Slovak	Oxid deutéria	Liečba rakoviny pankreasu
Slovenian	Devterijev oksid	Zdravljenje raka trebušne slinavke
Spanish	Óxido de deuterio	Tratamiento del cáncer de páncreas
Swedish	Deuteriumoxid	Behandling av pankreascancer
Norwegian	Deuteriumoksid	Behandling av pankreascancer
Icelandic	sýri af þungu vatni	meðhöndlun krabbameins í brisi