



**COMMITTEE FOR ORPHAN MEDICINAL PRODUCTS**

**PUBLIC SUMMARY OF  
POSITIVE OPINION FOR ORPHAN DESIGNATION  
OF  
nimotuzumab  
for the treatment of pancreatic cancer**

On 3 June 2008, orphan designation (EU/3/08/550) was granted by the European Commission to Oncoscience AG, Germany, for nimotuzumab for the treatment of pancreatic cancer.

**What is pancreatic cancer?**

Pancreatic cancer is a cancer of the pancreas, a small organ that lies behind the stomach. The pancreas has two functions: producing a juice that helps with the digestion of food, and producing hormones such as insulin. About 95% of pancreatic cancers affect the cells that make the pancreatic juice. These are called adenocarcinomas.

Pancreatic cancer is a very severe and life-threatening disease.

**What treatments are available?**

At the time of submission of the application for orphan drug designation, several medicines were authorised for pancreatic cancer in the European Union. The choice of treatment for pancreatic cancer depends on several factors, including the stage of the disease. Treatments may include surgery, radiotherapy (treatment with radiation), and chemotherapy (medicines used to treat cancer). The sponsor has provided satisfactory documentation to justify the assumption that nimotuzumab might be of potential significant benefit for the treatment of pancreatic cancer. This is mainly because nimotuzumab seems to have fewer side effects compared with other medicines in the same class. This assumption will need to be confirmed at the time of a marketing authorisation, to maintain the orphan status of the medicine.

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

Based on the information provided by the sponsor and previous knowledge of the Committee, pancreatic cancer was considered to affect approximately 1.3 in 10,000 people in the European Union, which, at the time of designation, corresponded to about 65,000 people.

**How is this medicinal product expected to act?**

Nimotuzumab is an anticancer medicine that belongs to the group 'epidermal growth factor receptor (EGFR) inhibitors'. It blocks the receptors for a protein called 'epidermal growth factor', which are found on the surface of certain tumour cells. Epidermal growth factor normally stimulates cells to grow and divide. By blocking its receptor, nimotuzumab prevents the tumour cells receiving the messages they need for growth, progression and spreading.

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\* Disclaimer: For the purpose of the designation, the number of patients affected by the condition is estimated and assessed based on data from the European Union (EU 27), Norway, Iceland and Lichtenstein. This represents a population of 502,282,135 (Eurostat 2008).. This estimate is based on available information and calculations presented by the sponsor at the time of the application.

**What is the stage of development of this medicinal product?**

The effects of nimotuzumab have been evaluated in experimental models.

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

At the time of submission, nimotuzumab was not authorised anywhere in the world for the treatment of pancreatic cancer or designated as orphan medicinal product elsewhere for this condition.

According to Regulation (EC) No 141/2000 of 16 December 1999, the Committee for Orphan Medicinal Products (COMP) adopted on 8 April 2008 a positive opinion recommending the granting of the above-mentioned designation.

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Opinions on orphan medicinal products designations are based on the following cumulative criteria: (i) the seriousness of the condition, (ii) the existence or not of alternative methods of diagnosis, prevention or treatment and (iii) either the rarity of the condition (considered to affect not more than five in ten thousand persons in the Community) or the insufficient return of development investments.

Designated orphan medicinal products 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 the product's quality, safety and efficacy is necessary before it 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	Nimotuzumab	Treatment of pancreatic cancer
Bulgarian	Нимотузумаб	Лечение на рак на панкреаса
Czech	Nimotuzumab	Léčba karcinomu pankreatu
Danish	Nimotuzumab	Behandling af pancreascancer
Dutch	Nimotuzumab	Behandeling van pancreaskanker
Estonian	Nimotuzumab	Pankreasevähi ravi
Finnish	Nimotutsumabi	Haimasyövän hoito
French	Nimotuzumab	Traitement du cancer pancréatique
German	Nimotuzumab	Behandlung des Pankreaskarzinoms
Greek	Νιμοτουζουμάμπη	Θεραπεία καρκίνου του παγκρέατος
Hungarian	Nimotuzumab	Hasnyálmirigyrák kezelése
Italian	Nimotuzumab	Trattamento del cancro pancreatico
Latvian	Nimotuzumabs	Aizkuņģa dziedzera vēža ārstēšana
Lithuanian	Nimotuzumabas	Kasos vėžio gydymas
Maltese	Nimotuzumab	Kura tal-kanċer tal-frixa
Polish	Nimotuzumab	Leczenie raka trzustki
Portuguese	Nimotuzumab	Tratamento do cancro do pâncreas
Romanian	Nimotuzumab	Tratamentul cancerului pancreatic
Slovak	Nimotuzumab	Liečba rakoviny pankreasu
Slovenian	Nimotuzumab	Zdravljenje raka trebušne slinavke
Spanish	Nimotuzumab	Tratamiento del cáncer de páncreas
Swedish	Nimotuzumab	Behandling av pancreascancer
Norwegian	Nimotuzumab	Behandling av pancreascancer
Icelandic	Nímótúsumab	Meðferð briskrabbameins