



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation chimeric antibody to mesothelin for the treatment of pancreatic cancer

On 17 March 2008, orphan designation (EU/3/08/536) was granted by the European Commission to Chiltern International Limited, United Kingdom, for chimeric antibody to mesothelin for the treatment of pancreatic cancer.

The sponsorship was transferred to Eisai Europe Limited, United Kingdom, in June 2010.

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: first, it produces a juice that helps to digest (break down) and absorb food; second, it produces hormones (substances that circulate in the blood), 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 a very severe disease and is life-threatening.

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

At the time of designation, pancreatic cancer affected approximately 1.2 in 10,000 people in the European Union (EU)*. This is equivalent to a total of around 60,000 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 the 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. Chimeric antibody to mesothelin might be of potential significant benefit for the treatment of pancreatic cancer. It might

*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 498,000,000 (Eurostat 2006). This estimate is based on available information and calculations presented by the sponsor at the time of the application.



offer a treatment to patients for whom other anti-cancer agents are not effective. This 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?

Mesothelin is a protein that can be found on the surface of some normal cells and it is also found on the surface of cancer cells. Mesothelin and other substances that are present outside the cells interact with other substances in the cell surroundings and are part of the mechanisms that allow cells to grow and move (migrate). This is important for the development of cancers as these mechanisms are necessary for cancer growth and spreading. Antibodies are proteins in the body that target and bind specific structures on the surface of foreign bodies, such as bacteria or cancer cells. This antibody to mesothelin is able to bind mesothelin and interfere with its function on cell growth and migration. The product is expected to be able to inhibit cancer cell growth and spreading in the body.

What is the stage of development of this medicine?

At the time of submission of the application for orphan designation, no clinical trials in patients with pancreatic cancer were initiated.

Chimeric antibody to mesothelin was not authorised anywhere worldwide for pancreatic cancer or designated as orphan medicinal product elsewhere for this condition, at the time of submission.

In accordance with Regulation (EC) No 141/2000 of 16 December 1999, the COMP adopted a positive opinion on 6 February 2008 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 European Union) 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:

Eisai Europe Limited
European Knowledge Centre
Mosquito Way
Hatfield, Herts AL10 9SN
United Kingdom
Telephone: +44 (0) 845 676 5089
Telefax: +44 (0) 845 676 1401

Patient associations' contact points

Cancer BACUP

3 Bath Place
Rivington Street
London
EC2A 3JR
United Kingdom
Telephone: +44 20 76 96 90 03 / 0808 800 1234 (freephone for UK)
Telefax: +44 20 76 96 90 02

Ligue Nationale contre le Cancer (LNCC)

12, rue Corvisart
75013 Paris
France
Telephone : +33 1 53 55 24 00
Telefax : +33 1 43 36 91 10
E-mail: lique@lique-cancer.net

Translations of the active ingredient and indication in all official EU languages¹, Norwegian and Icelandic

Language	Active Ingredient	Indication
English	Chimeric antibody to mesothelin	Treatment of pancreatic cancer
Bulgarian	Химерно анти тяло срещу мезотелин	Лечение на рак на панкреаса
Czech	Chimérická protilátka proti mezotelinu	Léčba karcinomu pankreatu
Danish	Kimærisk antistof mod mesothelin	Behandling af pancreascancer
Dutch	Chimerisch antilichaam gericht tegen mesothelin	Behandeling van pancreaskanker
Estonian	Mesoteliini vastane kimäärne antikeha	Pankreasevähki ravi
Finnish	Kimeerinen vasta-aine mesoteliinille	Haimasyövän hoito
French	Anticorps chimérique dirigé contre la mésothéline	Traitement du cancer pancréatique
German	Chimärer Antikörper gegen Mesothelin	Behandlung des Pankreaskarzinoms
Greek	Χιμαϊρικά Αντισώματα εναντίον της Μεσοθηλίνης	Θεραπεία καρκίνου του παγκρέατος
Hungarian	Mesothelin elleni kiméra antitest	Hasnyálmirigyrák kezelése
Italian	Anticorpo chimerico verso la mesotelina	Trattamento del cancro pancreatico
Latvian	Himērās antivielas pret mezotelīnu	Aizkuģa dziedzera vēža ārstēšana
Lithuanian	Chimeriniai antikūnai prieš mezotelį	Kasos vėžio gydymas
Maltese	Anti-korp kimeriku għall-mesothelin	Kura tal-kanċer tal-frixa
Polish	Chimeryczne przeciwciało przeciw mezotelinie	Leczenie raka trzustki
Portuguese	Anticorpo Quimérico contra Mesotelina	Tratamento do cancro do pâncreas
Romanian	Anticorp chimeric anti mezotelină	Tratamentul cancerului pancreatic
Slovak	Chimérická protilátka proti mezotelínu	Liečba rakoviny pankreasu
Slovenian	Himerno protitelo za mezotelin	Zdravljenje raka trebušne slinavke
Spanish	Anticuerpo quimérico contra la mesotelina	Tratamiento del cáncer de páncreas
Swedish	Chimär antikropp till mesothelin	Behandling av pankreascancer
Norwegian	Kimerisk antistoff mot mesotelin	Behandling av pankreascancer
Icelandic	Blendningsmótefni gegn mesóþelíni	Meðferð briskrabbameins

¹ At the time of designation