



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

3 February 2014
EMA/COMP/188397/2008 Rev.2
Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

Catumaxomab for the treatment of gastric cancer

First publication	23 February 2009
Rev.1: administrative update	27 May 2011
Rev.2: sponsor's name change	3 February 2014
Disclaimer Please note that revisions to the Public Summary of Opinion are purely administrative updates. Therefore, the scientific content of the document reflects the outcome of the Committee for Orphan Medicinal Products (COMP) at the time of designation and is not updated after first publication.	

On 3 November 2006, orphan designation (EU/3/06/414) was granted by the European Commission to Fresenius Biotech GmbH, Germany, for catumaxomab for the treatment of gastric cancer.

In January 2014, Fresenius Biotech GmbH changed name to Neovii Biotech GmbH.

What is gastric cancer?

Cancer tumours that originate in the stomach are called gastric cancers. Most gastric cancers are adenocarcinomas, so called because they start in the glandular cells that line the inside of the stomach (the mucosa). These cancers are usually first discovered and diagnosed in the affected patients at an advanced stage of the disease when the tumours have spread to surrounding organs in the abdomen or other parts of the body. Symptoms of gastric cancer include loss of appetite, vomiting, weight loss, bleeding in the stomach and subsequent anaemia (fewer red blood cells in the blood than normal). Gastric cancer is chronically debilitating and life threatening.

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

At the time of designation, gastric cancer affected approximately 3 in 10,000 people in the European Union (EU). This was equivalent to a total of around 141,000 people*, and is below the ceiling for

*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. At the time of designation, this represented a population of 468,900,000 (Eurostat 2006).



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 gastric cancers depends on several factors, including the stage of the disease. Treatments may include surgery, radiation therapy, and chemotherapy (using drugs to kill cancer cells). There were several medicinal products authorised for the treatment of gastric cancer in the Community at the time of orphan status designation.

Satisfactory argumentation has been submitted by the sponsor to justify the assumption that catumaxomab might be of potential significant benefit for the treatment of gastric cancer mainly because it has a new mechanism of action and may be used in combination with other treatments and because it may provide a major contribution to patient care. 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?

Catumaxomab is an antibody designed to bind specifically on three different types of cells: tumour cells, T cells and accessory immune cells (e.g. macrophages, dendritic cells and natural killer cells). By binding to the three types of cells, the product is expected to induce activation of T cells and accessory cells against cancer cells. This is thought to lead to elimination of the cancer cells.

What is the stage of development of this medicine?

The effects of catumaxomab were evaluated in experimental models.

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

Catumaxomab was not authorised anywhere worldwide for the treatment of gastric cancer nor 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 4 October 2006 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	Catumaxomab	Treatment of gastric cancer
Czech	Catumaxomab	Léčba karcinomu žaludku
Danish	Catumaxomab	Behandlingen af cancer ventriculi
Dutch	Catumaxomab	Behandeling van maagkanker
Estonian	Catumaxomab	Maovähi ravi
Finnish	Katumaksomabi	Mahasyövän hoito
French	Catumaxomab	Traitement du cancer gastrique
German	Catumaxomab	Behandlung von Magenkrebs
Greek	Catumaxomab	Θεραπεία του γαστρικού καρκίνου
Hungarian	Catumaxomab	Gyomorrák kezelése
Italian	Catumaxomab	Trattamento del cancro gastrico
Latvian	Catumaxomab	Kuņģa vēža ārstēšana
Lithuanian	Katumaksomabas	Skrandžio vėžio gydymas
Polish	Katumaksomab	Leczenie raka żołądka
Portuguese	Catumaxomab	Tratamento do cancro gástrico
Slovak	Katumaxomab	Liečba rakoviny žalúdka
Slovenian	Catumaxomab	Zdravljenje karcinoma želodca
Spanish	Catumaxomab	Tratamiento del cáncer de estómago
Swedish	Catumaxomab	Behandling av magcancer
Norwegian	Catumaxomab	Behandling av magekreft
Icelandic	Catumaxómab	Meðferð við magakrabbameini

¹ At the time of designation