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Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

Ramucirumab for the treatment of gastric cancer

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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 4 July 2012, orphan designation (EU/3/12/1004) was granted by the European Commission to Eli Lilly Nederland B.V., the Netherlands, for ramucirumab for the treatment of gastric cancer.

What is gastric cancer?

Gastric cancer is a cancer that starts in the stomach, generally in the glandular cells lining the inside of the stomach. Gastric cancer is often detected late as the early signs of the disease are the same as those of less serious stomach conditions (heartburn, gas, excessive belching). At a later stage, gastric cancer causes unexplained weight loss, loss of appetite and general decline in health. Bleeding can occur, leading to anaemia (low red blood cell counts). Men are about twice as likely to develop the disease as women.

Gastric cancer is a serious and life-threatening illness that is associated with shortened life expectancy.

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

At the time of designation, gastric cancer affected not more than 3 in 10,000 people in the European Union (EU). This was equivalent to a total of not more than 153,000 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).

*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 27), Norway, Iceland and Liechtenstein.
At the time of designation, this represented a population of 509,000,000 (Eurostat 2012).

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What treatments are available?

At the time of designation, some patients with gastric cancer were treated with surgery to remove part or the whole of the stomach. Chemotherapy (medicines to treat cancer) was generally used after surgery or on its own if surgery was not possible or the disease had spread to other parts of the body. Several chemotherapy medicines were authorised in the EU for use in gastric cancer, such as cisplatin, docetaxel, doxorubicin, capecitabine, epirubicin, 5-fluorouracil, mitomycin and trastuzumab. They were often used in combination.

The sponsor has provided sufficient information to show that ramucirumab might be of significant benefit for patients with gastric cancer because early studies suggest it may partly improve the symptoms of patients with gastric cancer who had not responded to other treatments. 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?

Ramucirumab is a monoclonal antibody (a type of protein) that has been designed to recognise and attach to a receptor called 'vascular endothelial growth factor receptor' (VEGFR), found on the surface of cancer cells. It thereby blocks the action of vascular endothelial growth factor (VEGF), which is present at high levels in gastric tumours and is responsible for the development of new blood vessels that supply the tumours. This slows down the growth of cancer cells by reducing their blood supply.

What is the stage of development of this medicine?

The effects of ramucirumab have been evaluated in experimental models.

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

At the time of submission, ramucirumab was not authorised anywhere in the EU for gastric cancer. Orphan designation of ramucirumab had been granted in the United States of America for gastric cancer.

In accordance with Regulation (EC) No 141/2000 of 16 December 1999, the COMP adopted a positive opinion on 11 May 2012 recommending the granting of this designation.

Update: ramucirumab (Cyramza) has been authorised in the EU since 19 December 2014. Cyramza monotherapy is indicated for the treatment of adult patients with advanced gastric cancer or gastro-oesophageal junction adenocarcinoma with disease progression after prior platinum or fluoropyrimidine chemotherapy, for whom treatment in combination with paclitaxel is not appropriate.

More information on Cyramza can be found in the European public assessment report (EPAR) on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports

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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 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 languages[1], Norwegian and Icelandic

Language	Active ingredient	Indication
English	Ramucirumab	Treatment of gastric cancer
Bulgarian	Рамуцирумаб	Лечение на карцином на стомаха
Czech	Ramucirumab	Léčba karcinomu žaludku
Danish	Ramucirumab	Behandlingen af cancer ventriculi
Dutch	Ramucirumab	Behandeling van maagkanker
Estonian	Ramutsirumab	Maovähi ravi
Finnish	Ramusirumabi	Mahasyövän hoito
French	Ramucirumab	Traitement du cancer gastrique
German	Ramucirumab	Behandlung von Magenkarzinom
Greek	Ραμουσιρουμάμπη	Θεραπεία του γαστρικού καρκίνου
Hungarian	Ramucirumab	Gyomorrák kezelése
Italian	Ramucirumab	Trattamento del cancro gastrico
Latvian	Ramucirumabs	Kuņģa vēža ārstēšana
Lithuanian	Ramucirumabas	Skrandžio vėžio gydymas
Maltese	Ramucirumab	Kura tal-kanċer gastriku
Polish	Ramucyrumab	Leczenie raka żołądka
Portuguese	Ramucirumab	Tratamento do carcinoma gástrico
Romanian	Ramucirumab	Tratamentul cancerului gastric
Slovak	Ramucirumab	Liečba rakoviny žalúdka
Slovenian	Ramucirumab	Zdravljenje karcinoma želodca
Spanish	Ramucirumab	Tratamiento del cáncer de estómago
Swedish	Ramucirumab	Behandling av magcancer
Norwegian	Ramucirumab	Behandling av magekreft
Icelandic	Ramúcírúmab	Meðferð við magakrabbameini

[1] At the time of designation