27 August 2014
EMA/COMP/358832/2014
Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

Rilotumumab for the treatment of gastric cancer

On 29 July 2014, orphan designation (EU/3/14/1291) was granted by the European Commission to Amgen Europe BV, the Netherlands, for rilotumumab 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 (such as heartburn, gas and 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 approximately 2.4 in 10,000 people in the European Union (EU). This was equivalent to a total of around 123,000 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).

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 capecitabine, cisplatin, docetaxel, doxorubicin, epirubicin, 5-fluorouracil, mitomycin and trastuzumab. They were often used in combination.

*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 28), Norway, Iceland and Liechtenstein. This represents a population of 511,100,000 (Eurostat 2014).

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The sponsor has provided sufficient information to show that rilotumumab might be of significant benefit for patients with gastric cancer because early clinical studies show that it may improve the survival of patients when used in combination with standard treatment. 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?

Rilotumumab is a monoclonal antibody (a type of protein) that has been designed to recognise and attach to a protein called 'human hepatocyte growth factor/scatter factor' (HGF/SF), which is involved in the growth and survival of cells. High levels of HGF have been found in some cancers including gastric cancer. By attaching to HGF, rilotumumab is expected to block its action, thereby slowing down the growth and spread of the cancer cells.

What is the stage of development of this medicine?

The effects of rilotumumab have been evaluated in experimental models.

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

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

In accordance with Regulation (EC) No 141/2000 of 16 December 1999, the COMP adopted a positive opinion on 12 June 2014 recommending the granting of this 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 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	Rilotumumab	Treatment of gastric cancer
Bulgarian	рилотумумаб	Лечение на карцином на стомаха
Croatian	Rilotumumab	Liječenje raka želuca
Czech	Rilotumumab	Léčba karcinomu žaludku
Danish	Rilotumumab	Behandlingen af cancer ventriculi
Dutch	Rilotumumab	Behandeling van maagkanker
Estonian	Rilotumumab	Maovähi ravi
Finnish	Rilotumumabi	Mahasyövän hoito
French	Rilotumumab	Traitement du cancer gastrique
German	Rilotumumab	Behandlung von Magenkarzinom
Greek	Ριλοτουμουμάμπη	Θεραπεία του γαστρικού καρκίνου
Hungarian	Rilotumumab	Gyomorrák kezelése
Italian	Rilotumumab	Trattamento del cancro gastrico
Latvian	Rilotumumabs	Kuņģa vēža ārstēšana
Lithuanian	Rilotumumabas	Skrandžio vėžio gydymas
Maltese	Rilotumumab	Kura tal-kanċer gastriku
Polish	Rylotumumab	Leczenie raka żołądka
Portuguese	Rilotumumab	Tratamento do carcinoma gástrico
Romanian	Rilotumumab	Tratamentul cancerului gastric
Slovak	Rilotumumab	Liečba rakoviny žalúdka
Slovenian	Rilotumumab	Zdravljenje karcinoma želodca
Spanish	Rilotumumab	Tratamiento del cáncer de estómago
Swedish	Rilotumumab	Behandling av magcancer
Norwegian	Rilotumumab	Behandling av magekreft
Icelandic	Rílótúmúmab	Meðferð við magakrabbameini

[1] At the time of designation