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Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

Avelumab for the treatment of gastric cancer

On 12 December 2016, orphan designation (EU/3/16/1798) was granted by the European Commission to Merck Serono Europe Limited, United Kingdom, for avelumab 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. It is often detected late because 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 between 2.3 to 4.5 in 10,000 people in the European Union (EU). This was equivalent to a total of between 118,000 to 231,000 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, fluorouracil, mitomycin, ramucirumab 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 513,700,000 (Eurostat 2016).

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The sponsor has provided sufficient information to show that avelumab might be of significant benefit for patients with gastric cancer because early studies have found that patients might live longer when given avelumab as part of their initial cancer treatment as might patients who receive avelumab after at least two treatments with other cancer medicines. 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?

Avelumab is a monoclonal antibody, a protein designed to attach to PD-L1. PD-L1 is a protein produced by several cancers and it prevents the activation of T cells, which are part of the body's immune (defence) system. By attaching to PD-L1, avelumab stops the action of PD-L1 and so allows activation of T cells to attack cancer cells. In addition, by attaching to cancer cells, avelumab makes them a target for attack by immune system cells called natural killer (NK) cells. In this way avelumab is expected to prevent growth of the cancer.

What is the stage of development of this medicine?

The effects of avelumab have been evaluated in experimental models.

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

At the time of submission, avelumab was not authorised anywhere in the EU for gastric cancer. Orphan designation of the medicine had been granted in the EU and the United States for Merkel cell carcinoma (a type of skin cancer).

In accordance with Regulation (EC) No 141/2000 of 16 December 1999, the COMP adopted a positive opinion on 4 November 2016 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:

Contact details of the current sponsor for this orphan designation can be found on EMA website, on the medicine's rare disease designations page.

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	Avelumab	Treatment of gastric cancer
Bulgarian	Авелумаб	Лечение на карцином на стомаха
Croatian	avelumab	Liječenje raka želuca
Czech	Avelumab	Léčba karcinomu žaludku
Danish	Avelumab	Behandlingen af cancer ventriculi
Dutch	Avelumab	Behandeling van maagkanker
Estonian	Avelumaab	Maovähi ravi
Finnish	Avelumabi	Mahasyövän hoito
French	Avelumab	Traitement du cancer gastrique
German	Avelumab	Behandlung von Magenkarzinom
Greek	Αβελουμάμπη	Θεραπεία του γαστρικού καρκίνου
Hungarian	avelumab	Gyomorrák kezelése
Italian	Avelumab	Trattamento del cancro gastrico
Latvian	Avelumabs	Kuņģa vēža ārstēšana
Lithuanian	Avelumabas	Skrandžio vėžio gydymas
Maltese	Avelumab	Kura tal-kanċer gastriku
Polish	Awelumab	Leczenie raka żołądka
Portuguese	Avelumab	Tratamento do carcinoma gástrico
Romanian	Avelumab	Tratamentul cancerului gastric
Slovak	Avelumab	Liečba rakoviny žalúdka
Slovenian	Avelumab	Zdravljenje karcinoma želodca
Spanish	Avelumab	Tratamiento del cáncer de estómago
Swedish	Avelumab	Behandling av magcancer
Norwegian	Avelumab	Behandling av magekreft
Icelandic	Avelúmab	Meðferð við magakrabbameini

[1] At the time of designation