EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

Tesetaxel for the treatment of gastric cancer

On 17 December 2010, orphan designation (EU/3/10/829) was granted by the European Commission to Genta Development Ltd, United Kingdom, for tesetaxel 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 gastric cancer?

At the time of designation, gastric cancer affected approximately 3 in 10,000 people in the European Union (EU)*. This is equivalent to a total of around 152,000 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, patients with gastric cancer were treated first with surgery to remove part of or the whole stomach. Chemotherapy (medicines to treat cancer) was generally used after surgery. Many chemotherapy medicines were authorised in the EU for use in gastric cancer, such as docetaxel, doxorubicin, capecitabine, carmustine, epirubicin, 5-fluorouracil, mitomycin C 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 27), Norway, Iceland and Liechtenstein. This represents a population of 506,500,000 (Eurostat 2010).

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The sponsor has provided sufficient information to show that Tesetaxel might be of significant benefit for patients with gastric cancer, mainly because it is expected to be given by mouth as opposed to by injection. 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?

Tesetaxel belongs to the group of anticancer medicines known as the taxanes. It is expected to work by blocking the ability of cells to break down their internal 'skeleton' that allows cells to divide and multiply. With the skeleton still in place, the cancer cells cannot divide and they eventually die.

What is the stage of development of this medicine?

The effects of tesetaxel have been evaluated in experimental models.

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

At the time of submission, tesetaxel was not authorised anywhere in the EU for gastric cancer. Orphan designation of tesetaxel for the treatment of gastric cancer and melanoma (a type of skin cancer) had been granted in the United States of America.

In accordance with Regulation (EC) No 141/2000 of 16 December 1999, the COMP adopted a positive opinion on 7 October 2010 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 languages[1], Norwegian and Icelandic

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

[1] At the time of designation