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EMA/COMP/630502/2013
Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

Trebananib for the treatment of ovarian cancer

On 13 November 2013, orphan designation (EU/3/13/1207) was granted by the European Commission to Amgen Europe BV, the Netherlands, for trebananib for the treatment of ovarian cancer.

What is ovarian cancer?

Ovarian cancer is cancer of the ovaries, the two organs in the female reproductive system that produce eggs. Most ovarian cancers occur in women over the age of 50 years. Due to the absence of symptoms in the early stages of the disease, the majority of patients are diagnosed when the cancer has spread to other parts of the body.

Ovarian cancer is a life-threatening disease that is associated with poor long-term survival.

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

At the time of designation, ovarian cancer affected less than 3 in 10,000 people in the European Union (EU). This was equivalent to a total of fewer than 154,000 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, several medicines were authorised in the EU for the treatment of ovarian cancer. The choice of treatment depended mainly on how advanced the disease was. Treatments included surgery and chemotherapy (medicines to treat cancer).

The sponsor has provided sufficient information to show that trebananib might be of significant benefit for patients with ovarian cancer because studies suggest that it might improve the survival in patients with ovarian cancer, when used in combination with the chemotherapy medicine paclitaxel. This assumption will need to be confirmed at the time of marketing authorisation, in order to maintain the orphan status.

*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 512,200,000 (Eurostat 2013).

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How is this medicine expected to work?

Trebananib works by blocking the action of angiopoietin 1 and angiopoietin 2, two proteins that play an important role in the growth of blood vessels in cancer tissues. By blocking the activity of angiopoeitins, trebananib is expected to reduce the blood supply to the cancer cells, thereby helping to slow down the progression of the cancer.

What is the stage of development of this medicine?

The effects of trebananib have been evaluated in experimental models.

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

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

In accordance with Regulation (EC) No 141/2000 of 16 December 1999, the COMP adopted a positive opinion on 9 October 2013 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	Trebananib	Treatment of ovarian cancer
Bulgarian	Требананиб	Лечение на рак на яйчниците
Czech	Trebananib	Léčba karcinomu vaječníků
Croatian	Trebananib	Liječenje raka jajnika
Danish	Trebananib	Behandling af ovarie cancer
Dutch	Trebananib	Behandeling van ovariumkanker
Estonian	Trebananib	Munasarjavähi ravi
Finnish	Trebananibi	Munasarjasyövän hoito
French	Trebananib	Traitement du cancer de l'ovaire
German	Trebananib	Behandlung des Ovarialkarzinoms
Greek	Τρεμπανανίμπη	Θεραπεία του καρκίνου των ωοθηκών
Hungarian	Trebananib	Petefészekrák kezelése
Italian	Trebananib	Trattamento del carcinoma dell'ovaio
Latvian	Trebananibs	Olnīcu vēža ārstēšana
Lithuanian	Trebananibas	Kiaušidžių vėžio gydymas
Maltese	Trebananib	Kura tal-kanċer ta' l-ovarji
Polish	Trebananib	Leczenie raka jajnika
Portuguese	Trebananib	Tratamento do carcinoma do ovário
Romanian	Trebananib	Tratamentul cancerului ovarian
Slovak	Trebananib	Liečba rakoviny vaječníkov
Slovenian	Trebananib	Zdravljenje raka na jajčnikih
Spanish	Trebananib	Tratamiento del cáncer de ovario
Swedish	Trebananib	Behandling av ovarialcancer
Norwegian	Trebananib	Behandling av eggstokkreft
Icelandic	Trebananíb	Meðferð eggjastokkakrabbameins

[1] At the time of designation