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Public summary of opinion on orphan designation

Anetumab ravtansine for the treatment of ovarian cancer

On 19 November 2018, orphan designation (EU/3/18/2084) was granted by the European Commission to Bayer AG, Germany, for anetumab ravtansine 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 aged over 50 years. Due to the absence of clear symptoms in the early stages of the disease, the majority of women are diagnosed when the cancer has spread to other parts of the body.

Ovarian cancer is a debilitating and 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 approximately 4.9 in 10,000 people in the European Union (EU). This was equivalent to a total of around 254,000 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 the medicine might be of significant benefit for patients with ovarian cancer because early results suggest that it may produce improved responses in patients with the condition compared with existing products. 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 517,400,000 (Eurostat 2018).

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How is this medicine expected to work?

Anetumab ravtansine is made of two parts that are linked together. One part is a monoclonal antibody, a type of protein that has been designed to attach to mesothelin, a protein produced in excessive amounts by certain cancer cells such as ovarian cancer cells. The other part is a powerful cancer medicine that kills cells by interfering with a process called microtubule formation, which cells need in order to grow and multiply. When the medicine attaches to mesothelin on the cancer cells, the cancer agent is expected to be absorbed into the cancer cells and cause them to die, thus slowing down or stopping the growth of the cancer.

What is the stage of development of this medicine?

The effects of anetumab ravtansine have been evaluated in experimental models.

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

At the time of submission, anetumab ravtansine was not authorised anywhere in the EU for ovarian cancer or designated as an orphan medicinal product elsewhere for this condition.

In accordance with Regulation (EC) No 141/2000 of 16 December 1999, the COMP adopted a positive opinion on 11 October 2018 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:

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	Anetumab ravtansine	Treatment of ovarian cancer
Bulgarian	Анетумаб равтанзин	Лечение на рак на яйчниците
Croatian	Anetumab ravtanzin	Liječenje raka jajnika
Czech	Anetumabum ravtansin	Léčba karcinomu vaječníků
Danish	Anetumabravtansin	Behandling af ovarie cancer
Dutch	Anetumab ravtansine	Behandeling van ovariumkanker
Estonian	Anetumabravtansiin	Munasarjavähi ravi
Finnish	Anetumabi ravtansiini	Munasarjasyövän hoito
French	Anétumab ravtansine	Traitement du cancer de l'ovaire
German	Anetumab Ravtansin	Behandlung des Ovarialkarzinoms
Greek	Ανετουμάμπη ραβτανσίνη	Θεραπεία του καρκίνου των ωοθηκών
Hungarian	Anetumab ravtanzin	Petefészekrák kezelése
Italian	Anetumab ravtansine	Trattamento del carcinoma dell'ovaio
Latvian	Anetumaba ravtanzīns	Olnīcu vēža ārstēšana
Lithuanian	Anetumabas ravtansinas	Kiaušidžių vėžio gydymas
Maltese	Anetumab ravtansin	Kura tal-kanċer ta' l-ovarji
Polish	Anetumab rawtanzyna	Leczenie raka jajnika
Portuguese	Anetumab ravtansina	Tratamento do carcinoma do ovário
Romanian	Anetumab ravtansin	Tratamentul cancerului ovarian
Slovak	Anetumab ravtanzín	Liečba rakoviny vaječníkov
Slovenian	Anetumab ravtanzin	Zdravljenje raka na jajčnikih
Spanish	Anetumab ravtansina	Tratamiento del cáncer de ovario
Swedish	Anetumab ravtansin	Behandling av ovarialcancer
Norwegian	Anetumab ravtansin	Behandling av eggstokkreft
Icelandic	Anetúmab ravtansín	Meðferð eggjastokkakrabbameins

[1] At the time of designation