



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Committee for Orphan Medicinal Products

## Public summary of opinion on orphan designation

### Chimeric monoclonal antibody against claudin 6 for the treatment of ovarian cancer

On 24 January 2013, orphan designation (EU/3/12/1092) was granted by the European Commission to GANYMED Pharmaceuticals AG, Germany, for chimeric monoclonal antibody against claudin 6 for the treatment of ovarian cancer.

#### What is ovarian cancer?

Ovarian cancer is cancer of the ovaries (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 long-term 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 3 in 10,000 people in the European Union (EU). This was equivalent to a total of around 153,000 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 studies in experimental models suggest it might

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\*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 509,000,000 (Eurostat 2013).



improve the treatment of patients with this condition. 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?**

This medicine is a monoclonal antibody, a type of protein that has been designed to recognise and attach to a specific structure (called an antigen) that is found on the surface of cancer cells. This medicine has been designed to target an antigen called claudin 6, which is a protein found on the surface of many ovarian cancer cells (particularly in advanced disease), but not on the surface of healthy cells. By attaching to claudin 6 on the cancer cells, the monoclonal antibody is expected to cause the cells to die, slowing down the growth of the cancer.

### **What is the stage of development of this medicine?**

The effects of chimeric monoclonal antibody against claudin 6 have been evaluated in experimental models.

At the time of submission of the application for orphan designation, no clinical trials with the medicine in patients with ovarian cancer had been started.

At the time of submission, chimeric monoclonal antibody against claudin 6 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 6 December 2012 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<sup>1</sup>, Norwegian and Icelandic

Language	Active ingredient	Indication
English	Chimeric monoclonal antibody against claudin 6	Treatment of ovarian cancer
Bulgarian	Химерно моноклонално антитяло към клаудин 6	Лечение на рак на яйчниците
Czech	Chimerická monoklonální protilátka proti claudinu 6	Léčba karcinomu vaječníků
Danish	Kimærisk monoklonalt antistof mod claudin 6	Behandling af ovarie cancer
Dutch	Chimeer monoklonaal antilichaam gericht tegen claudine 6	Behandeling van ovariumkanker
Estonian	Klaudiin 6 vastane kimäärne monoklonaalne antikeha	Munasarjavähi ravi
Finnish	Klaudiini 6:n kimeerinen, monoklonaalinen vasta-aine	Munasarjasyövän hoito
French	Anticorps monoclonal chimérique dirigé contre la claudine 6	Traitement du cancer de l'ovaire
German	Chimärer monoklonaler Antikörper gegen Claudin-6	Behandlung des Ovarialkarzinoms
Greek	Χιμαϊρικό μονοκλωνικό αντίσωμα έναντι της κλωντίνης 6	Θεραπεία του καρκίνου των ωθηκών
Hungarian	Klaudin-6 elleni kiméra monoklonális antitest	Petefészekrák kezelése
Italian	Anticorpo monoclonale chimerico diretto contro la claudina 6	Trattamento del carcinoma dell'ovaio
Latvian	Himēriskā monoklonāla antivielā pret klaudīnu 6	Olnīcu vēža ārstēšana
Lithuanian	Chimerinis monokloninis antikūnas, naudojamas prieš klaudiną 6	Kiaušidžių vėžio gydymas
Maltese	Anti-korp monoklonali kimeriku kontra claudin 6	Kura tal-kanċer ta' l-ovarji
Polish	Chimeryczne przeciwciało monoklonalne przeciw kludynie 6	Leczenie raka jajnika
Portuguese	Anticorpo monoclonal quimérico anti claudina 6	Tratamento do carcinoma do ovário
Romanian	Anticorp monoclonal chimeric anti-claudin 6	Tratamentul cancerului ovarian
Slovak	Chimerická monoklonálna protilátka proti klaudínu-6	Liečba rakoviny vaječníkov
Slovenian	Himerno monoklonsko protitelo proti klavdinu 6	Zdravljenje raka na jajčnikih
Spanish	Anticuerpo monoclonal quimérico contra la claudina 6	Tratamiento del cáncer de ovario

<sup>1</sup> At the time of designation

Language	Active ingredient	Indication
Swedish	Chimerisk monoklonal antikropp mot claudin 6	Behandling av ovarialcancer
Norwegian	Kimerisk monoklonalt antistoff mot claudin-6	Behandling av eggstokkreft
Icelandic	Einstofna blendingsmótefni gegn claudín-6	Meðferð eggjastokkakrabbameins

Withdrawn