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Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

Murine anti-idiotypic antibody against OC125 antibody against CA125 antigen for the treatment of ovarian cancer

First publication	8 October 2003
Rev.1: transfer of sponsorship	27 October 2005
Rev.2: administrative update	4 January 2006
Rev.3: withdrawal from the Community Register	29 October 2012
Rev.4: administrative update	10 December 2013
Disclaimer Please note that revisions to the Public Summary of Opinion are purely administrative updates. Therefore, the scientific content of the document reflects the outcome of the Committee for Orphan Medicinal Products (COMP) at the time of designation and is not updated after first publication.	

Please note that this product was withdrawn from the Community Register of designated orphan medicinal products in September 2012 on request of the sponsor.

On 9 July 2003, orphan designation (EU/3/03/155) was granted by the European Commission to Cell Control Biomedical Laboratories AG, Germany, for murine anti-idiotypic antibody against OC125 antibody against CA125 antigen (ACA125) for the treatment of ovarian cancer.

The sponsorship was transferred to Menarini Ricerche S.p.A. in December 2004.

What is ovarian cancer?

Tumours that begin in the ovaries are known as ovarian tumours. Tumours which have potential to grow rapidly and infiltrate surrounding healthy tissues are called ovarian cancers. Due to the absence of symptoms in early stages of the disease the majority of the patients are diagnosed when the tumours have spread locally or to distant parts of the body. Ovarian cancer is a life-threatening condition.

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

At the time of designation, ovarian cancer affected approximately 2.4 in 10,000 persons in the European Union (EU). This was equivalent to a total of 92,000 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?

Several anticancer medicinal products had been authorised for the condition in the Community at the time of submission of the application for orphan designation. Although a significant percentage of patients respond to the initial chemotherapy (using drugs to kill cancer cells), most ovarian cancers grow again and respond moderately or poorly to subsequent chemotherapy.

ACA125 might be of potential significant benefit for the treatment of ovarian cancer, because it may offer a new mechanism of action to fight the disease. This assumption will have to be confirmed. This will be necessary to maintain the orphan status.

How is this medicine expected to work?

Antibodies are proteins in the body that target specific shapes on the surface of foreign bodies, such as bacteria or cancer cells. CA125 is a protein that can be found on the surface of the ovarian cancer cells. ACA125 is a special type of antibody that mimicks CA125, and this is in turn expected to trigger the production of other antibodies against CA125. Antibodies such as ACA125 that trigger the production of other antibodies are called “anti-idiotypic” antibodies. This anti-idiotypic antibody is shaped as a “double mirror-image” of the CA125 protein. By mimicking the CA125 protein, ACA125 may help the body's immune system to attack and kill the cancer cells.

What is the stage of development of this medicine?

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

At the time of submission, ACA125 was not marketed anywhere worldwide for ovarian cancer or designated as 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 13 June 2003 recommending the granting of this designation.

[*]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.
At the time of designation, this represented a population of 382,800,000 (Eurostat 2003).

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

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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	Murine anti-idiotypic antibody against OC125 antibody against CA125 antigen	Treatment of ovarian cancer
Czech	Myšší antiidiotypická protilátka proti protilátce OC125 proti CA 125 antigenu	Léčba karcinomu ovaria
Danish	Murin monoklonalt anti-idiotypisk antistof mod OC125 antistof mod CA125 antigen	Behandling af ovarie cancer
Dutch	Murien anti-idiotypie antilichaam tegen OC125 antilichaam tegen CA125 antigeen.	Behandeling van ovariumkanker.
Estonian	Hiire anti-idiotüüpne antikeha CA125 antigeeni vastase OC125 antikeha vastu.	Munasarja vähi ravi.
Finnish	Hiiriperäinen antiidiotyyppinen vasta-aine OC125 vasta-ainetta vastaan CA125 antigeenia vastaan	Munasarjasyövän hoito
French	Anticorps d'origine murine anti-idiotypique de l'anticorps OC125 dirigé contre l'antigène CA125	Traitement du cancer de l'ovaire
German	Muriner antiidiotypischer Antikörper, gegen OC125 Antikörper gegen Antigen CA125	Behandlung von Ovarialkarzinom
Greek	Αντι-ιδιοτυπικό αντίσωμα από ποντίκι έναντι του αντισώματος OC125 έναντι του αντιγόνου CA125	Θεραπεία του καρκίνου των ωοθηκών
Hungarian	CA 125 antigén ellenes OC125 ellenanyagra ható murin anti-idiotípiás ellenanyag	Ovárium rák kezelése
Italian	Anticorpo di origine murina anti-idiotipo, diretto contro l'anticorpo OC125, diretto contro l'antigene CA125	Trattamento del carcinoma dell'ovaio
Latvian	Peļu antiidiotipiskā antiviela pret OC125 antivielu pret CA125 antigēnu	Olnīcu vēža ārstēšana
Lithuanian	Murino anti-idiotipinis antikūnas prieš OC125 antikūną prieš CA125 antigeną	Kiaušidžių vėžio gydymas
Polish	Mysie anty-idiotypowe przeciwciało przeciw przeciwciału OC125 przeciw antygenowi CA125	Leczenie raka jajnika
Portuguese	Anticorpo antiidiotípico murínico contra o anticorpo OC125 contra o antígeno CA125	Tratamento do cancro do ovário

[1] At the time of transfer of sponsorhsip

Language	Active ingredient	Indication
Slovak	Myšacia proti–idiotypická protilátka proti OC125 protilátke proti CA125 antigénu	Liečba ovariálnych nádorov
Slovenian	Mišje antiidiotipsko protitelo proti protitelesu za antigen CA 125	Zdravljenje ovarijskega karcinoma
Spanish	Anticuerpo antiidiotípico murino contra el anticuerpo OC125 contra el antígeno CA125	Tratamiento del cáncer de ovario
Swedish	Murin antiidiotypisk antikropp mot OC125 antikropp mot CA 125 antigenen	Behandling av ovarialcancer