29 January 2014
EMA/COMP/69/2004 Rev.2
Committee for Orphan Medicinal Products

# Public summary of opinion on orphan designation

## Anti-epithelial cell adhesion molecule / anti-CD3 monoclonal antibody for the treatment of ovarian cancer

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| First publication | 11 October 2005 |
| Rev.1: administrative update | 27 October 2005 |
| Rev.2: sponsor's name and address change | 29 January 2014 |

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.

On 8 March 2004, orphan designation (EU/3/04/193) was granted by the European Commission to Fresenius Biotech GmbH, Germany, for anti-epithelial cell adhesion molecule / anti-CD3 monoclonal antibody for the treatment of ovarian cancer.

In January 2014, Fresenius Biotech GmbH changed name to Neovii Biotech GmbH.

### 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.

### 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 people in the European Union (EU). This was equivalent to a total of around 111,0000 people*, and is below the ceiling for

*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 25), Norway, Iceland and Liechtenstein.
At the time of designation, this represented a population of 464,200,000 (Eurostat 2004).

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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.

Anti-epithelial cell adhesion molecule / anti-CD3 monoclonal antibody 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. Anti-epithelial cell adhesion molecule / anti-CD3 monoclonal antibody is an antibody that has three locations where it can bind to specific shapes of different types of cells. The cells that it will recognise and bind are 1) the ovarian tumour cell, 2) the T cells, a type of cells that are part of the human body defence system and 3) other specific cells of the human body needed to activate these T cells. By physically binding these different types of cells, anti-epithelial cell adhesion molecule / anti-CD3 monoclonal antibody may help the body's immune system to attack and kill the ovarian 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, anti-epithelial cell adhesion molecule / anti-CD3 monoclonal antibody 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 5 February 2004 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 | Anti-epithelial cell adhesion molecule / anti-CD3 monoclonal antibody | Treatment of ovarian cancer |
| Danish | Antiepitheliel celle adhæsionsmolekyle / anti CD3 monoklonalt antistof | Behandling af ovarie cancer |
| Dutch | Anti-epitheliale cel adhesiemolecule/ anti-CD3 monoclonaal antilichaam | Behandeling van ovariumkanker |
| Finnish | Antiepiteliaalinen soluadheesiomolekyyli / anti-CD3 monoklonaalinen vasta-aine | Munasarjasyövän hoito |
| French | Anticorps monoclonal anti-molécule d'adhésion à la cellule épithéliale / anti-CD3 | Traitement du cancer de l'ovaire |
| German | Antieoitheliales Zelladhesionsmolekül/anti CD3 monoklonarer AntikörperAntikörper | Behandlung von Ovarialkarzinom |
| Greek | Μονοκλωνικό αντίσωμα έναντι CD3 / μορίου προσκόλλησης επιθηλιακού κυττάρου | Θεραπεία του καρκίνου των ωοθηκών |
| Italian | Anticorpo monoclonale contro la molecola di adesione epiteliale ed il recettore CD3 | Trattamento del carcinoma dell'ovaio |
| Portuguese | Anticorpo monoclonal contra a molécula de adesão das células epiteliais e o receptor CD3 | Tratamento do cancro do ovário |
| Spanish | Anticuerpo monoclonal dirigido contra la molécula de adhesión de las células epiteliales y el receptor CD3 | Tratamiento del cáncer de ovario |
| Swedish | Anti-epitelial celladhesionsmolekyl / anti-CD3 monoklonal antikropp | Behandling av ovarialcancer |

[1] At the time of designation