1 April 2009
EMEA/COMP/453951/2006 *Correction*[1]

Public summary of opinion on orphan designation

Paclitaxel (micellar) for the treatment of ovarian cancer

On 18 December 2006, orphan designation (EU/3/06/422) was granted by the European Commission to Oasmia Pharmaceutical AB, Sweden, for paclitaxel (micellar) for the treatment of ovarian cancer.

What is ovarian cancer?

Tumours that begin in the ovaries are known as ovarian tumours and those with the potential to grow rapidly and infiltrate the surrounding healthy tissues are called ovarian cancers. Due to the absence of symptoms in early stages of the disease the majority of 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 2.9 in 10,000 people in the European Union (EU)[*]. This is equivalent to a total of around 133,000 people, and is below the threshold for orphan designation, which is 5 people in 10,000. This is based on the information provided by the sponsor and knowledge of the Committee for Orphan Medicinal Products (COMP).

What treatments are available?

Several anticancer medicinal products were 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.

Paclitaxel (micellar) might be of potential significant benefit for the treatment of ovarian cancer because it causes fewer side-effects than currently used treatments. This assumption will have to be confirmed at the time of marketing authorisation. This will be necessary to maintain orphan status.

[1] Correction of active ingredient in the first paragraph of the summary of opinion, 2 October 2018.
[*] 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 459,700,000 (Eurostat 2004).

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How is this medicine expected to work?

Cells contain small structures (so-called microtubules), which are responsible for the structure of the cell and also help during cell-division. Paclitaxel (micellar) blocks the microtubules in the cancer cells in such a way that the cells cannot divide, leading to the destruction of the cell itself. Paclitaxel (micellar) is a new type of formulation.

What is the stage of development of this medicine?

The evaluation of the effects of paclitaxel (micellar) in experimental models is ongoing.

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

Paclitaxel (micellar) was not authorised anywhere worldwide for treatment of ovarian cancer or designated as orphan medicinal product elsewhere for this condition, at the time of submission.

According to Regulation (EC) No 141/2000 of 16 December 1999, the Committee for Orphan Medicinal Products (COMP) adopted on 9 November 2006 a positive opinion recommending the grant of the above-mentioned 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 Community) 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[2], Norwegian and Icelandic

Language	Active Ingredient	Indication
English	Paclitaxel (micellar)	Treatment of ovarian cancer
Czech	Paclitaxel (micelární)	Léčba karcinomu vaječníků.
Danish	Paclitaxel (micellar)	Behandling af ovarie cancer
Dutch	Paclitaxel (micellair)	Behandeling van ovariumkanker
Estonian	Paclitaxel (mitsellaarne)	Munasarjavähi ravi
Finnish	Paklitakseeli (misellarinen)	Munasarjasyövän hoito
French	Paclitaxel (micellaire)	Traitement du cancer de l'ovaire
German	Paclitaxel (mizellar)	Behandlung des Ovarialkarzinoms
Greek	Paclitaxel (διάλυμα μικυλλίων)	Θεραπεία του καρκίνου των ωοθηκών
Hungarian	Paclitaxel (micelláris)	Petefészekrák kezelése
Italian	Paclitaxel (micellare)	Trattamento del carcinoma dell'ovaio
Latvian	Paclitaxel (sajaukts jonizēts šķīdums)	Olnīcu vēža ārstēšanai
Lithuanian	Paklitakselis (micelių)	Kiaušidžių vėžio gydymas
Polish	Paklitaksel (mitsellaarne)	Leczenie raka jajnika
Portuguese	Paclitaxel (micelar)]	Tratamento do cancro do ovário
Slovak	Paklitaxel (micelárny)	Liečba rakoviny vaječníkov
Slovenian	Paklitaksel (micelarni)	Zdravljenje raka na jajčnikih
Spanish	Paclitaxel [micelas]	Tratamiento del cáncer de ovario
Swedish	Paklitaxel (micellär)	Behandling av ovarialcancer
Norwegian	Paklitaksel (i miceller)	Behandling av eggstokkreft
Icelandic	Paklítaxel (mísellulausn)	Meðferð eggjastokkakrabbameins

[2] At the time of designation