



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

8 August 2006
EMA/COMP/22896/2006 *Correction*¹

Public summary of opinion on orphan designation

Imexon for the treatment of ovarian cancer

On 23 December 2005, orphan designation (EU/3/05/341) was granted by the European Commission to ICON Clinical Research (U.K.) Limited, United Kingdom, for imexon for the treatment of ovarian cancer.

What is ovarian cancer?

Tumours that begin in the ovaries are known as ovarian tumours. Tumours which have the 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 are the methods of treatment 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.

Imexon might be of potential significant benefit for the treatment of ovarian cancer, particularly in combination with currently authorised medicinal products, because it might improve the long-term outcome of the patients. This assumption will have to be confirmed at the time of marketing authorisation. This will be necessary to maintain the orphan status.

¹ Correction of orphan indication in the first paragraph of the summary of opinion, 2 October 2018.



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

According to the information provided by the sponsor, ovarian cancer was considered to affect about 133,000 persons in the European Union.

How is this medicinal product expected to act?

Cells contain several substances needed for their normal functioning (e.g. glutathione, cysteine, thiols). They also contain small structures (so-called mitochondria), responsible for the production of the energy necessary for the cell functioning, through a process named "cellular respiration". Imexon might induce a certain reaction in the cancer cells leading to a shortage of the cell fundamental substances and the destruction of the surface of the mitochondria. This would then induce the destruction of the cell itself, through a process called "programmed cell death" (apoptosis).

What is the stage of development of this medicinal product?

The effects of imexon were evaluated in experimental models.

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

Imexon was not authorised anywhere worldwide for ovarian cancer, at the time of submission. Orphan designation of imexon was granted in Europe and in the United States for the treatment of pancreatic adenocarcinoma and additionally for treatment of multiple myeloma and for treatment of metastatic malignant melanoma in the United States only.

According to Regulation (EC) No 141/2000 of 16 December 1999, the Committee for Orphan Medicinal Products (COMP) adopted on 10 November 2005 a positive opinion recommending the grant of the above-mentioned designation.

Opinions on orphan medicinal products designations are based on the following cumulative criteria: (i) the seriousness of the condition, (ii) the existence or not of alternative methods of diagnosis, prevention or treatment and (iii) either the rarity of the condition (considered to affect not more than five in ten thousand persons in the Community) or the insufficient return of development investments.

Designated orphan medicinal products are still investigational products which were considered for designation on the basis of potential activity. An orphan designation is not a marketing authorisation. As a consequence, demonstration of the quality, safety and efficacy will be necessary before this product can be granted a marketing authorisation.

*Disclaimer: For the purpose of the designation, the number of patients affected by the condition is estimated and assessed based on data from the European Union (EU 25), Norway, Iceland and Lichtenstein. This represents a population of 459,700,000 (Eurostat 2004). This estimate is based on available information and calculations presented by the sponsor at the time of the application.

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 languages², Norwegian and Icelandic

Language	Active Ingredient	Indication
English	Imexon	Treatment of ovarian cancer
Czech	Imexon	Léčba karcinomu vaječníků.
Danish	Imexon	Behandling af ovarie cancer
Dutch	Imexon	Behandeling van ovariumkanker
Estonian	Imexon	Munasarjavähi ravi
Finnish	Imeksoni	Munasarjasyövän hoito
French	Imexon	Traitement du cancer de l'ovaire
German	Imexon	Behandlung des Ovarialkarzinoms
Greek	Imexon	Θεραπεία του καρκίνου των ωοθηκών
Hungarian	Imexon	Petefészekrák kezelése
Italian	Imexon	Trattamento del carcinoma dell'ovaio
Latvian	Imexon	Olnīcu vēža ārstēšanai
Lithuanian	Imexon	Kiaušidžių vėžio gydymas
Polish	Imekson	Leczenie raka jajnika
Portuguese	Imexon	Tratamento do cancro do ovário
Slovak	Imexon	Liečba rakoviny vaječníkov
Slovenian	Imexon	Zdravljenje raka na jajčnikih
Spanish	Imexón	Tratamiento del cáncer de ovario
Swedish	Imexon	Behandling av ovarialcancer
Norwegian	Imekson	Behandling av eggstokkreft
Icelandic	Imexon	Meðferð eggjastokkkrabbameins

² At the time of designation