



European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

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COMMITTEE FOR ORPHAN MEDICINAL PRODUCTS

PUBLIC SUMMARY OF POSITIVE OPINION FOR ORPHAN DESIGNATION OF cisplatin (liposomal) for the treatment of pancreatic cancer

On 8 June 2007, orphan designation (EU/3/07/451) was granted by the European Commission to Regulon AE, Greece, for cisplatin (liposomal) for the treatment of pancreatic cancer.

What is pancreatic cancer?

Cancer that begins in the pancreas is called pancreatic cancer. The pancreas is a small organ that lies behind the stomach and in front of the spine. The pancreas has two main functions in the body: first, it produces a juice that helps to digest (break down) and absorb food; second, it produces hormones (substances that circulate in the blood), such as insulin, that help to control blood sugar levels. About 95% of pancreatic cancers come from the cells that make the juice to digest. These cancers of the pancreas are called adenocarcinomas. Pancreatic cancer is a very severe disease and is life-threatening.

What are the methods of treatment available?

The choice of the treatment of pancreatic cancer depends on several factors, including the stage of the disease. Treatments may include surgery, radiation therapy (using high-dose x-rays or other high-energy rays to kill cancer cells), and chemotherapy (using drugs to kill cancer cells). There are anti-cancer drugs that have been authorised for treatment of pancreatic cancer. Cisplatin (liposomal) might be of potential significant benefit for the treatment of pancreatic cancer. It might offer a treatment to patients for whom other anti-cancer agents are not effective. This assumption will have to be confirmed at the time of marketing authorisation. This will be necessary to maintain the orphan status.

What is the estimated number of patients affected by pancreatic cancer?**

According to the information provided by the sponsor, pancreatic cancer was considered to affect approximately 55,000 persons in the European Union.

How is this medicinal product expected to act?

Cisplatin (liposomal) is a new formulation of cisplatin, which has been an anti-cancer drug for a long time. The inclusion of cisplatin in liposomes (special particles coated with molecules of fat) is expected to increase the concentration of the drug in the cancer cells, compared to normal cells, and decrease the adverse effects of the drug. Cisplatin works by damaging and eventually killing cancer cells, through the formation of special compounds, called "reactive oxygen species", which are toxic for the cells.

* 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.

What is the stage of development of this medicinal product?

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

Cisplatin (liposomal) was not marketed anywhere worldwide for pancreatic 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 12 April 2007 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.

For more information:

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**Translations of the active ingredient and indication in all EU languages
and Norwegian and Icelandic**

Language	Active Ingredient	Indication
English	Cisplatin (liposomal)	Treatment of pancreatic cancer
Bulgarian	Цисплатин (липозомен)	Лечение на рак на панкреаса
Czech	Cisplatina (liposomální)	Léčba karcinomu pankreatu
Danish	Cisplatin (liposomal)	Behandling af pancreascancer
Dutch	Cisplatin (liposomaal)	Behandeling van pancreaskanker
Estonian	Cisplatin (liposomaalne)	Pankreasevähi ravi
Finnish	Sisplatiini (liposomaalinen)	Haimasyövän hoito
French	Cisplatine (liposomal)	Traitement du cancer pancréatique
German	Cisplatin (liposomal)	Behandlung des Pankreaskarzinoms
Greek	Σισπλατίνη (λιποσωμική)	Θεραπεία καρκίνου του παγκρέατος
Hungarian	Cisplatin (liposómában)	Hasnyálmirigyrák kezelése
Italian	Cisplatino (liposomiale)	Trattamento del cancro pancreatico
Latvian	Cisplatīns (liposomu)	Aizkuņģa dziedzerā vēža ārstēšana
Lithuanian	Cisplatina (liposomu)	Kasos vėžio gydymas
Maltese	Cisplatin (liposomal)	Kura tal-kancer tal-frixa
Polish	Cisplatin (postać liposomalna)	Leczenie raka trzustki
Portuguese	Cisplatina (lipossomal)	Tratamento do cancro do pâncreas
Romanian	Cisplatină (lipozomal)	Tratamentul cancerului pancreatic
Slovak	Cisplatina (lipozomálna)	Liečba rakoviny pankreasu
Slovenian	Cisplatin (liposomalni)	Zdravljenje raka trebušne slinavke
Spanish	Cisplatino (liposomal)	Tratamiento del cáncer de páncreas
Swedish	Cisplatin (liposomal)	Behandling av pancreascancer
Norwegian	Cisplatin (liposomal)	Behandling av pancreascancer
Icelandic	Cisplatin (í fitukornum)	Meðferð briskrabbameins