



COMMITTEE FOR ORPHAN MEDICINAL PRODUCTS

**PUBLIC SUMMARY OF
POSITIVE OPINION FOR ORPHAN DESIGNATION
OF
bovine bile extract
for the treatment of pancreatic cancer**

On 20 June 2005, orphan designation (EU/3/05/287) was granted by the European Commission to GMG BioBusiness Ltd, United Kingdom, for bovine bile extract for the treatment of pancreatic cancer.

The sponsorship was transferred to Dr Ulrich Granzer, Germany, in December 2006.

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. It makes a juice that helps to digest (break down) food. It also produces hormones, 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 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. Bovine bile extract might be of potential significant benefit for the treatment of pancreatic 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.

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

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

How is this medicinal product expected to act?

This medicinal product is a biological preparation isolated from the bile of cattle. The mechanism of action of bovine bile extract is not fully known. It is believed to activate a certain type of white blood cells, a type of cell belonging to the body's defence system (immune system), the so-called macrophages. The main role of macrophages is to take-up material (such as bacteria, cancer cells or cell fragments). Following the uptake they degrade the material and present parts of this material to the other components of the body's defence system. Activation of these cells may thus stimulate an immune response of the organism, which might cause the immune system to recognise and kill the cancer cells.

What is the stage of development of this medicinal product?

The effects of bovine bile extract were evaluated in experimental models. At the time of submission of the application for orphan designation, clinical trials in patients with pancreatic cancer were ongoing.

Bovine bile extract was not marketed anywhere worldwide for pancreatic cancer, at the time of submission. Orphan designation of bovine bile extract was granted in United States for pancreatic cancer in February 2001.

According to Regulation (EC) No 141/2000 of 16 December 1999, the Committee for Orphan Medicinal Products (COMP) adopted on 12 May 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.

For more information:

Sponsor's contact details:

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*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.

Patients' associations contact points:

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

Language	Active Ingredient	Indication
English	Bovine bile extract	Treatment of pancreatic cancer
Czech	Výtažek z hovězí žluči	Léčba karcinomu pankreatu
Danish	Bovint galdeekstrakt	Behandling af pancreascancer
Dutch	Runder galextract	Behandeling van pancreaskanker
Estonian	Veisesapi ekstrakt	Pankreasevähi ravi
Finnish	Naudan sappiuute	Haimasyövän hoito
French	Extrait de bile bovine	Traitement du cancer pancréatique
German	Boviner Gallenflüssigkeitsextrakt	Behandlung von Pankreaskrebs
Greek	Εκχύλισμα βόειας χολής	Θεραπεία καρκίνου του παγκρέατος
Hungarian	Szarvasmarha epe- kivonat	Hasnyálmirigyrák kezelése
Italian	Estratto di bile bovina	Trattamento del cancro pancreatico
Latvian	Vērša žults ekstrakts	Aizkuņģa dziedzerā vēža ārstēšanai
Lithuanian	Galvijų tulžies ekstraktas	Kasos vėžio gydymas
Polish	Ekstrakt żółci wołowej.	Leczenie raka trzustki
Portuguese	Extracto de bilis bovina	Tratamento do cancro do pâncreas
Slovak	Výťažok z hovädzej žlče	Liečba rakoviny pankreasu
Slovenian	Izvleček govejega žolča	Zdravljenje raka trebušne slinavke
Spanish	Extracto de bilis bovina	Tratamiento del cáncer de páncreas
Swedish	Bovint galleextrakt	Behandling av pankreascancer
Norwegian	Bovint galleekstrakt	Behandling av pankreascancer
Icelandic	Nautagallsextrakt	meðhöndlun krabbameins í brisi