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EMA/COMP/892/2003 Rev.1
Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

Iodine (^{131}I) anti-CEA sheep-human chimeric monoclonal antibody for the treatment of pancreatic cancer

Please note that this product was withdrawn from the Community Register of designated orphan medicinal products in June 2011 on request of the sponsor.

On 7 May 2003, orphan designation (EU/3/03/142) was granted by the European Commission to KS Biomedix Limited, United Kingdom, for iodine (^{131}I) anti-CEA sheep-human chimeric monoclonal antibody 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. It makes a juice that helps to digest (break down) food. It makes 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 is the estimated number of patients affected by the condition?

At the time of designation, pancreatic cancer affected approximately 1 in 10,000 people in the European Union (EU)*. This is equivalent to a total of 38,000 people, and is below the ceiling for 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).

*Disclaimer: The number of patients affected by the condition is estimated and assessed for the purpose of the designation, for a European Community population of 377,000,000 (Eurostat 2001) and may differ from the true number of patients affected by the condition. This estimate is based on available information and calculations presented by the sponsor at the time of the application.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

What treatments are 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, and chemotherapy (using drugs to kill cancer cells). There are anti-cancer agents that have been authorised for treatment of pancreatic cancer. Iodine (^{131}I) anti-CEA sheep-human chimeric monoclonal antibody might be useful for the treatment of pancreatic cancer. It might offer a treatment which can better distinguish the cancer cells from the normal ones. This assumption remains to be proven. This will be necessary to maintain the orphan status.

How is this medicine expected to work?

Antibodies are proteins that are able to distinguish certain foreign substances called antigens. Examples of antigens are proteins found on the surface of cancer cells or bacteria. Anti-CEA sheep-human chimeric monoclonal antibody targets a substance present on the surface of pancreatic cancer cells. This substance is called carcinoembryonic antigen, or CEA. The antibody is called chimeric because it is composed of parts that were first found in different species of living things. In this case, the species are sheep, and man. It is called monoclonal because it is produced using cells that have identical genes, and produce exactly the same antibody. The antibody is also linked (labelled) with a tiny part, called iodine-131. Iodine-131 can give off radiation. Radiation can damage and kill cells, especially those that are dividing, such as cancer cells. Thus, the antibody is used to deliver the radiation to the pancreatic cancer cells and to kill them with the radiation.

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 pancreatic cancer were ongoing.

Iodine (^{131}I) anti-CEA sheep-human chimeric monoclonal antibody was not marketed anywhere worldwide for pancreatic cancer or designated as orphan medicinal product elsewhere for this condition, at the time of submission.

In accordance with Regulation (EC) No 141/2000 of 16 December 1999, the COMP adopted a positive opinion on 19 March 2003 recommending the granting of this 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 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:

KS Biomedix Limited
Ground Floor, 1 Occam Court, Surrey Research Park, Guildford
Surrey, GU2 7HJ
United Kingdom
Telephone: +44 (0) 1483 307500
Telefax: +44 (0) 1483 307501
E-mail: info@ksbiomedix.com

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	Iodine (131I) anti-CEA sheep-human chimeric monoclonal antibody	Treatment of pancreatic cancer
Danish	Jod (131I) anti-CEA får-humant kimærisk monoklonalt antistof	Behandling af pancreascancer
Dutch	Iodine (131I) anti-CEA schaap-humaan chimerisch monoclonaal antilichaam	Behandeling van pancreaskanker
Finnish	Jodi (131I) merkitty ihmisen ja lampaan kimeerinen monoklonaalinen anti-CEA-vasta-aine	Haimasyövän hoito
French	Anticorps chimérique monoclonal anti-ACE ovin-humain marqué à l'iode (131I)	Traitement du cancer du pancréas
German	Jod (131I) Ovin-humaner, chimärer, monoklonaler Anti-CEA-Antikörper	Behandlung des Pankreaskarzinoms
Greek	ιώδιο-(I131) - Πρόβειο-ανθρώπινο χιμαιρικό μονοκλωνικό αντίσωμα έναντι του αντικαρκινοεμβρυικού αντιγόνου (Anti-CEA)	Θεραπευτική αγωγή για τον καρκίνο του παγκρέατος
Italian	Iodio (131I) anticorpo monoclonale chimerico umano-ovino anti-CEA	Trattamento del cancro del pancreas
Portuguese	Iodo (131I) anticorpo monoclonal quimérico ovino-humano anti-CEA	Tratamento de cancro pancreático
Spanish	Yodo (131I) anticuerpo monoclonal quimérico ovino-humano anti CEA	Tratamiento de cáncer pancreático
Swedish	Jod (131I) anti-CEA får –human chimär monoklonal antikropp	Behandling av bukspottscancer

[1] At the time of designation