



Document Date: London, 2 June 2004
EMA/COMP/1286/03

Please note that this product was withdrawn from the Community Register of designated Orphan Medicinal Products in July 2004 on request from the sponsor.

COMMITTEE FOR ORPHAN MEDICINAL PRODUCTS

PUBLIC SUMMARY OF POSITIVE OPINION FOR ORPHAN DESIGNATION OF human milk fat globule 1 / Yttrium (⁹⁰Y) human milk fat globule 1 – S-p-isothiocyanatobenzyl-diethylenetriaminepentaacetic acid for the treatment of ovarian cancer

On 30 May 2001, orphan designation (EU/3/01/043) was granted by the European Commission to Antisoma Plc, United Kingdom, human milk fat globule 1 / Yttrium (⁹⁰Y) human milk fat globule 1 - S-p-isothiocyanatobenzyl-diethylenetriaminepentaacetic acid (HMFG1) for the treatment of ovarian cancer.

What is ovarian cancer?

Tumours that begin in the ovaries are known as ovarian tumours. Tumours which have 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 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 patients relapse and respond moderately or poorly to subsequent chemotherapy.

HMFG1 might be of potential significant benefit for the treatment of ovarian cancer because it might improve the effect on the tumour in some 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, ovarian cancer was considered to affect about 82,500 people in the European Union.

How is this medicinal product expected to act?

HMFG1 is a radio labelled monoclonal antibody complex. A monoclonal antibody is a substance, usually a protein, which can be synthesised in the laboratory in pure form by a single clone (population) of cultivated cells. These antibodies can be made in large quantities as the number of cells producing them can be amplified as much as necessary. Once they are synthesised, they are labelled, in other words combined, to Yttrium (⁹⁰Y), a chemical element which can give off localised radiation. HMFG1 may recognise a specific antigen on the cancer cell and locks on to it (like a key in a lock). This might then trigger the body's immune system to attack the cancer cells. In addition, Yttrium (⁹⁰Y) can give off radiation which can damage and kill cells in its vicinity, especially those dividing, such as cancer cells.

What is the stage of development of this medicinal product?

The effects of HMFG1 were evaluated in experimental models. At the time of submission of the application for orphan designation, two clinical trials in patients with ovarian cancer were completed and one was ongoing.

HMFG1 was not marketed anywhere worldwide for the treatment of ovarian cancer, at the time of submission. Orphan designation of HMGF1 was granted in the United States for adjuvant treatment of ovarian cancer.

According to Regulation (EC) No 141/2000 of 16 December 1999, the Committee for Orphan Medicinal Products (COMP) adopted on 10 April 2001 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:

Antisoma Plc

West Africa House

Hanger Lane

Ealing

London W5 3QR

United Kingdom

Telephone: (44-20) 8799 8200

Telefax: (44-20) 8799 8203

E-mail: enquiries@antisoma.com

*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.

Translations of the active ingredient and indication in all EU languages

Language	Active Ingredient	Indication
English	Human Milk Fat Globule 1 / Yttrium (⁹⁰ Y) Human Milk Fat Globule 1 - S-p-isothiocyanatobenzyl-diethylenetriaminepentaacetic acid	Treatment of ovarian cancer
Danish	Humaan Melk Vet Globule 1 / Yttrium (⁹⁰ Y) Humaan Melk Vet Globule 1 - S-p-isothiocyanatobenzyl-diethylen-triamin-pentaeddikesyre	Behandling af cancer ovarii
Dutch	Human Milk Fat Globule 1 / Yttrium (⁹⁰ Y) Human Milk Fat Globule 1-S-p-isothiocyanatobenzyl-diethyleentriamine-pentaazijnzuur	Voor het behandelen van ovarium kanker
Finnish	Äidinmaidon rasvapallosten vasta-aine 1 / Yttriumin (⁹⁰ Y) äidinmaidon rasvapallosten vasta-aine 1 - S-p-isotiosyanaattibentsyylidietyleenitriamiinipentaetikahappo	Munasarjasyövän hoito
French	Globules de matières grasses du lait humain 1 / Globules de matières grasses du lait humain 1 - acide S-p-isothiocyanatobenzyl-diéthylène-triamine penta-acétique à utiliser avec l'yttrium (⁹⁰ Y)	Traitement du cancer ovarien
German	Human Milk Fat Globule 1 / Yttrium (⁹⁰ Y) Human Milk Fat Globule 1-S-p-Isothiocyanatobenzyl-diethylen-triamin-pentaessigsäure	Behandlung des Ovarialkarzinoms
Greek	Λιποσφαιρίδιο του ανθρώπινου μητρικού γάλακτος 1 / ύτριο (⁹⁰ Y) λιποσφαιρίδιο του ανθρώπινου μητρικού γάλακτος 1 - S-p-ισοθειοκυανοτοβενζυλ-διαιθυλενικό τριαμινικό πενταοξικό οξύ	Αγωγή στον καρκίνο της ωοθήκης
Italian	Human Milk Fat Globule 1 / Ittrio (⁹⁰ Y) Human Milk Fat Globule 1- acido S-p-isotiocianatobenzil-dietilen-triammina-pentaacetico	Trattamento del cancro dell'ovaio
Portuguese	Glóbulo da gordura de leite humano 1 / Ítrio (⁹⁰ Y) glóbulo da gordura de leite humano 1 - ácido S-p-isotiocianatobenzil-dietileno-triamina-pentacético	Tratamento do cancro do ovário
Spanish	Human Milk Fat Globule 1 / Itrio (⁹⁰ Y) Human Milk Fat Globule 1 ácido S-p-isotiocianatobenzil-dietilen-triamino-pentaacético	Tratamiento de cancer de ovario
Swedish	Human Milk Fat Globule 1 / Yttrium (⁹⁰ Y) Human Milk Fat Globule 1- S-p-isotiocyanatobensyl-dietylen-triamin-pentaättiksyra	Behandling av ovarialcancer