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

Document Date: London, 4 January 2006
Doc.Ref.: EMEA/COMP/122308/2004

COMMITTEE FOR ORPHAN MEDICINAL PRODUCTS

PUBLIC SUMMARY OF POSITIVE OPINION FOR ORPHAN DESIGNATION OF biotinylated anti-tenascin monoclonal antibody for use with ^{90}-Yttrium for the treatment of glioma

On 20 October 2004, orphan designation (EU/3/04/232) was granted by the European Commission to Sigma-Tau Industrie Farmaceutiche Riunite S.p.A., Italy, for biotinylated anti-tenascin monoclonal antibody for use with ^{90}-Yttrium for the treatment of glioma.

What is glioma?
Tumours that begin in brain tissue are known as primary brain tumours. Primary brain tumours are classified by the type of tissue from which they originate, the most common being gliomas, which begin in the glial (supportive) tissue.
Gliomas represent a debilitating and life-threatening condition. Patients affected by gliomas can suffer from severe symptoms of the nervous system, depending on where in the brain the tumour develops.

What are the methods of treatment available?
Treatment for gliomas depends on a number of factors and encompasses several methods such as surgery, radiotherapy (using high-dose x-rays or other high-energy rays to kill cancer cells) or chemotherapy (using drugs to kill cancer cells), as well as some symptomatic treatments. Symptomatic treatments include certain steroid hormones (corticosteroids) to control the effects of raised pressure within the skull, and medication to help control seizures, as required. Methods of treatment of glioma were authorised in the Community at the time of submission of the application for orphan designation.
Biotinylated anti-tenascin monoclonal antibody for use with ^{90}-Yttrium might be of potential significant benefit for the treatment of gliomas because it might help to improve the localisation of the radiotherapy to the glioma. The 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, glioma was considered to affect about 46,000 persons in the European Union.

How is this medicinal product expected to act?
The product comprises a kit containing an antibody, a number of other proteins and a radioactive element (^{90}-Yttrium). Antibodies are proteins in the body that target specific shapes on the surface of foreign entities, such as bacteria and viruses, but also on abnormal body cells such as cancer cells.
In this case, the antibody is intended to target a protein (tenascin), which is present in particular in the space that exists between the tumour cells and is therefore expected to accumulate in the tumour. The other proteins in the kit are administered to clear the excess antibody from the rest of the body and assist in targeting the radioactive element (^{90}-Yttrium) to the glioma. The purpose of the targeting of the radioactive element inside the tumour mass is to kill the maximum tumour cells and minimise the amount of rays in the rest of the body.

Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 75 23 70 40
E-mail: orphandrugs@emea.eu.int www.emea.eu.int
©EMEA 2006 Reproduction and/or distribution of this document is authorised for non-commercial purposes only provided the EMEA is acknowledged

What is the stage of development of this medicinal product?
The evaluation of the effects of biotinylated anti-tenascin monoclonal antibody for use with ^{90}-Yttrium in experimental models is ongoing. At the time of submission of the application for orphan designation, no clinical trials in patients with glioma were initiated.

The medicinal product was not marketed anywhere worldwide for glioma 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 9 September 2004 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:
Sigma-Tau Industrie Farmaceutiche Riunite S.p.A.
Viale Shakespeare 47
I-00144 Roma
Italy
Telephone: +39 06 91 39 33 03
Telefax: +39 06 91 08 260
E-mail: adelaide.petraroja@sigma-tau.it

Patients' associations contact points:

Cancer BACUP
3 Bath Place
Rivington Street
London
EC2A 3JR
United Kingdom
Telephone: +44 20 76 96 90 03 / 0808 800 1234 (freephone for UK)
Telefax: +44 20 76 96 90 02

Deutsche Krebshilfe e.V.
Buschstrasse 32

*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.

©EMEA 2006

53113 Bonn
Postfach 1467
53004 Bonn
Germany
Telephone: +49 2 28 72 99 00
Telefax: +49 22 87 29 90 11
E-mail: deutsche@krebshilfe.de

Ligue Nationale Contre le Cancer
13 Av. de la Grande Armee
75116 Paris
France
Telephone: +33 1 45 00 00 17
Tefefax: +33 1 45 00 63 06
E-mail: ligue@ligue-cancer.net

*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.

©EMEA 2006

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

English	Biotinylated anti-tenascin monoclonal antibody for use with 90-Yttrium	Treatment of glioma
Czech	Biotin-Monoklonální protilátka proti tenascinu vázaná na Yttrium 90	Léčba gliomu
Danish	Biotinyleret anti-tenascin monoklonalt antistof til brug med 90-Yttrium	Behandling af gliom
Dutch	Biotine anti-tenascine monoclonaal antilichaam voor gebruik met 90 Yttrium	Behandeling van glioma
Estonian	Biotinüleeritud anti-tenastsiin monoklonaalne antikeha kasutamiseks koos 90-Ütriumiga	Glioomi ravi
Finnish	Biotinyloitu tenaskiinia estävä monoklonaalinen vasta-aine käytettäväksi yhdessä Yttrium 90:n kanssa	Gliooman hoito
French	Anticorps monoclonal biotinilé anti-tenascine pour une utilisation avec Yttrium 90	Traitement des gliomes
German	Monoklonaler Biotinylat-Antitenazyn-Antikörper zur Anwendung mit Yttrium 90	Behandlung des Glioms
Greek	Βιοτυνιλιωμένο μονοκλωνικό αντίσωμα αντιτενασκίνης για χρήση με Υττριο 90	Θεραπεία του γλοιώματος
Hungarian	Biotinilált anti-tenascin monoklonális ellenanyag Ittrium 90-el együtt alkalmazva	Glioma kezelése
Italian	Anticorpo monoclonale biotinilato anti-tenascina per l'uso con Ittrio 90	Trattamento del glioma
Latvian	Biotinilēta monoklonāla antitenascīna antiviela lietošanai ar Itriju 90	Gliomas ārstēšana
Lithuanian	Biotinilato monokloninis anti-tenascino antikūnis skirtas naudojimui su itriu 90.	Gliomos gydymas
Maltese	Biotinylated anti-tenascin monoclonal antibody for use with 90-Yttrium	Treatment of glioma
Polish	Biotynowane przeciwciało monoklonalne przeciw tenascynie do stosowania z Itrem 90	Leczenie glejaka
Portuguese	Anticorpo monoclonal biotinilado anti-tenascina para o uso com o Itrio 90	Tratamento do glioma
Slovak	Monoklonálna anti-tenascín protilátka s biotínom na použitie s Yttriom 90	Liečba gliómu
Slovenian	Biotinsko anti-tenascin monoklonsko protitelo za uporabo z Itrijem 90	Zdravljenje glioma
Spanish	Anticuerpo monoclonal biotinylado antitenacina para uso con Itrio 90	Tratamiento del glioma
Swedish	Biotinylerad monoklonal anti-tenascin antikropp för användning med 90-Yttrium	Behandling av gliom
Norwegian	Biotinylert anti-tenascin monoklonalt antistoff til bruk sammen med yttrium 90	Behandling av gliom
Icelandic	Biotinylerað and-tenascin einstofna mótefni til nota ásamt 90-Yttrium	Meðhöndlun glioma

©EMEA 2006