6 March 2015
EMA/COMP/221961/2008 Rev.2
Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

Iodine (^{131}I) anti-tenascin monoclonal antibody 81C6 for the treatment of glioma

First publication	15 June 2009
Rev.1: transfer of sponsorship	16 May 2011
Rev.2: sponsor's change of address	6 March 2015
Disclaimer Please note that revisions to the Public Summary of Opinion are purely administrative updates. Therefore, the scientific content of the document reflects the outcome of the Committee for Orphan Medicinal Products (COMP) at the time of designation and is not updated after first publication.	

On 30 October 2006, orphan designation (EU/3/06/418) was granted by the European Commission to BCG (Europe) Ltd, United Kingdom, for iodine (^{131}I) anti-tenascin monoclonal antibody 81C6 for the treatment of glioma.

The sponsorship was transferred to The Weinberg Group LLC, United Kingdom, in June 2007, to The Weinberg Group Limited, United Kingdom, in March 2009 and subsequently to Biological Consulting Europe Ltd, United Kingdom, in December 2010.

What is glioma?

Glioma is a type of brain tumour that begins in 'glial' cells (the cells that surround and support nerve cells). Patients with gliomas can suffer from different symptoms, depending on the part of the brain where the tumour develops. Glioma is a life-threatening disease.

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

At the time of designation glioma affected approximately 1 in 10,000 people in the European Union (EU). This was equivalent to a total of around 47,000 people*, and is below the threshold for orphan

*Disclaimer: For the purpose of the designation, the number of patients affected by the condition is estimated and assessed on the basis of data from the European Union (EU 25), Norway, Iceland and Liechtenstein.
At the time of designation, this represented a population of 468,900,000 (Eurostat 2006).

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designation, which is 5 people in 10,000. This is based on the information provided by the sponsor and knowledge of the Committee for Orphan Medicinal Products (COMP).

What treatments are available?

Treatment for glioma may combine different methods such as surgery, radiotherapy (treatment with radiation) and chemotherapy (medicines used to treat cancer). Other treatments are used to relieve the disease's symptoms, including corticosteroids that help to reduce pressure within the skull, and medicines that help with the control of seizures (fits). At the time of orphan designation, several medicines were authorised in the European Union for the treatment of glioma and its symptoms.

Satisfactory argumentation has been submitted by the sponsor to justify the assumption that iodine (^{131}I) anti-tenascin monoclonal antibody 81C6 might be of potential significant benefit for the treatment of glioma, mainly because it may provide a major benefit to patient care. This assumption will have to be confirmed at the time of marketing authorisation. This will be necessary to maintain the orphan status.

How is this medicine expected to work?

The product is a radioactive element (iodine 131) attached to a protein, which specifically binds to glioma cells. Iodine-131 can give off radiation, which in turn damages and kills cells, especially those that are dividing, such as cancer cells. Thus, it is expected that iodine (^{131}I) anti-tenascin monoclonal antibody 81C6 will build up in the glioma cancer cells, and then kill these cells with the radiation produced by the radioactive iodine contained in the molecule.

What is the stage of development of this medicine?

The effects of iodine (^{131}I) anti-tenascin monoclonal antibody 81C6 were evaluated in experimental models.

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

Iodine (^{131}I) anti-tenascin monoclonal antibody 81C6 was not authorised anywhere worldwide for the treatment of glioma, at the time of submission.

Orphan designation of iodine (^{131}I) anti-tenascin monoclonal antibody 81C6 was granted in the United States for the treatment of primary brain tumours.

In accordance with Regulation (EC) No 141/2000 of 16 December 1999, the COMP adopted a positive opinion on 4 October 2006 recommending the granting of this designation.

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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:

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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 (^{131}I) anti-tenascin monoclonal antibody 81C6	Treatment of glioma
Bulgarian	Йод(^{131}I) анти- тенасцин моноклонално антитяло	Лечение на глиома
Czech	Jódová (^{131}I) anti-tenascinová monoklonální antilátka 81C6	Léčba gliomů
Danish	^{131}I (Jod-131) antitenascin monoklont antistof 81C6	Behandling af gliom
Dutch	Iodium^{131} anti-tenascin monoklonaal antilichaam 81C6	Behandeling van glioma
Estonian	Jood-^{131}I tenastsiinivastane monoklonaalne antikeha 81C6	Glioomi ravi
Finnish	Jodi (^{131}I) antitenaskiini monoklonaalinen vasta-aine 81C6	Glioman hoito
French	Anticorps monoclonal anti-tenascin 81C6 marqué à l'iode ^{131}I	Traitement des gliomes
German	Monoklonaler Iod (^{131}) Antitenascin-Antikörper 81C6	Behandlung von Gliomen
Greek	μονοκλωνικό αντίσωμα 81C6 κατά της tenascin επισημασμένο με ιώδιο (^{131}I)	Θεραπεία του γλοιώματος
Hungarian	Jód (^{131}J) antitenascin 81C6 monoklonális antitest	Glioma kezelése
Italian	Anticorpo monoclonale antitenascina, con iodio-131	Trattamento del glioma
Latvian	Joda (^{131}I izotopa) antitenascīna monoklonālā antiviela 81C6	Gliomas ārstēšana
Lithuanian	Jodido (^{131}I) radionuklido monokloninis antikūnis 81C6	Gliomos gydymas
Maltese	Anti-korp monoklonali anti-*tenascin* 81Ċ6 mal-jodju (^{131}I)	Kura tal-glioma
Polish	Przeciwciało monoklonalne 81C6 przeciw tenascynie z izotopem jodu I^{131}	Leczenie glejaka
Portuguese	Anticorpo monoclonal anti-tenascina 81C6 de iodo (^{131}I)	Tratamento do glioma
Romanian	Anticorp monoclonal 81C6 anti-tenascină marcat cu Iod (^{131}I)	Tratamentul gliomului
Slovak	Jód (^{131}I) anti-tenascínová monoklonálna protilátka 81C6	Liečba gliómu
Slovenian	Jodova (^{131}I) antitenascinska monoklonalna protitelesa 81C6	Zdravljenje glioma
Spanish	Anticuerpo monoclonal 81C6 antitenascina marcado con yodo (^{131}I)	Tratamiento del glioma

[1] At the time of transfer of sponsorship

Language	Active Ingredient	Indication
Swedish	Jod (^{131}I) anti-tenascin monoklonal antikropp 81C6	Behandling av gliom
Norwegian	Jod (^{131}I) antitenasin monoklonalt antistoff 81C6	Behandling av gliom
Icelandic	Joð (^{131}I) andtenascin einstofna mótefni 81C6	Meðhöndlun á glióma