



Committee for Orphan Medicinal Products

Public summary of positive opinion for orphan designation of human monoclonal antibody against *Pseudomonas aeruginosa* serotype O11 for the treatment of pneumonia caused by serotype O11 *Pseudomonas aeruginosa*

On 29 June 2006, orphan designation (EU/3/06/381) was granted by the European Commission to MDS Pharma Services GB Limited, United Kingdom, for human monoclonal antibody against *Pseudomonas aeruginosa* serotype O11 for the treatment of pneumonia caused by serotype O11 *Pseudomonas aeruginosa*.

The sponsorship was transferred to Voisin Consulting, France, in July 2007.

What is pneumonia caused by serotype O11 *Pseudomonas aeruginosa*?

Pneumonia is an inflammation (reaction of the immune system, the body's natural defence system) in the lung tissue. It can be caused by several microorganisms such as different kinds of bacteria, virus and fungi. It can also be caused by chemicals that are breathed in. The inflammation leads to a diminished function of the lungs and common symptoms are associated to the decreased ability of the blood to take up oxygen from the air. Especially in the hospital setting, pneumonia can be caused by infection by the bacteria *Pseudomonas aeruginosa*. A serotype is defined by the kind of antibodies (proteins of the immune system that bind to foreign molecules) that are induced by different strains of microorganisms, in this case the bacterium. Serotype O11 is one of the most common strains of *Pseudomonas aeruginosa*. Pneumonia caused by serotype O11 *Pseudomonas aeruginosa* is a life-threatening condition.

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

At the time of designation pneumonia caused by serotype O11 *Pseudomonas aeruginosa* affected less than 5 in 10,000 people in the European Union (EU)*. This is based on the information provided by the sponsor and knowledge of the Committee for Orphan Medicinal Products (COMP). This is below the threshold for orphan designation which is 5 in 10,000. This is equivalent to a total of around 230,000 people.

What treatments are available?

Several types of antibiotics (drugs that kill bacteria) were authorised for the treatment of the condition in the Community at the time of submission of application for orphan drug designation. Most antibiotics work by disrupting the building of the bacterial cell wall and thus preventing the bacteria from growing and multiplying.

Satisfactory argumentation has been submitted by the sponsor to justify the assumption that human monoclonal antibody against *Pseudomonas aeruginosa* serotype O11 might be of potential significant

* 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 Liechtenstein. This represents a population of 459,700,000 (Eurostat 2006).

benefit for the treatment of pneumonia caused by serotype O11 *Pseudomonas aeruginosa*, mainly because it has a new mechanism of action. 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?

A monoclonal antibody is a protein that recognises and binds to a specific structure on a molecule. In this case, human monoclonal antibody against *Pseudomonas aeruginosa* serotype O11 is designed to bind to the specific type of *Pseudomonas aureginosa* bacteria called serotype O11. The antibody can promote the killing and elimination of the bacteria with the help of the the immune system. The medicinal product is intended to be used in combination with antibiotics. It is expected that the mode of action of this monoclonal antibody is killing *Pseudomonas aeruginosa* bacteria independent from the microbiological sensitivity of antibiotics.

What is the stage of development of this medicine?

The effects of human monoclonal antibody against *Pseudomonas aeruginosa* serotype O11 were evaluated in experimental models.

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

Human monoclonal antibody against *Pseudomonas aeruginosa* serotype O11 was not authorised anywhere worldwide for the treatment of pneumonia, nor 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 16 May 2006 a positive opinion recommending the grant of the above-mentioned 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;
- and either the rarity of the condition (affecting not more than five in 10,000 people in the Community) or the 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 the 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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Patients' associations contact point: Not available

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

Language	Active Ingredient	Indication
English	Human monoclonal antibody against <i>Pseudomonas aeruginosa</i> serotype O11	Treatment of pneumonia caused by serotype O11 <i>Pseudomonas aeruginosa</i>
Czech	Lidská monoklonálníprotilátka proti <i>Pseudomonas aeruginosa</i> sérotypu O11	Léčba pneumonie způsobené <i>Pseudomonadou aeruginosa</i> sérotypu O11
Danish	Human monoklonalt antistof mod <i>Pseudomonas aeruginosa</i> serotype O11	Behandling af pneumoni forårsaget af serotype O11 <i>Pseudomonas aeruginosa</i>
Dutch	Humaan monoklonaal antilichaam tegen <i>Pseudomonas aeruginosa</i> serotype O11	Behandeling van pneumonia veroorzaakt door serotype O11 <i>Pseudomonas aeruginosa</i>
Estonian	Inimese monoklonaalne <i>Pseudomonas aeruginosa</i> serotüübi O11 vastane antikeha	Serotüüp O11 <i>Pseudomonas aeruginosa</i> põhjustatud pneumoonia ravi
Finnish	Ihmisen monoklonaalinen vasta-aine <i>Pseudomonas aeruginosa</i> serotyypistä O11 vastaan	<i>Pseudomonas aeruginosa</i> serotyypin O11 aiheuttaman pneumonian hoito
French	Anticorps monoclonal humain contre le <i>Pseudomonas aeruginosa</i> de sérotype O11	Traitement de la pneumonie causée par le <i>Pseudomonas aeruginosa</i> de sérotype O11
German	Humaner monoklonaler Antikörper gegen <i>Pseudomonas aeruginosa</i> Serotyp 0O11	Behandlung von durch Serotyp O11 <i>Pseudomonas aeruginosa</i> verursachter Pneumonie
Greek	Ανθρώπινο μονοκλωνικό αντίσωμα κατά του ορότυπου O11 της ψευδομονάδας <i>aeruginosa</i>	Θεραπευτική αγωγή πνευμονίας που προκλήθηκε από ορότυπο O11 της ψευδομονάδας <i>aeruginosa</i>
Hungarian	<i>Pseudomonas aeruginosa</i> O11 szerotípus elleni humán monoklonális antitest	<i>Pseudomonas aeruginosa</i> O11 szerotípus által okozott pneumónia kezelése
Italian	Anticorpi monoclonali umani contro il serotipo <i>Pseudomonas aeruginosa</i> O11	Terapia della polmonite provocata da <i>Pseudomonas aeruginosa</i> serotipo O11
Latvian	Cilvēka monoklonālās antivielas pret <i>Pseudomonas aeruginosa</i> serotipu O11	<i>Pseudomonas aeruginosa</i> serotipa O11 izraisītas pneimonijas ārstēšana
Lithuanian	Žmogaus monokloniniai antikūnai prieš <i>Pseudomonas aeruginosa</i> O11 serotipą	Pneumonijos, sukeltos <i>Pseudomonas aeruginosa</i> O11 serotipo, gydymas
Polish	Ludzkie przeciwciało monoklonalne przeciw <i>Pseudomonas aeruginosa</i> serotyp O11	Leczenie zapalenia płuc wywołanego <i>Pseudomonas aeruginosa</i> (serotyp O11)
Portuguese	Anticorpo monoclonal humano contra a <i>Pseudomonas</i>	Tratamento de Pneumonia causada pelo serotipo O11 da <i>Pseudomonas aeruginosa</i>

	<i>aeruginosa</i> serotipo O11	
Slovak	Ľudská monoklonálna protilátka proti <i>Pseudomonas aeruginosa</i> sérotypu O11	Liečba pneumónie spôsobenej <i>Pseudomonas aeruginosa</i> sérotypu O11
Slovenian	Humanizirano monoklonsko protitelo, usmerjeno proti bakteriji <i>Pseudomonas aeruginosa</i> serotipa O11	Zdravljenje ki jo povzroča serotip O11 bakterija <i>Pseudomonas aeruginosa</i>
Spanish	Anticuerpo humano monoclonal contra <i>Pseudomonas aeruginosa</i> serotipo O11	Tratamiento de la neumonía causada por <i>Pseudomonas aeruginosa</i> serotipo O11
Swedish	Mänsklig monoklonal antikropp mot <i>Pseudomonas aeruginosa</i> serotyp O11	Behandling av pneumoni orsakad av serotyp O11 <i>Pseudomonas aeruginosa</i>
Norwegian	Humant monoklonalt antistoff mot <i>Pseudomonas aeruginosa</i> serotype O11	Behandling av pneumoni forårsaket av serotype O11 <i>Pseudomonas aeruginosa</i>
Icelandic	Manna einstofna mótefni gegn <i>Pseudomonas aeruginosa</i> af sermisgerð O11	Meðferð við <i>Pseudomonas aeruginosa</i> sermisgerð O11 lungnabólgu