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

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COMMITTEE FOR ORPHAN MEDICINAL PRODUCTS

PUBLIC SUMMARY OF POSITIVE OPINION FOR ORPHAN DESIGNATION OF bimosiamose disodium for the treatment of acute lung injury

On 27 May 2005, orphan designation (EU/3/05/285) was granted by the European Commission to Revotar Biopharmaceuticals AG, Germany, for bimosiamose disodium for the treatment of acute lung injury.

What is acute lung injury?
Tiny air sacs called alveoli are located at the tips of the lungs. The alveoli are responsible for exchanging oxygen and carbon dioxide between air and blood. When an infection or a disease injures the lungs, blood and fluid begin to leak into the alveoli. When this happens, air cannot enter the alveoli, which means that the normal functions of the lung tissue are impaired. This will lead to inflammation (a response to the injury caused to the tissue) and progressive formation of scar tissue in the walls of the alveoli. The patient will develop an increasing shortness of breath. There are many possible causes of acute lung injury such as inhaling high concentrations of smoke, toxins, or oxygen; severe burns; blood infection; lung infection; or trauma to other parts of the body. Acute lung injury is a life-threatening condition.

What are the methods of treatment available?
No medicinal products were authorised for the treatment of acute respiratory distress syndrome in the Community at the time of submission of the application for orphan drug designation. The treatment options for acute lung injury were limited to symptomatic care like ventilator support. Antibiotics were also used to treat the infections and reduce the inflammation.

What is the estimated number of patients affected by the condition*?
According to the information provided by the sponsor, acute lung injury was considered to affect about 92,000 persons in the European Union.

How is this medicinal product expected to act?
In acute lung injury, neutrophils (a type of white blood cells, thus belonging to the group of cells of the body's defence system-the immune system) are drawn to the small lung bloodvessels and migrate into the air sacs (alveoli). There they release substances, which cause the inflammation leading to further destruction of the lung tissue. Bimosiamose disodium is expected to hinder the migration of these neutrophils into the alveoli.

What is the stage of development of this medicinal product?
The effects of bimosiamose disodium were evaluated in experimental models. At the time of submission of the application for orphan designation, no clinical trials in patients with acute lung injury were initiated.

7 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

The medicinal product was not marketed anywhere worldwide for acute lung injury 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 7 April 2005 a positive opinion recommending the grant of the above-mentioned designation.

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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:
Revotar Biopharmaceuticals AG
Neuendorfstrasse 24a
16761 Henningsdorf
Germany
Telephone: +49 3302 202 50 10
Telefax: +49 3302 202 50 30
E-mail: info@revotar-ag.de

Patients' association contact point: Not available

*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.

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

Language	Active Ingredient	Indication
English	Bimosiamose disodium	Treatment of acute lung injury
Czech	Bimosiamose Disodium	Léčba akutního poškození plic
Danish	Biamosiamos dinatrium	Behandling af akut lungeskade syndrome
Dutch	Dinatrium bimosiamose	Behandeling van acute longbeschadiging
Estonian	Bimosiamoos-disoodium	Ägeda kopsuvigastuse ravi
Finnish	Bimosiamose dinatrium	Akuutin keuhkovamman hoito
French	Bimosiamose Disodique	Traitement de l'aggression pulmonaire aiguë
German	Dinatrium Bimosiamos	Behandlung der akuten Lungenversagens
Greek	Bimosiamose δινατριούχος	Θεραπεία της οξείας πνευμονικής βλάβης
Hungarian	Dinátrium bimosiamose	Akut tüdőkárosodás kezelése
Italian	Bimosiamose bisodico	Trattamento della Lesione polmonare acuta
Latvian	Bimoziamoze dinātrijs	Akūta plaušu bojājuma ārstēšana
Lithuanian	Bimosiamozas dinatris	Ūmaus plaučių pažeidimo gydymas
Polish	Bimozjamos disodowy	Leczenie ostrego uszkodzenia płuc
Portuguese	Bimosiamosa dissódica	Tratamento da lesão pulmonar aguda
Slovak	Bimosiamos dvojsodný	Liečba akútneho poškodenia pľúc
Slovenian	Bimosiamos dinatrij	Zdravljenje akutne poškodbe pljuč
Spanish	Bimosiamosa disódica	Tratamiento de la lesión pulmonar aguda
Swedish	Dinatriumbimosiamos	Behandling av akut lungskada
Norwegian	Bimosiamosdinatrium	Behandling av akutt lungeskade
Icelandic	Bímósiamós tvínatríum	Til meðferðar á bráðum lungnaskaða