



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

human *Staphylococcus aureus* immunoglobulin for the treatment of *Staphylococcus aureus* bacteraemia

On 3 November 2005, orphan designation (EU/3/05/319) was granted by the European Commission to Nabi Biopharmaceuticals Europe Ltd, Ireland, for human *Staphylococcus aureus* immunoglobulin for the treatment of *Staphylococcus aureus* bacteraemia.

The sponsorship was transferred to Biotest Pharma GmbH, Germany, in February 2008.

What is *Staphylococcus aureus* bacteraemia?

Staphylococcus aureus is a microorganism that is a normal component of the human flora, which are the microorganisms that normally live in areas of our body. However sometimes these microorganisms can cause infections in human beings, particularly in patients with a compromised defence system (immunity). *Staphylococcus aureus* can have a harming effect directly through the effect of a toxic substance (toxin) that it is able to produce. *Staphylococcus aureus* can cause a range of different diseases, from mild skin infections to life-threatening generalised (systemic) infections.

Bacteraemia is defined as the presence of a microorganism in the blood. This way microorganisms spread from a localised point of infection to a systemic infection and affect organs that are far from the original site of the infection.

Staphylococcus aureus bacteraemia is life threatening, as it can lead to the development of severe complications.

What are the methods of treatment available?

Staphylococcus aureus bacteraemia should be treated with appropriate antibiotics. Antibiotics are drugs that are able to kill microorganisms. The choice of antibiotic is usually dictated in the clinical practice by the type of the microorganism causing the infection and a number of factors like the primary localisation of the infection in the body, the immune situation of the patient, the risk for complications, the presence of other diseases, etc. Several antibiotics were authorised for the condition in some countries in the Community at the time of submission of the application for orphan drug designation.

Staphylococcus aureus immunoglobulin might be of potential significant benefit for patients affected by the condition because it would offer an alternative treatment that could be used in combination with antibiotics. 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*?

Based on the information provided by the sponsor and previous knowledge of the Committee, *Staphylococcus aureus* bacteraemia was considered to affect approximately 2.4 in 10,000 persons in the European Union, which, at the time of designation, corresponded to about 110,000 persons.

How is this medicinal product expected to act?

Immunoglobulins are proteins that the human immune system produces to fight infection or any external intruder in the body. The human *Staphylococcus aureus* immunoglobulin was obtained by giving a vaccine containing *Staphylococcus aureus* to healthy people who then produced the natural immunoglobulin against that microorganism. The human *Staphylococcus aureus* immunoglobulin is then purified from the plasma of the vaccinated persons and processed into the final medicinal product form. This product, administered to a patient with *Staphylococcus aureus* in his blood would recognise the micro-organism and would interact with it helping other cells of the patient to kill the micro-organism.

What is the stage of development of this medicinal product?

At the time of submission of the application for orphan designation, clinical trials in patients with *Staphylococcus aureus* bacteraemia were ongoing.

Human *Staphylococcus aureus* immunoglobulin was not authorised anywhere worldwide for *Staphylococcus aureus* bacteraemia, 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 2005 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:

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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	Human <i>Staphylococcus aureus</i> immunoglobulin	Treatment of <i>Staphylococcus aureus</i> bacteremia
Czech	Lidský Imunoglobulin proti <i>Staphylococcus aureus</i>	Terapie bakteriemií <i>Staphylococcus aureus</i>
Danish	Humant immunoglobulin mod <i>Staphylococcus aureus</i>	Behandling af <i>Staphylococcus aureus</i> -bakteriæmia
Dutch	Humaan <i>Staphylococcus aureus</i> immunoglobuline	Behandeling van <i>Staphylococcus aureus</i> bacteriëmie
Estonian	<i>Staphylococcus aureus</i> inimimmuunglobuliin	<i>Staphylococcus aureus</i> bakterieemia ravi
Finnish	Ihmisperäinen <i>Staphylococcus aureus</i> immunoglobuliini	<i>Staphylococcus aureus</i> –bakteriemia
French	Immunoglobuline humaine contre le staphylocoque doré	Traitement des bactériémies à staphylocoque doré
German	Humanisches <i>Staphylococcus aureus</i> Immunglobulin	Behandlung einer <i>Staphylococcus aureus</i> –Bakteriämie
Greek	Ανθρώπινη Ανοσοσφαιρίνη κατά του χρυσίζοντος σταφυλόκοκκου	Θεραπεία βακτηριαιμίας από χρυσίζοντα σταφυλόκοκκο
Hungarian	Humán <i>Staphylococcus aureus</i> immunoglobulin	<i>Staphylococcus aureus</i> bacteremia kezelése
Italian	Immunoglobulina umana per <i>Staphylococcus aureus</i>	Trattamento della batteriemia da <i>Staphylococcus aureus</i>
Latvian	<i>Staphylococcus aureus</i> cilvēka imūnglobulīns	<i>Staphylococcus aureus</i> bakteriēmijas ārstēšana
Lithuanian	Žmogaus auksinio stafilokoko (<i>Staphylococcus aureus</i>) imunoglobulinas	Auksinio stafilokoko (<i>Staphylococcus aureus</i>) sukeltos bakteremijos gydymas
Polish	Immunoglobulina ludzka skierowana przeciwko <i>Staphylococcus aureus</i>	Leczenie bakteriemii <i>Staphylococcus aureus</i>
Portuguese	Imunoglobulina humana de <i>Staphylococcus aureus</i>	Tratamento da bacterémia por <i>Staphylococcus aureus</i>
Slovak	Ľudský imunoglobulín voči <i>Staphylococcus aureus</i>	Liečba bakteriémie vyvolanej <i>Staphylococcus aureus</i>
Slovenian	Humani imunoglobulin proti <i>Staphylococcus aureus</i>	Zdravljenje bakteriemije s <i>Staphylococcus aureus</i>
Spanish	Inmunoglobulina humana para <i>Staphylococcus aureus</i>	Tratamiento de la bacteremia por <i>Staphylococcus aureus</i>
Swedish	Human <i>Staphylococcus aureus</i> immunoglobulin	Behandling av patienter med <i>Staphylococcus aureus</i> -bakteriemi
Norwegian	Immunoglobulin mot <i>Staphylococcus aureus</i> (humant)	Behandling av <i>Staphylococcus aureus</i> -bakteriemi
Icelandic	Manna ónæmisglóbúlín gegn <i>Staphylococcus aureus</i>	Meðferð við <i>Staphylococcus aureus</i> Blóðsýkingu