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 cytomegalovirus immunoglobulin for the prevention of congenital cytomegalovirus infection following primary cytomegalovirus infection

On 31 October 2006, orphan designation (EU/3/06/408) was granted by the European Commission to Biotest Pharma GmbH, Germany, for human cytomegalovirus immunoglobulin for the prevention of congenital cytomegalovirus infection following primary cytomegalovirus infection in pregnant women.

What is congenital cytomegalovirus infection following primary cytomegalovirus infection?
Cytomegalovirus is a virus that infects many people worldwide. In the majority of cases the virus is latent (inactive) and causes neither disease nor any symptoms of any kind in man. Usually, the virus is only activated in patients who, for some reason, have a weaker immune system. Cytomegalovirus disease can affect several organs in the body, such as the eyes, liver, lungs and the gastrointestinal tract (the stomach and intestines) and cause organ failure. If a woman is infected (primary infection) with cytomegalovirus while pregnant, the virus can pass to the unborn baby who does not yet have a very strong immune system. When congenital (in-born), the disease can also cause growth retardation and brain damage. Congenital cytomegalovirus disease is chronically debilitating and life-threatening.

What is the estimated number of patients at risk of developing the condition?
At the time of designation cytomegalovirus infection affected approximately 1.4 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 65,000 people.

What methods of prevention are available?
There were no medicinal products authorised for the prevention of congenital cytomegalovirus infection following primary cytomegalovirus infection in pregnant women in the Community at the time of submission of application for orphan drug designation.

How is this medicine expected to work?
Human cytomegalovirus immunoglobulin is a mix of antibodies (proteins of the immune system that can bind to a specific molecular structure) directed at cytomegalovirus particles. Antibodies can neutralise infectious agents or start processes that lead to their destruction by cells of the immune system. According to the sponsor, human cytomegalovirus immunoglobulin will thus reduce the amount of cytomegalovirus in the pregnant woman's blood and reduce the risk of the unborn baby becoming infected.

[*]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).

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What is the stage of development of this medicine?
The effects of human cytomegalovirus immunoglobulin were evaluated in experimental models.

At the time of submission of the application for orphan designation, clinical trials in pregnant women with primary cytomegalovirus infection were ongoing.

The medicinal product was not designated as orphan medicinal product anywhere worldwide, 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 6 September 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.

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Sponsor's contact details:
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Patients' association 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 cytomegalovirus immunoglobulin	Prevention of congenital cytomegalovirus infection following primary cytomegalovirus infection
Czech	Lidský imunoglobulin proti cytomegaloviru	Prevence kongenitální cytomegalovirové infekce po primární cytomegalovirové infekci
Danish	Humant cytomegalovirus immunglobulin	Forebyggelse af kongenit cytomegalovirus-infektion efter førstegangs cytomegalovirus-infektion
Dutch	Humaan anti-cytomegalovirus immunoglobuline	Preventie van congenitale cytomegalovirus-infectie na primaire cytomegalovirus-infectie
Estonian	Inimese tsütomegaloviiruse immunoglobuliin	Kaasasündinud tsütomegaloviirus-infektsiooni ennetamine peale esmast tsütomegaloviirusinfektsiooni.
Finnish	Ihmisen sytomegalovirus-immunoglobuliini	Primaarin sytomegalovirustulehduksen aiheuttaman synnynnäisen sytomegalotulehduksen ehkäisy
French	Immunoglobuline humaine dirigée contre le cytomégalovirus	Prévention de l'infection congénitale à cytomégalovirus à la suite d'une primo-infection par le cytomégalovirus
German	Human-Immunglobulin, spezifisch gegen Zytomegalie-Virus	Prävention der angeborenen Zytomegalie-Virus-Infektion nach primärer Zytomegalie-Virus-Infektion
Greek	Ανθρώπινη ανοσοσφαιρίνη μεγαλοκυτταροϊού	Πρόληψη της εκ γενετής λοίμωξης με μεγαλοκυτταροϊό μετά από πρωτοπαθή λοίμωξη με μεγαλοκυτταροϊό
Hungarian	Humán cytomegalovirus immunoglobulin	Primer cytomegalovirus-fertőzés okozta congenitalis cytomegalovirus-fertőzések megelőzése
Italian	Immunoglobulina umana anti-citomegalovirus	Prevenzione dell'infezione congenita da citomegalovirus a seguito di un'infezione primaria da citomegalovirus
Latvian	Cilvēka citomegalovīrusu imūnglobulīns	Iedzimtas citomegalovīrusu infekcijas profilakse pēc primāras citomegalovīrusu infekcijas
Lithuanian	Žmogaus citomegalo viruso imunoglobulinas	Įgimtos citomegaloviruso infekcijos, sąlygotos pirminės citomegaloviruso infekcijos, prevencija
Polish	Ludzka immunoglobulina przeciwko wirusowi cytomegalii	Zapobieganie wrodzonym zakażeniom wirusem cytomegalii spowodowanym pierwotnym zakażeniem wirusem cytomegalii
Portuguese	Imunoglobulina humana contra o citomegalovírus	Prevenção de infecção congénita pelo citomegalovírus a seguir à infecção primária pelo citomegalovírus.
Slovak	Ľudský imunoglobulín proti cytomegalovírusu	Prevencia vrodenej cytomegalovírusovej infekcie po primárnej cytomegalovírusovej infekcii
Slovenian	Humani imunoglobulin proti citomegalovirusu	Preprečevanje kongenitalne okužbe s citomegalovirusom po primarni okužbi s citomegalovirusom
Spanish	Inmunoglobulina humana contra citomegalovirus	Prevención de la infección congénita por citomegalovirus tras infección primaria por

		citomegalovirus
Swedish	Människligt cytomegalovirus-immunglobulin	Förebyggande av kongenital cytomegalovirusinfektion efter primär cytomegalovirusinfektion
Norwegian	Humant cytomegalovirus immunglobulin	Forebygging av medfødt cytomegalovirusinfeksjon etter primær cytomegalovirusinfeksjon
Icelandic	Stórfrumuveiru-ónæmisglóbúlín úr mönnum	Til forvarnar gegn meðfæddri stórfrumuveirusýkingu í kjölfar fyrstu stórfrumuveirusýkingar hjá barnshafandi konum