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EMA/COMP/172586/2011
Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

S-Nitrosoglutathione for the treatment of pre-eclampsia

On 13 May 2011, orphan designation (EU/3/11/870) was granted by the European Commission to Salupont Consulting Ltd, United Kingdom, for S-nitrosoglutathione for the treatment of pre-eclampsia.

What is pre-eclampsia?

Pre-eclampsia is a condition that may occur from 20 weeks of pregnancy, in which the woman, who previously had normal blood pressure, develops sustained high blood pressure and presents significant amounts of protein in the urine. Pre-eclampsia can lead to a more serious condition called eclampsia, in which the woman have seizures (fits). The exact cause of pre-eclampsia is unknown. The condition normally resolves when the baby is born.

Pre-eclampsia is a life-threatening condition due to its complications, such as the risk of seizures, damage to different organs such as the kidney and cerebral haemorrhage (bleeding in the brain). Pre-eclampsia also carries risks for the baby who tends to be smaller and have a higher risk of prematurity and death.

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

At the time of designation, pre-eclampsia affected less than 4.5 in 10,000 people in the European Union (EU)*. This is equivalent to a total of fewer than 228,000 people and is below the ceiling for orphan designation, which is 5 people in 10,000. This is based on the information provided by the sponsor and the knowledge of the Committee for Orphan Medicinal Products (COMP).

What treatments are available?

Several medicines were authorised for the treatment of pre-eclampsia in the EU at the time of designation, including medicines to lower blood pressure and medicines to prevent seizures. However, the only cure for pre-eclampsia is the delivery of the baby.

*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 27), Norway, Iceland and Liechtenstein. This represents a population of 506,300,000 (Eurostat 2011).

The sponsor has provided sufficient information to show that S-nitrosoglutathione might be of potential significant benefit to women with pre-eclampsia because it works in a different way to existing treatments and early studies show that it might improve the outcome of women with this condition. This assumption will need to be confirmed at the time of marketing authorisation, in order to maintain the orphan status.

How is this medicine expected to work?

S-nitrosoglutathione is made up of a natural substance, glutathione, to which a molecule of nitric oxide (NO) has been attached. It is expected to be given to women with pre-eclampsia by a drip into a vein. Once in the blood, it is expected to break down and act as a 'nitric oxide donor' to release NO. NO acts on the muscles of blood vessels, causing them to relax and thereby helping to reduce blood pressure. NO also acts on platelets (components that help the blood to clot) blocking their activation; this is also expected to benefit women with pre-eclampsia who often have over-activated platelets.

What is the stage of development of this medicine?

The effects of S-nitrosoglutathione have been evaluated in experimental models.

At the time of submission of the application for orphan designation, clinical trials with S-nitrosoglutathione in women with pre-eclampsia were ongoing.

At the time of submission, S-nitrosoglutathione was not authorised anywhere in the EU for pre-eclampsia or designated as an orphan medicinal product elsewhere for this condition.

In accordance with Regulation (EC) No 141/2000 of 16 December 1999, the COMP adopted a positive opinion on 9 February 2011 recommending the granting of this 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;
- 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

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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 languages¹, Norwegian and Icelandic

Language	Active ingredient	Indication
English	S-nitrosoglutathione	Treatment of pre-eclampsia
Bulgarian	S-нитрозоглутатион	Лечение на прееклампсия
Czech	S-nitrosoglutathione	Léčba preeklampsie
Danish	S-nitrosoglutathion	Behandling af præeklamsi
Dutch	S-nitrosoglutathione	Behandeling van pre-eclampsie
Estonian	S-nitrosoglutatioonoe	Preeklampsia ravi
Finnish	S-nitrosoglutationi	Pre-eclampsian hoito
French	S-nitrosoglutathione	Traitement de la pré-éclampsie
German	S-nitrosoglutathione	Behandlung der Präeklampsie
Greek	S-νιτροζογλουταθειόνη	θεραπεία της προεκλαμψίας
Hungarian	S-nitrosoglutathion	Pre-eclampsia kezelése
Italian	S-nitrosoglutathione	Trattamento della preeclampsia
Latvian	S-nitrosoglutathions	Preeklampsijas ārstēšana
Lithuanian	S-nitrozoglutationas	Preeklampsijos gydymas
Maltese	S-nitrosoglutathione	Kura tal-pre-eklampsja
Polish	S-nitrozoglutation	Leczenie stanu przedrzucawkowego
Portuguese	S-nitrosoglutathiona	Tratamento da pré-eclâmpsia
Romanian	S-nitrozoglutation	Tratamentul preeclampsiei
Slovak	S-nitrózoglutathión	Liečba preeklampsie
Slovenian	S-nitrozoglutation	Zdravljenje preeklampsije
Spanish	S-nitrosoglutathion	Tratamiento de la preeclampsia
Swedish	S-nitrosoglutathion	Behandling av preeklamsi
Norwegian	S-nitrosoglutathione	Behandling av svangerskapsforgiftning
Icelandic	S-nítrósóglútathíón	Meðferð meðgöngueitrunar

¹ At the time of designation