



COMMITTEE FOR ORPHAN MEDICINAL PRODUCTS

**PUBLIC SUMMARY OF
POSITIVE OPINION FOR ORPHAN DESIGNATION
OF
N-adamantanyl-N'-Geranyl-ethylenediamine
for the treatment of tuberculosis**

On 14 September 2007, orphan designation (EU/3/07/479) was granted by the European Commission to RLM Consulting, Belgium, for N-adamantanyl-N'-Geranyl-ethylenediamine for the treatment of tuberculosis.

What is tuberculosis?

Tuberculosis is an infection caused by a group of bacteria called Mycobacterium. It spreads from person to person droplets generated by sneezing and coughing. The manifestation of the infection is variable and not all patients who are infected will develop disease. The disease is characterised by fever, cough and breathing difficulties. Granulomas (accumulation of large number of cells leading to chronic inflammatory lesions) can develop in any body tissue, but most often in the lungs (pulmonary tuberculosis). The disease can also affect the central nervous system (meningitis), lymphatic system, genitourinary system, bones and joints. Tuberculosis is a life-threatening condition.

What are the methods of treatment available?

Treatment consists of the administration of a combination of antibiotics for long periods of time. Several medicinal products were authorised for the condition in the Community, at the time of submission of the application for orphan designation. Satisfactory argumentation has been submitted by the sponsor to justify the assumption that N-adamantanyl-N'-Geranyl-ethylenediamine might be of potential significant benefit for the treatment of tuberculosis, mainly because it might improve the long-term outcome of the patients. The assumption of benefit 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, tuberculosis was considered to affect not more than 2 in 10,000 persons in the European Union, which, at the time of designation, corresponded to about 100,000 persons in total.

How is this medicinal product expected to act?

N-adamantanyl-N'-Geranyl-ethylenediamine is considered as a potential anti-mycobacterial agent. According to the sponsor, it acts by inhibiting (blocking) the synthesis of the cell wall of the bacteria causing tuberculosis, thus preventing the bacteria from growing and potentially killing the bacteria itself.

* 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 27), Norway, Iceland and Lichtenstein. This represents a population of 498,000,000 (Eurostat 2006). This estimate is based on available information and calculations presented by the sponsor at the time of the application.

What is the stage of development of this medicinal product?

The effects of N-adamantanyl-N'-Geranyl-ethylenediamine were evaluated in experimental models.

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

N-adamantanyl-N'-Geranyl-ethylenediamine was not authorised anywhere worldwide for the treatment of tuberculosis 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 25 July 2007 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:

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

Language	Active Ingredient	Indication
English	N-adamantanyl-N'-geranyl-ethylenediamine	Treatment of tuberculosis
Bulgarian	N-адамантил-N'-Геранил-етилендиамин	Лечение на туберкулоза
Czech	N-adamantanyl-N'-Geranyl-ethylendiamin	Léčba tuberkulózy
Danish	N-adamantanyl-N'-geranyl-ethylendiamin	Behandling af tuberkulose
Dutch	N-adamantanyl-N'-geranyl-ethyleendiamine	Behandeling van tuberculose
Estonian	N-adamantüül-N'-geranüül-etüleendiamiid	Tuberkuloosi ravi
Finnish	N-adamantanyyli-N'-geranyyli-etyleenidiamiini	Tuberkuloosin hoito
French	N-adamantanyl-N'-géranyl-éthylènediamine	Traitement de la tuberculose
German	N-Adamantanyl-N'-geranyl-ethylendiamin	Behandlung der Tuberkulose
Greek	N-αδαμαντανυλ-N'-Γερανυλ-αιθυλενοδιαμίνη	Θεραπεία της φυματίωσης
Hungarian	N-adamantanil-N'-geranil-etiléndiamin	Tuberculosis kezelése
Italian	N-adamantanil-N'-geranil-etilendiammina	Trattamento della tubercolosi
Latvian	N-adamantanil-N'-geranil-etilēndiamīns	Tuberkulozes ārstēšana
Lithuanian	N-adamantanil-N'-geranil-etilenediaminas	Tuberkuliozės gydymas
Maltese	N-adamantanyl-N'-Geranyl-ethylenediamine	Kura tat-tuberkulosi
Polish	N-adamantanyl-N'-geranylo- etylenodiamina	Leczenie gruźlicy
Portuguese	N-adamantanil-N'-geranil-etilenodiamina	Tratamento da tuberculose
Romanian	N-adamantanil-N'-geranil-etilendiamină	Tratamentul tuberculozei
Slovak	N-adamantanyl-N'-geranyl-etyléndiamín	Liečba tuberkulózy
Slovenian	N-adamantanil-N'-geranil-etilendiamin	Zdravljenje tuberkoloze
Spanish	N-adamantanil-N'-geranil-etilendiamina	Tratamiento de la tuberculosis
Swedish	N-adamantanyl-N'-geranyl-etylendiamin	Behandling av tuberkulos
Norwegian	N-adamantanyl-N'-geranyl-etylendiamin	Behandling av tuberkulose
Icelandic	N-adamantanýl-N'-geranýl-etýlendíamín	Meðferð við berklum