



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

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*Please note that this product was withdrawn from the Community Register of designated Orphan Medicinal Products in May 2007 on request of the sponsor.*

## **COMMITTEE FOR ORPHAN MEDICINAL PRODUCTS**

### **PUBLIC SUMMARY OF POSITIVE OPINION FOR ORPHAN DESIGNATION OF interferon gamma for the treatment of idiopathic pulmonary fibrosis**

On 27 May 2005, orphan designation (EU/3/05/281) was granted by the European Commission to Mondobiotec Laboratories Anstalt, Liechtenstein, for interferon gamma for the treatment of idiopathic pulmonary fibrosis.

The sponsorship was transferred to InterMune Europe Ltd, United Kingdom, in September 2006.

#### **What is idiopathic pulmonary fibrosis?**

Fibrosis is the formation of scar tissue as part of the natural repair process of the body following tissue damage. Idiopathic pulmonary fibrosis consists of a chronic inflammation (a response to the injury caused to the tissue) and progressive formation of fibrous tissue in the walls of the small cells containing air in the lungs. Since the injury causing these changes is unknown, it is called idiopathic. The progressive formation of scars impairs the normal functions of lung tissue, which are to enable exchange of oxygen and carbon dioxide between air and blood. The symptoms developed are persistent cough, progressive severe shortness of breath and recurrent lung infections.

Idiopathic pulmonary fibrosis is a chronically debilitating and life threatening disease due to the progression of symptoms, severe respiratory complications and short life expectancy.

#### **What are the methods of treatment available?**

No satisfactory methods exist that were authorised at the time of application. Only symptomatic treatments to reduce the inflammation were used (corticosteroids and medicinal products that suppress the immune system) or for some patients lung transplantation was performed.

#### **What is the estimated number of patients affected by the condition\*?**

According to the information provided by the sponsor, idiopathic pulmonary fibrosis was considered to affect about 138,000 persons in the European Union.

#### **How is this medicinal product expected to act?**

Scar formation (fibrosis) is regulated by several substances produced in the body during the inflammation that precedes fibrosis. These substances stimulate the so-called fibroblasts (the main cells responsible for formation of the fibrosis). Although it is not yet fully understood how interferon gamma acts in idiopathic pulmonary fibrosis, it could stimulate the production of proteins that would prevent fibrosis and re-establish the balance between the molecules that stimulate fibrosis and those that prevent it happening.

#### **What is the stage of development of this medicinal product?**

The effects of interferon gamma were evaluated in experimental models.

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

Interferon gamma was not marketed anywhere worldwide for idiopathic pulmonary fibrosis, 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:

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Patients' associations contact points: 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**

<b>Language</b>	<b>Active Ingredient</b>	<b>Indication</b>
English	Interferon gamma	Treatment of idiopathic pulmonary fibrosis
Czech	Interferon gamma	Léčba idiopatické plicní fibrózy
Danish	Interferon gamma	Behandling af idiopatisk lungefibrose
Dutch	Interferon gamma	Behandeling van idiopathische longfibrose
Estonian	Interferoon gamma	Idiopaatilise kopsufibroosi ravi
Finnish	Interferon gamma	Idiopaattisen keuhkofibroosin hoito
French	Interféron gamma	Traitement de la fibrose pulmonaire idiopathique
German	Interferon gamma	Behandlung von Idiopathischer Pulmonaler Fibrose
Greek	Ιντερφερόνη γάμμα	Θεραπεία της ιδιοπαθούς πνευμονικής ίνωσης
Hungarian	Interferon gamma	Idiopathiás tüdőfibrózis kezelése
Italian	Interferon gamma	Trattamento della fibrosi polmonare idiopatica
Latvian	Gamma interferons	Idiopātiskās plaušu fibrozes ārstēšana
Lithuanian	Gama interferonas	Idiopatinės plaučių fibrozės gydymas
Polish	Interferon gamma	Leczenie idiopatycznego z włóknienia płuc
Portuguese	Interferão gamma	Tratamento da fibrose pulmonar idiopática
Slovak	Interferón gamma	Liečba idiopatickej pľúcnej fibrózy
Slovenian	Interferon gama	Zdravljenje idiopatske pljučne fibroze
Spanish	Interferón gamma	Tratamiento de la fibrosis pulmonar idiopática
Swedish	Interferon gamma	Behandling av idiopatisk lungfibros
Norwegian	Interferon gamma	Behandling av idiopatisk lungefibrose
Icelandic	Interferón gamma	Meðferð sjálfvakinnar bandvefsmyndunar í lungum