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Withdrawal of application to change the marketing authorisation for Esbriet (pirfenidone)

Roche Registration GmbH withdrew its application for the use of Esbriet in the treatment of patients with unclassifiable interstitial lung disease.

The company withdrew the application on 19 May 2021.

What is Esbriet and what is it used for?

Esbriet is a medicine used to treat adults with mild to moderate idiopathic pulmonary fibrosis (IPF). IPF is a long-term disease in which fibrous scar tissue continuously forms in the lungs, causing persistent cough, frequent lung infections and severe shortness of breath. 'Idiopathic' means that the cause of the disease is unknown.

Esbriet has been authorised in the EU since February 2011.

It contains the active substance pirfenidone and is available as capsules and tablets to be taken by mouth.

Further information on Esbriet's current uses can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/esbriet.

What change had the company applied for?

The company applied to extend the use of Esbriet to treat patients with unclassifiable interstitial lung disease. Interstitial lung disease (ILD) is a group of diseases that cause scarring in the lungs. In around 10% of patients, the disease has characteristics that do not allow it to be classified as a specific subset of ILD and is therefore referred to as unclassifiable ILD (UILD).

How does Esbriet work?

The mechanism of action of pirfenidone, the active substance in Esbriet, is not fully understood but it has been shown to reduce the production of fibroblasts and other substances involved in the formation of fibrous (scar) tissue during the body's tissue repair process, thereby slowing down the progression of the disease in IPF patients.

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In unclassifiable interstitial lung disease, Esbriet is expected to work in the same way as it does in its existing indication.

What did the company present to support its application?

The company presented the results of a main study involving 253 patients with UILD who were given either Esbriet or placebo (a dummy treatment). The main measure of effectiveness was the change in the functioning of the patients' lungs after 24 weeks of treatment, measured by their 'forced vital capacity' (FVC). FVC is the maximum amount of air the patient can breathe out forcefully after taking in a deep breath, which decreases as the condition gets worse.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the initial information from the company and had prepared questions for the company. The company had not responded to the questions at the time of the withdrawal.

What did the Agency recommend at that time?

Based on the review of the available information, at the time of the withdrawal, the Agency had some concerns and its provisional opinion was that Esbriet could not have been authorised for the treatment of UILD. In particular, the Agency had concerns about the robustness of the data and the duration of the main study. The Agency was also not in agreement with the wording of the proposed indication.

Therefore, at the time of the withdrawal, the Agency's opinion was that the benefits of Esbriet in the treatment of UILD did not outweigh its risks.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of application, the company stated that its decision was based on EMA's requirement for further justification and data on the use of Esbriet in the proposed indication.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that there are no consequences for patients in clinical trials using Esbriet.

If you are in a clinical trial and need more information about your treatment, speak with your clinical trial doctor.

What is happening with Esbriet for the treatment of other diseases?

There are no consequences on the use of Esbriet in the treatment of IPF.