



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Ofev

nintedanib

On 20 November 2014 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ofev, 100 mg and 150 mg, soft capsules intended for adults in the treatment of Idiopathic Pulmonary Fibrosis (IPF). Ofev was designated as an orphan medicinal product on 26 April 2013.

The applicant for this medicinal product is Boehringer Ingelheim International GmbH. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Ofev is nintedanib a tyrosine kinase inhibitor (L01XE) blocking vascular endothelial growth factor receptors (VEGFR 1-3), platelet-derived growth factor receptors (PDGFR α and β) and fibroblast growth factor receptors (FGFR 1-3) kinase activity crucial for the proliferation and migration of lung fibroblasts cells, and eventually inhibiting lung fibrosis.

The benefits with Ofev are its ability to reduce the rate of deterioration of lung function measured as decline of absolute volume of Forced Vital Capacity (FVC) in patients with idiopathic pulmonary fibrosis. It is noted that demonstration of this effect in the two pivotal clinical studies showed a clear and consistent benefit in reducing the decline of FVC by approximately 94 mL/year and 125 mL/year respectively.

The most common side effects are: gastrointestinal disorders, diarrhoea, vomiting, nausea, alanine aminotransferase increase, aspartase aminotransferase increase.

A pharmacovigilance plan for Ofev will be implemented as part of the marketing authorisation.

The approved indication is: "indicated in adults for the treatment of Idiopathic Pulmonary Fibrosis (IPF)". It is proposed that Ofev be prescribed by physicians experienced in the diagnosis and treatment of Idiopathic Pulmonary Fibrosis (IPF).

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.



Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Ofev and therefore recommends the granting of the marketing authorisation.