EMA/568301/2021

European Medicines Agency decision

P/0438/2021

of 29 October 2021

on the acceptance of a modification of an agreed paediatric investigation plan for nintedanib (Ofev, Vargatef), (EMEA-001006-PIP05-18-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

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The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0150/2019 issued on 17 April 2019,

Having regard to the application submitted by Boehringer Ingelheim International GmbH on 31 May 2021 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 10 September 2021, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for nintedanib (Ofev, Vargatef), capsule, soft, oral use, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 - Ingelheim am Rhein, Germany.

EMA/PDCO/325787/2021
Amsterdam, 10 September 2021

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-001006-PIP05-18-M01

Scope of the application

Active substance(s):

Nintedanib

Invented name:

Ofev

Vargatef

Condition(s):

Treatment of fibrosing interstitial lung diseases

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Capsule, soft

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Boehringer Ingelheim International GmbH

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Boehringer Ingelheim International GmbH submitted to the European Medicines Agency on 31 May 2021 an application for

modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0150/2019 issued on 17 April 2019.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 12 July 2021.

Scope of the modification

Some measures of the Paediatric Investigation Plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion.

   The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

1.1. Condition:

Treatment of fibrosing interstitial lung diseases

The waiver applies to:

- the paediatric population from birth to less than 6 years;
- capsule, soft, oral use;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric investigation plan

2.1. Condition:

Treatment of fibrosing interstitial lung diseases

2.1.1. Indication(s) targeted by the PIP

Treatment of fibrosing interstitial lung diseases in paediatric patients

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 6 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Capsule, soft

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of age-appropriate oral solid dosage form
Non-clinical studies	0	Not applicable
Clinical studies	1	**Study 2 (1199.337)** 6-month, double-blind, placebo-controlled study to evaluate the dose-exposure and safety of nintedanib (Part A), followed by an open label phase with active treatment (Part B), in children from 6 to less than 18 years of age with fibrosing interstitial lung diseases (ILD)

Extrapolation, modelling and simulation studies	2	***Study 3*** Modelling and simulation study to define dose regimen in children from 6 to less than 18 years of age with fibrosing interstitial lung diseases ***Study 4*** Extrapolation study to summarize/synthesize all available data in adults in the various conditions and make inferences regarding efficacy and safety to the paediatric population
Other studies	0	Not applicable
Other measures	0	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By March 2023
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of idiopathic pulmonary fibrosis

Authorised indication(s):

- Ofev is indicated in adults for the treatment of idiopathic pulmonary fibrosis (IPF).
- Ofev is also indicated in adults for the treatment of other chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype (see section 5.1).

2. Treatment of non-small cell lung cancer

Authorised indication(s):

- In combination with docetaxel for the treatment of adult patients with locally advanced, metastatic or locally recurrent non-small cell lung cancer (NSCLC) of adenocarcinoma tumour histology after first line chemotherapy.

3. Treatment of systemic sclerosis

Authorised indication(s):

- Ofev is indicated in adults for the treatment of systemic sclerosis associated interstitial lung disease (SSc-ILD).

Authorised pharmaceutical form(s):

Capsule, soft

Authorised route(s) of administration:

Oral use