EMA/215279/2019

European Medicines Agency decision

P/0150/2019

of 17 April 2019

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for nintedanib (Ofev, Vargatef), (EMEA-001006-PIP05-18) 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 application submitted by Boehringer Ingelheim International GmbH on 18 May 2018 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 1 March 2019, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation and Article 13 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a deferral.

(4) It is therefore appropriate to adopt a decision granting a waiver.

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

Has adopted this decision:

Article 1

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

Article 2

A deferral for nintedanib (Ofev, Vargatef), capsule, soft, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

A waiver for nintedanib (Ofev, Vargatef), capsule, soft, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 4

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

EMA/PDCO/840708/2018 Corr
London, 1 March 2019

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMEA-001006-PIP05-18

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

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Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Boehringer Ingelheim International GmbH submitted for agreement to the European Medicines Agency on 18 May 2018 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 26 June 2018.

Supplementary information was provided by the applicant on 23 November 2018. The applicant proposed modifications to the paediatric investigation plan.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 17(1) of said Regulation;
   - to grant a deferral in accordance with Article 21 of said Regulation;
   - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population.

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

2. The measures and timelines of the agreed 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 (ILD)

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 (ILD)

2.1.1. Indication(s) targeted by the PIP

Treatment of fibrosing ILDs 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):

- Treatment of idiopathic pulmonary fibrosis.

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.

Authorised pharmaceutical form(s):

Capsule, soft

Authorised route(s) of administration:

Oral use