EMA/640003/2008

European Medicines Agency decision

P/0139/2020

of 17 April 2020

on the acceptance of a modification of an agreed paediatric investigation plan for elafibranor (EMEA-001857-PIP01-15-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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on the acceptance of a modification of an agreed paediatric investigation plan for elafibranor (EMEA-001857-PIP01-15-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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/0237/2016 issued on 9 September 2016,

Having regard to the application submitted by Genfit SA on 29 November 2019 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 28 February 2020, 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 elafibranor, capsule, hard, coated tablet, 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 GENFIT SA, 885, avenue Eugène Avinée, 59120 – LOOS, France.

EMA/PDCO/687606/2019
Amsterdam, 28 February 2020

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

EMEA-001857-PIP01-15-M01

Scope of the application

Active substance(s):

Elafibranor

Condition(s):

Treatment of non-alcoholic fatty liver disease including non-alcoholic steatohepatitis

Pharmaceutical form(s):

Capsule, hard

Coated tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Genfit SA

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Genfit SA submitted to the European Medicines Agency on 29 November 2019 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/0237/2016 issued on 9 September 2016.

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

The procedure started on 6 January 2020.

Scope of the modification

Some measures and timelines 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 annex 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 non-alcoholic fatty liver disease (NAFLD) including non-alcoholic steatohepatitis (NASH)

The waiver applies to:

- the paediatric population from birth to less than 2 years of age;
- capsule, hard, coated tablet, oral use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric investigation plan

2.1. Condition:

Treatment of non-alcoholic fatty liver disease (NAFLD) including non-alcoholic steatohepatitis (NASH)

2.1.1. Indication(s) targeted by the PIP

Treatment of non-alcoholic fatty liver disease (NAFLD) including non-alcoholic steatohepatitis (NASH)

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

From 2 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Capsule, hard

Coated tablet

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of an age appropriate formulation
Non-clinical studies	1	**Study 2** Definitive juvenile toxicity study in rats
Clinical studies	4	**Study 3** Pharmacokinetic (PK)/pharmacodynamic (PD) study in children and adolescents 8 to less than 18 years of age with NASH (GFT505E-218-1)

Area	Number of measures	Description
		Study 4 Double-blind, placebo-controlled efficacy and safety study in children and adolescents 8 to less than 18 years of age with NAFLD **Study 5** Pharmacokinetic (PK)/pharmacodynamic (PD) study in children 2 to less than 8 years of age with NAFLD **Study 6** Double-blind, placebo-controlled efficacy and safety study in children 2 to less than 8 years of age with NAFLD
Extrapolation, modelling and simulation studies	1	**Study 7** Modelling and simulation study to evaluate the use of the product in the treatment of children from 2 to less than 18 years of age with NAFLD
Other studies	1	**Study 8** Review of NAFLD/NASH natural history studies
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:	No
Date of completion of the paediatric investigation plan:	By December 2025
Deferral for one or more measures contained in the paediatric investigation plan:	Yes