EMA/170348/2023

European Medicines Agency decision

P/0148/2023

of 21 April 2023

on the acceptance of a modification of an agreed paediatric investigation plan for encorafenib (Braftovi), (EMEA-001588-PIP01-13-M03) 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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0054/2016 issued on 18 March 2016, the decision P/0071/2018 issued on 16 March 2018 and the decision P/0487/2022 issued on 2 December 2022,

Having regard to the application submitted by Pierre Fabre Médicament on 16 December 2022 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 31 March 2023, 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 and to the deferral.

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

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

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for encorafenib (Braftovi), capsule, hard, oral use, including changes to the deferral, 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 Pierre Fabre Médicament, Les Cauquillous, 81500 – Lavaur, France.

EMA/PDCO/3547/2023
Amsterdam, 31 March 2023

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

EMEA-001588-PIP01-13-M03

Scope of the application

Active substance(s):

Encorafenib

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of melanoma

Pharmaceutical form(s):

Capsule, hard

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Pierre Fabre Médicament

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Pierre Fabre Médicament submitted to the European Medicines Agency on 16 December 2022 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/0054/2016 issued on 18 March 2016, the decision P/0071/2018 issued on 16 March 2018 and the decision P/0487/2022 issued on 2 December 2022.

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

The procedure started on 30 January 2023.

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 and to the deferral in the scope set out in the Annex I of this opinion.

   The Paediatric Committee member of Norway 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 melanoma

The waiver applies to:

- the paediatric population from birth to less than 12 years of age;
- capsule, hard, 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 melanoma

2.1.1. Indication(s) targeted by the PIP

Encorafenib in combination with binimetinib is indicated for the treatment of patients aged 12 years and older with unresectable or metastatic melanoma harbouring BRAF V600 mutations

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

From 12 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Capsule, hard

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1** *deleted in procedure EMEA-001588-PIP01-13-M03*
Non-clinical studies	Not applicable
Clinical studies	**Study 2** *deleted in procedure EMEA-001588-PIP01-13-M03*

Extrapolation, modelling and simulation studies	**Study 3** Modelling and simulation study to evaluate and to determine the dose of encorafenib used in combination with binimetinib which matches adult plasma exposure and for the use of the products in the treatment of melanoma in adolescents from 12 to less than 18 years of age with unresectable or metastatic BRAF V600 mutant melanoma (same as in PIP EMEA-001454-PIP03-15 and all modifications thereof).
Other studies	Not applicable
Extrapolation plan	Study 3 is part of an extrapolation plan covering the paediatric population with unresectable or metastatic BRAF V600 mutant melanoma from 12 years to less than 18 years of age, as agreed by the PDCO. *Added in procedure EMEA-001588-PIP01-13-M03*

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 January 2024
Deferral for one or more measures contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Condition(s) and authorised indication(s)

1. Treatment of melanoma

Authorised indication(s):

- Encorafenib is indicated in combination with binimetinib for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation.
  - Invented name(s): Braftovi
  - Authorised pharmaceutical form(s): Hard capsule
  - Authorised route(s) of administration: Oral use
  - Authorised via centralised procedure

2. Treatment of colorectal carcinoma

Authorised indication(s):

- Encorafenib is indicated in combination with cetuximab, for the treatment of adult patients with metastatic colorectal cancer (CRC) with a BRAF V600E mutation, who have received prior systemic therapy.
  - Invented name(s): Braftovi
  - Authorised pharmaceutical form(s): Hard capsule
  - Authorised route(s) of administration: Oral use
  - Authorised via centralised procedure