EMA/575722/2022

European Medicines Agency decision

P/0226/2022

of 8 July 2022

on the acceptance of a modification of an agreed paediatric investigation plan for indacaterol (acetate) / mometasone (furoate) (Atectura Breezhaler and its duplicate authorization Bemrist Breezhaler), (EMEA-001217-PIP01-11-M08) 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/0184/2012 issued on 21 August 2012, the decision P/0193/2015 issued on 4 September 2015, the decision P/0104/2016 issued on 15 April 2016, the decision P/0141/2017 issued on 7 June 2017, the decision P/0057/2018 issued on 16 March 2018, the decision P/0292/2018 issued on 12 September 2018 and the decision P/0155/2021 issued on 16 April 2021,

Having regard to the application submitted by Novartis Europharm Limited on 21 February 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 20 May 2022, 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, 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 indacaterol (acetate) / mometasone (furoate) (Atectura Breezhaler and its duplicate authorization Bemrist Breezhaler), inhalation powder, hard capsule, inhalation 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 Novartis Europharm Limited, Vista Building Elm Park, Merrion Road, 4 – Dublin, Ireland.

EMA/PDCO/117523/2022 corr
Amsterdam, 20 May 2022

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

EMEA-001217-PIP01-11-M08

Scope of the application

Active substance(s):

Indacaterol (acetate) / mometasone (furoate)

Invented name:

Atectura Breezhaler and its duplicate authorization Bemrist Breezhaler

Condition(s):

Treatment of asthma

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Inhalation powder, hard capsule

Route(s) of administration:

Inhalation use

Name/corporate name of the PIP applicant:

Novartis Europharm Limited

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Novartis Europharm Limited submitted to the European Medicines Agency on 21 February 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/0184/2012 issued on 21 August 2012, the decision P/0193/2015 issued on 4 September 2015, the decision P/0104/2016 issued on 15 April 2016, the decision P/0141/2017 issued on 7 June 2017, the decision P/0057/2018 issued on 16 March 2018, the decision P/0292/2018 issued on 12 September 2018 and the decision P/0155/2021 issued on 16 April 2021.

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

The procedure started on 21 March 2022.

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.
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 asthma

The waiver applies to:

- all subsets of the paediatric population from birth to less than 6 years of age;
- inhalation powder, hard capsule, inhalation use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan

2.1. Condition

Treatment of asthma

2.1.1. Indication(s) targeted by the PIP

Treatment of persistent asthma

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

From 6 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Inhalation powder, hard capsule

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1** Open label, uncontrolled trial to investigate the inhalation flow profiles generated through Concept1 inhaler in children from 6 to less than 18 years of age with asthma.
Non-clinical studies	Not applicable
Clinical studies	**Study 2** Double-blind, double-dummy, randomised, multiple dose, parallel-group active-controlled trial to evaluate efficacy and safety and pharmacokinetics of two doses of mometasone (furoate), delivered via Concept1 or Twisthaler in terms of non-inferiority in children from 12 to less than 18 years of age (and in adults) with persistent asthma.

	Study 3 (CQMF149G2202) Double-blind, randomised, multiple dose, parallel-group, active-controlled trial to evaluate PK and PD, safety and tolerability of different doses of indacaterol (acetate) in children from 6 to less than 12 years of age with asthma. **Study 4** (CQVM149B2303) Double blind, double-dummy, randomised, parallel group, active-controlled trial to evaluate efficacy and safety of indacaterol (acetate) / mometasone (furoate) compared to mometasone (furoate) in terms of superiority in children from 12 to less than 18 years of age (and in adults) with asthma. Study 5 Deleted in procedure EMEA-001217-PIP01-11-M01 Study 6 Deleted in procedure EMEA-001217-PIP01-11-M01 **Study 7** (CQMF149G2301) Double-blind, randomised, active-controlled, two-way cross-over, two period, two treatment (indacaterol/mometasone furoate versus budesonide) study, with 12-week treatment duration each to evaluate the efficacy and safety of indacaterol (acetate) / mometasone (furoate) compared to budesonidein terms of superiority in children from 6 years to less than 12 years of age with asthma. **Study 8 (**CQVM149B2301) Double blind, triple-dummy, randomised, multiple dose, parallel group, active-controlled trial to evaluate efficacy and safety of indacaterol (acetate) / mometasone (furoate) compared to mometasone (furoate) in terms of superiority and to salmeterol / fluticasone in terms of non-inferiority in children from 12 to less than 18 years of age (and in adults) with asthma.
Extrapolation, modelling and simulation studies	Not applicable
Other studies	Not applicable
Other measures	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	August 2026
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of asthma

Authorised indication(s):

- Maintenance treatment of asthma in adults and adolescents 12 years of age and older not adequately controlled with inhaled corticosteroids and inhaled short-acting beta2-agonists.

Authorised pharmaceutical form(s):

Inhalation powder, hard capsule

Authorised route(s) of administration:

Inhalation use