EMA/146966/2023

European Medicines Agency decision

P/0132/2023

of 13 April 2023

on the acceptance of a modification of an agreed paediatric investigation plan for remibrutinib (EMEA-002582-PIP01-19-M02) 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.

European Medicines Agency decision

P/0132/2023

of 13 April 2023

on the acceptance of a modification of an agreed paediatric investigation plan for remibrutinib (EMEA-002582-PIP01-19-M02) 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 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/0158/2020 issued on 17 April 2020 and the decision P/0170/2022 issued on 13 May 2022.

Having regard to the application submitted by Novartis Europharm Limited on 15 November 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 24 February 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.

(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 remibrutinib, film-coated tablet, age-appropriate oral solid dosage form, 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 Novartis Europharm Limited, Vista Building, Elm Park, Merrion Road, D04A9N6 – Dublin, Ireland.

EMA/PDCO/925138/2022
Amsterdam, 24 February 2023

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

EMEA-002582-PIP01-19-M02

Scope of the application

Active substance(s):

Remibrutinib

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of chronic spontaneous urticaria

Pharmaceutical form(s):

Film-coated tablet

Age-appropriate oral solid dosage form

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Novartis Europharm Limited

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 15 November 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/0158/2020 issued on 17 April 2020 and the decision P/0170/2022 issued on 13 May 2022.

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

The procedure started on 3 January 2023.

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 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 chronic spontaneous urticaria

The waiver applies to:

- the paediatric population from birth to less than 6 years of age;
- age-appropriate oral solid dosage form, film-coated tablet, oral use;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric investigation plan

2.1. Condition:

Treatment of chronic spontaneous urticaria

2.1.1. Indication(s) targeted by the PIP

Treatment of chronic spontaneous urticaria in adolescents and children 6 years of age and above with an inadequate response to H1-antihistamine treatment

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)

Age-appropriate oral solid dosage form

Film-coated tablet

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1** Development of an appropriate strength of an oral solid dosage form for adolescents **Study 2** Development of an appropriate strength of an oral solid dosage form for children from 6 years to less than 12 years of age
Non-clinical studies	Not applicable

Clinical studies	**Study 3 (CLOU064F12301)** Double-blind, randomised, placebo-controlled trial to evaluate pharmacokinetics, safety and efficacy of LOU064 as add-on to best standard of care in adolescents from 12 years to less than 18 years of age with chronic spontaneous urticaria (CSU) and inadequate response to H1-antihistamine therapy **Study 4 (CLOU064F12302)** Open-label, uncontrolled trial to evaluate pharmacokinetics, activity and safety of LOU064 in children from 6 years to less than 12 years of age with CSU and inadequate response to H1-antihistamine therapy
Extrapolation, modelling and simulation studies	**Study 5** Modelling and Simulation Activity Part 1 (adolescents) **Study 6** Modelling and Simulation Activity Part 2 (children) **Study 7** Analysis of existing exposure, efficacy and safety data on LOU064 in adolescents from 12 years to less than 18 years of age with CSU **Study 8** Analysis of existing exposure, efficacy and safety data on LOU064 in children from 6 years to less than 12 years of age with CSU
Other studies	Not applicable
Other measures	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 August 2031
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.