EMA/143821/2023

European Medicines Agency decision

P/0111/2023

of 14 April 2023

on the acceptance of a modification of an agreed paediatric investigation plan for acalabrutinib (Calquence), (EMEA-001796-PIP03-16-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/0309/2017 issued on 30 October 2017, the decision P/0062/2019 issued on 15 March 2019 and the decision P/0408/2021 issued on 8 October 2021,

Having regard to the application submitted by Acerta Pharma, BV on 21 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 and to the deferral and to the waiver.

(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 and to the waiver.

[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 acalabrutinib (Calquence), capsule, hard, film-coated tablet, oral use, including changes to the deferral and to the waiver, 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 Acerta Pharma, BV, Pivot Park, Kloosterstraat 9, 5349 AB - OSS, The Netherlands.

EMA/PDCO/924535/2022
Amsterdam, 24 February 2023

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan and on the granting of a product-specific waiver

EMEA-001796-PIP03-16-M03

Scope of the application

Active substance(s):

Acalabrutinib

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of mature B cell neoplasms

Pharmaceutical form(s):

Capsule, hard

Film-coated tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Acerta Pharma, BV

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Acerta Pharma, BV submitted to the European Medicines Agency on 21 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/0309/2017 issued on 30 October 2017, the decision P/0062/2019 issued on 15 March 2019 and the decision P/0408/2021 issued on 8 October 2021.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral and changes to the waiver to cover the remaining subsets of the paediatric population.

The procedure started on 3 January 2023.

Scope of the modification

The waiver has been extended to cover all subsets of the paediatric population.

Opinion

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:

- to agree to changes to the paediatric investigation plan and to the deferral and to amend the scope of the waiver 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 as set out in Annex I of this opinion.

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

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition:

Treatment of mature B cell neoplasms

The waiver applies to:

- the paediatric population from birth to less than 1 year of age;
- capsule, hard, film-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).

AND

The waiver applies to:

- the paediatric population from 1 year to less than 18 years of age;
- capsule, hard, film-coated tablet, oral use;
- on the grounds that the specific medicinal product is likely to be ineffective.

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Condition(s) and authorised indication(s)

1. Treatment of mature B cell neoplasms

Authorised indication(s):

- Calquence as monotherapy or in combination with obinutuzumab is indicated for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL).
  - Invented name(s): Calquence
  - Authorised pharmaceutical form(s): Capsule, hard; film-coated tablet
  - Authorised route(s) of administration: oral use
  - Authorised via centralised procedure.
- Calquence as monotherapy is indicated for the treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy.
  - Invented name(s): Calquence
  - Authorised pharmaceutical form(s): Capsule, hard; film-coated tablet
  - Authorised route(s) of administration: oral use
  - Authorised via centralised procedure.