EMA/275723/2022

European Medicines Agency decision

P/0205/2022

of 10 June 2022

on the acceptance of a modification of an agreed paediatric investigation plan for zanubrutinib (Brukinsa), (EMEA-002354-PIP02-18-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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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/0398/2019 issued on 04 December 2019,

Having regard to the application submitted by BeiGene Ireland Ltd. on 24 January 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 22 April 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 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 zanubrutinib (Brukinsa), capsule, hard, 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 BeiGene Ireland Ltd., 10 Earlsfort Terrace, D02 T380 – Dublin, Ireland.

EMA/PDCO/194305/2022 corr
Amsterdam, 22 April 2022

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-002354-PIP02-18-M01

Scope of the application

Active substance(s):

Zanubrutinib

Invented name:

Brukinsa

Condition(s):

Treatment of lymphoplasmacytic lymphoma

Treatment of mature B-cell neoplasms (excluding lymphoplasmacytic lymphoma)

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Capsule, hard

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

BeiGene Ireland Ltd.

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, BeiGene Ireland Ltd. submitted to the European Medicines Agency on 24 January 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/0398/2019 issued on 04 December 2019.

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 21 February 2022.

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 report:

- 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 lymphoplasmacytic lymphoma

The waiver applies to:

- the paediatric population from birth to less than 18 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).

1.2. Condition:

Treatment of mature B-cell neoplasms (excluding lymphoplasmacytic lymphoma)

The waiver applies to:

- the paediatric population from birth to less than 1 year 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);

and

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

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of lymphoplasmacytic lymphoma

Authorised indication(s):

- BRUKINSA as monotherapy is indicated for the treatment of adult patients with Waldenström's macroglobulinaemia (WM) who have received at least one prior therapy, or in first line treatment for patients unsuitable for chemo-immunotherapy.

Authorised pharmaceutical form(s):

Capsule, hard

Authorised route(s) of administration:

Oral use