EMA/313177/2024

European Medicines Agency decision

P/0226/2024

of 10 July 2024

on the granting of a product specific waiver for zanubrutinib (Brukinsa), (EMEA-002354-PIP03-24) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 application submitted by BeiGene Ireland Ltd. on 10 June 2024 under Article 13 of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 28 June 2024 in accordance with Article 13 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee has given an opinion on the granting of a product specific waiver.

(2) It is therefore appropriate to adopt a decision granting a waiver.

Has adopted this decision:

Article 1

A waiver for zanubrutinib (Brukinsa), film-coated tablet, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 2

This decision is addressed to BeiGene Ireland Ltd., 10 Earlsfort Terrace, D02 T380 Dublin, Ireland.

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

EMA/PDCO/278341/2024
Amsterdam, 28 June 2024

Opinion of the Paediatric Committee on the granting of a product-specific waiver

EMEA-002354-PIP03-24

Scope of the application

Active substance(s):

Zanubrutinib

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of lymphoplasmacytic lymphoma

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

Pharmaceutical form(s):

Film-coated tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

BeiGene Ireland Ltd.

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, BeiGene Ireland Ltd. submitted to the European Medicines Agency on 10 June 2024 an application for a product-specific waiver on the grounds set out in Article 11 of said Regulation for the above mentioned medicinal product.

The procedure started on 14 June 2024.

Opinion

1. The Paediatric Committee, having assessed the waiver application in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to grant a product-specific waiver for all subsets of the paediatric population and all the above mentioned condition(s) 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 and Article 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended occurs only in adult populations.

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

2. The grounds for the granting of the waiver are set out in 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

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;
- 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).

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;
- 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 paediatric population from 1 year to less than 18 years of age;
- 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 lymphoplasmacytic lymphoma

Authorised indication(s):

- as monotherapy 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.
  - Invented name(s): Brukinsa
  - Authorised pharmaceutical form(s): capsule, hard
  - Authorised route(s) of administration: oral use
  - Authorised via centralised procedure

2. Treatment of mature B-cell neoplasms (excluding lymphocytic lymphoma)

Authorised indication(s):

- as monotherapy for the treatment of adult patients with chronic lymphocytic leukemia (CLL).
- as monotherapy for the treatment of adult patients with marginal zone lymphoma (MZL) who have received at least one prior anti-CD20-based therapy.
- in combination with obinutuzumab for the treatment of adult patients with refractory or relapsed follicular lymphoma (FL) who have received at least two prior systemic therapies.
  - Invented name(s): Brukinsa
  - Authorised pharmaceutical form(s): capsule, hard
  - Authorised route(s) of administration: oral use
  - Authorised via centralised procedure