EMA/324759/2020

European Medicines Agency decision

P/0242/2020

of 22 June 2020

on the granting of a product specific waiver for rucaparib (camsylate), (EMEA-002760-PIP01-19) 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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the application submitted by Clovis Oncology Ireland Ltd. on 24 February 2020 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 29 May 2020 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 rucaparib (camsylate), 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 Clovis Oncology Ireland Ltd., Regus Dublin Airport, Skybridge House – Dublin Airport, Swords, K67 P6K2 - Dublin, Ireland.

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

EMA/PDCO/132683/2020
Amsterdam, 29 May 2020

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

EMEA-002760-PIP01-19

Scope of the application

Active substance(s):

Rucaparib (camsylate)

Invented name:

Rubraca

Condition(s):

Treatment of fallopian tube cancer

Treatment of ovarian cancer

Treatment of prostate malignant neoplasms

Treatment of primary peritoneal cancer

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Film-coated tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Clovis Oncology Ireland Ltd.

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Clovis Oncology Ireland Ltd. submitted to the European Medicines Agency on 24 February 2020 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 31 March 2020.

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 conditions in accordance with 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, and with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

   The Norwegian Paediatric Committee member 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 fallopian tube cancer

The waiver applies to:

- all subsets of 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 occurs only in adult populations.

1.2. Condition:

Treatment of ovarian cancer

The waiver applies to:

- the paediatric population from birth to less than 12 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).

Treatment of ovarian cancer

The waiver applies to:

- adolescents from 12 years to less than 18 years of age;
- film-coated tablet, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

1.3. Condition:

Treatment of prostate malignant neoplasms

The waiver applies to:

- all subsets of 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 occurs only in adult populations.

1.4. Condition:

Treatment of primary peritoneal cancer

The waiver applies to:

- all subsets of 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 occurs only in adult populations.

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of fallopian tube cancer
2. Treatment of ovarian cancer
3. Treatment of primary peritoneal cancer

Authorised indication(s):

- Rubraca is indicated as monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy.
- Rubraca is indicated as monotherapy treatment of adult patients with platinum sensitive, relapsed or progressive, BRCA mutated (germline and/or somatic), high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have been treated with two or more prior lines of platinum based chemotherapy, and who are unable to tolerate further platinum based chemotherapy.

Authorised pharmaceutical form(s):

Film-coated tablet

Authorised route(s) of administration:

Oral use