EMA/227256/2019

European Medicines Agency decision

P/0167/2019

of 15 May 2019

on the granting of a product specific waiver for niraparib (Zejula), (EMEA-002268-PIP03-18) 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 Janssen Research & Development on 20 December 2018 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 March 2019 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 niraparib (Zejula), capsule, hard, 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 Janssen Research & Development, 50-100 Holmers Farm Way, HP12 4DP - High Wycombe, United Kingdom.

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

EMA/10182/2019
Amsterdam, 29 March 2019

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

EMEA-002268-PIP03-18

Scope of the application

Active substance(s):

Niraparib

Invented name:

Zejula

Condition(s):

Treatment of malignant prostate neoplasms

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Capsule, hard

Film-coated tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Janssen Research & Development

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Janssen Research & Development submitted to the European Medicines Agency on 20 December 2018 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 29 January 2019.

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 the above mentioned condition(s) 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.

   The Norwegian Paediatric Committee member does agree 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 malignant prostate neoplasms

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years 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 subsets.

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of Ovarian Carcinoma (excluding rhabdomyosarcoma and germ cell tumours)

Authorised indication:

- Indicated as monotherapy for the maintenance treatment of adult patients with platinum sensitive relapsed high grade serous epithelian ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy

Authorised pharmaceutical form(s):

Capsule, hard

Authorised route(s) of administration:

Oral use