EMA/291561/2024

European Medicines Agency decision

P/0229/2024

of 19 July 2024

on the acceptance of a modification of an agreed paediatric investigation plan for niraparib (tosylate monohydrate) (Zejula), (EMEA-002268-PIP02-18-M02) 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.

European Medicines Agency decision

P/0229/2024

of 19 July 2024

on the acceptance of a modification of an agreed paediatric investigation plan for niraparib (tosylate monohydrate) (Zejula), (EMEA-002268-PIP02-18-M02) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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/0313/2019 issued on 10 September 2019 and the decision P/0184/2021 issued on 10 May 2021,

Having regard to the application submitted by GlaxoSmithKline (Ireland) Limited on 23 February 2024 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 31 May 2024, 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.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

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

Article 1

Changes to the agreed paediatric investigation plan for niraparib (tosylate monohydrate) (Zejula), capsule, hard, tablet for oral suspension, tablet, oral use, 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 GlaxoSmithKline (Ireland) Limited, 12 River Walk Citywest Business Campus, D24 YK11 - Dublin 24, Ireland.

EMA/PDCO/90765/2024
Amsterdam, 31 May 2024

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-002268-PIP02-18-M02

Scope of the application

Active substance(s):

Niraparib (tosylate monohydrate)

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic and lymphoid malignancies)

Pharmaceutical form(s):

Capsule, hard

Tablet for oral suspension

Tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

GlaxoSmithKline (Ireland) Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, GlaxoSmithKline (Ireland) Limited submitted to the European Medicines Agency on 23 February 2024 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0313/2019 issued on 10 September 2019 and the decision P/0184/2021 issued on 10 May 2021.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 2 April 2024.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

Pharmaceutical form was amended.

Opinion

1. 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 in the scope set out in the Annex I of this opinion.
2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population are set out in the 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

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

Not applicable

2. Paediatric investigation plan

2.1. Condition:

Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic and lymphoid malignancies)

2.1.1. Indication(s) targeted by the PIP

Treatment of paediatric patients from birth to less than 18 years old with neuroblastoma and/or osteosarcoma

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From birth to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Capsule, hard

Tablet for oral suspension

Tablet

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1** Development of age-appropriate oral liquid dosage form
Non-clinical studies	Not applicable
Clinical studies	**Study 2** Open-label, multiple dose, two part trial to evaluate pharmacokinetics, safety, activity and acceptability of niraparib when given in combination with dostarlimab in children from 6 months of age to less than 18 years of age with recurrent/ refractory solid tumours, excluding central nervous system (CNS) tumours in part 1a and 1b and with recurrent/ refractory osteosarcoma and recurrent/ refractory neuroblastoma in Part 2. **Study 3** Open-label, randomised controlled, active comparator trial to evaluate efficacy and safety of niraparib in combination with dostarlimab against current standard of care in children from 6 months of age to less than 18

	years of age with relapsed/ refractory osteosarcoma and/or neuroblastoma **Study 4** Open-label, randomised controlled, active comparator trial to evaluate efficacy and safety of niraparib in combination with dostarlimab against current standard of care in children from birth to less than 18 years of age with newly diagnosed high risk osteosarcoma and/or Stage 4 neuroblastoma.
Extrapolation, modelling and simulation studies	**Study 5** Modelling and simulation study, to evaluate the use of niraparib and dostarlimab in the proposed paediatric indications in children from birth to less than 18 years of age
Other studies	Not applicable
Other measures	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By June 2040
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Condition(s) and authorised indication(s):

1. Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic and lymphoid malignancies)

Authorised indication(s):

- Monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy.
- Monotherapy for the maintenance treatment of adult patients with advanced epithelial (FIGO Stages III and IV) high-grade ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy.

Authorised pharmaceutical form(s):

Capsule, hard

Film coated tablets

Authorised route(s) of administration:

Oral use