EMA/251320/2021

# European Medicines Agency decision

P/0184/2021

of 10 May 2021

on the acceptance of a modification of an agreed paediatric investigation plan for niraparib (tosylate monohydrate), (Zejula), (EMEA-002268-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 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 European Medicines Agency's decision P/0313/2019 issued on 10 September 2019.

Having regard to the application submitted by GlaxoSmithKline (Ireland) Limited on 18 December 2020 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 26 March 2021, 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.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

***Article 1***

Changes to the agreed paediatric investigation plan for niraparib (tosylate monohydrate), (Zejula), film coated tablet, capsule, hard, age appropriate oral liquid formulation, 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 Riverwalk, Citywest Business, Campus, 24 – Dublin, Ireland.

EMA/PDCO/24430/2021 Corr
Amsterdam, 26 March 2021

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

EMEA-002268-PIP02-18-M01

## Scope of the application

**Active substance(s):**

Niraparib (tosylate monohydrate)

**Invented name:**

Zejula

**Condition(s):**

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

**Authorised indication(s):**

See Annex II

**Pharmaceutical form(s):**

Film coated tablet

Capsule, hard

Age appropriate oral liquid formulation

**Route(s) of administration:**

Oral use

**Name/corporate name of the PIP applicant:**

GlaxoSmithKline (Ireland) Limited

**Information about the authorised medicinal product:**

See Annex II

## 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 18 December 2020 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.

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

The procedure started on 26 January 2021.

## Scope of the modification

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

## 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;

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

2. The measures and timelines of the paediatric investigation plan 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)

Film coated tablet

Capsule, hard

Age appropriate oral liquid formulation

### 2.1.4. Measures

| Area | Number of measures | Description |
|---|---|---|
| Quality-related studies | 1 | **Study 1**<br>Development of age-appropriate oral liquid dosage form |
| Non-clinical studies | 0 | Not applicable |
| Clinical studies | 3 | **Study 2**<br>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 relapsed/ refractory solid tumours, excluding central nervous system (CNS) tumours in part 1a and 1b and with relapsed/ refractory osteosarcoma and relapsed/ refractory neuroblastoma in Part 2<br>**Study 3**<br>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<br><br>**Study 4**<br><br>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 | 1 | **Study 5**<br><br>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 | 0 | Not applicable |
| Other measures | 0 | 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

## 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

## Authorised route(s) of administration:

Oral use