MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan (MHRA-100623-PIP01-22-M02)

MHRA-100623-PIP01-22-M03

Scope of the Application

Active Substance(s)

NIRAPARIB TOSYLATE MONOHYDRATE

Condition(s)

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

Pharmaceutical Form(s)

Capsule, hard, Tablet, Oral suspension

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

GLAXOSMITHKLINE UK LIMITED

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, GLAXOSMITHKLINE UK LIMITED submitted to the licensing authority on 15/10/2025 11:07 BST an application for a Modification

The procedure started on 02/12/2025 12:25 GMT

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to accept change(s) to the agreed paediatric investigation plan

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-100623-PIP01-22-M03

Of 18/02/2026 18:20 GMT

On the adopted decision for NIRAPARIB TOSYLATE MONOHYDRATE (MHRA-100623-PIP01-22-M03) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for NIRAPARIB TOSYLATE MONOHYDRATE, Tablet, Oral suspension, Capsule, hard , ORAL USE .

This decision is addressed to GLAXOSMITHKLINE UK LIMITED, 79 New Oxford Street, London, UNITED KINGDOM, WC1A 1DG

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

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

2.2 Indication(s) targeted by the PIP:

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

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from birth to less than 18 years of age

2.4 Pharmaceutical Form(s):

Film coated tablet Capsule, hard Tablet for oral suspension

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Study 1 Deleted during procedure MHRA-100623-PIP01-22-M03.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	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 5 years 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 Deleted during procedure MHRA-100623-PIP01-22-M03 Study 4 Deleted during procedure MHRA-100623-PIP01-22-M03
Extrapolation, Modeling & Simulation Studies	0	Study 5 Deleted during procedure MHRA-100623-PIP01-22-M03.
Other Studies	0	Not applicable.
Other Measures	0	Not applicable.

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	31/08/2031
Deferral of one or more studies contained in the paediatric investigation plan:	Yes