

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

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Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-101901-PIP01-25

Scope of the Application

Active Substance(s)

Golcadomide; Golcadomide

Condition(s)

Treatment of mature B cell neoplasms

Pharmaceutical Form(s)

Capsule, hard Powder for oral suspension, Capsule, hard Powder for oral suspension

Route(s) of Administration

ORAL USE, ORAL USE

Name / Corporate name of the PIP applicant

Bristol-Myers Squibb EEIG

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Bristol-Myers Squibb EEIG submitted to the licensing authority on 16/04/2025 19:22 BST an application for a Paediatric Investigation Plan

The procedure started on 25/09/2025 19:52 BST

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 agree a paediatric investigation plan and grant a deferral and grant a waiver

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-101901-PIP01-25

Of 12/01/2026 11:15 GMT

On the adopted decision for Golcadomide (MHRA-101901-PIP01-25) 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 a paediatric investigation plan

This decision applies to a Paediatric Investigation Plan for Golcadomide, Capsule, hard Powder for oral suspension , ORAL USE .

This decision is addressed to Bristol-Myers Squibb EEIG, Plaza 254, Blanchardstown Corporate Park 2, Ballycoolin , Dublin 15, IRELAND, D15 T867

ANNEX I

1. Waiver

1.1 Condition:

Treatment of mature B cell neoplasms The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 months of age Pharmaceutical form(s): Capsule, hard Age-appropriate oral dosage form Route(s) of administration: ORAL USE Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of mature B cell neoplasms

2.2 Indication(s) targeted by the PIP:

Treatment of relapsed or refractory B cell non-Hodgkin lymphoma

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

The paediatric population from 6 months to less than 18 years of age

2.4 Pharmaceutical Form(s):

Capsule, hard Age-appropriate oral dosage form

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age-appropriate oral dosage form of golcadomide appropriate for the target population.
Non-Clinical Studies	1	Study 2 Study to determine the antitumor activity of golcadomide in human Burkitt lymphoma xenograft models.
Clinical Studies	1	Study 3 Adaptive, prospective, multicentre, open label, platform clinical trial to evaluate the safety and efficacy of novel agents, including golcadomide in combination with rituximab followed by golcadomide monotherapy (Arm IV of the Glo-BNHL platform study) for the treatment of children and adolescents from 6 months to less than 18 years of age (and young adults) with relapsed or refractory B-cell non-Hodgkin lymphoma.
Extrapolation, Modeling & Simulation Studies	3	Study 4 Use of a PopPK(/PD) model to confirm or modify the paediatric doses of golcadomide to be used in the expansion stage of Study 3. Study 5 Use of a physiologically-based (PB-PK) model to analyse (sparse) PK data collected in paediatric studies and pooled with adult PK data to inform dosing recommendation for golcadomide for treatment of relapsed or refractory B-cell non-Hodgkin lymphoma in

		paediatric patients. Study 6 Use of a PopPK(/PD) model to confirm the doses in paediatric patients.
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:	No
Date of completion of the paediatric investigation plan:	31/01/2032
Deferral of one or more studies contained in the paediatric investigation plan:	Yes