

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

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan (MHRA-100466-PIP01-22)

MHRA-100466-PIP01-22-M02

Scope of the Application

Active Substance(s)

zilovetamab vedotin

Condition(s)

Treatment of malignant neoplasms of haematopoietic and lymphoid tissue, Treatment of all conditions included in the category of malignant neoplasms (except nervous system, haematopoietic, and lymphoid tissue)

Pharmaceutical Form(s)

Powder for concentrate for solution for infusion

Route(s) of Administration

INTRAVENOUS USE

Name / Corporate name of the PIP applicant

Merck Sharp & Dohme (UK) Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Merck Sharp & Dohme (UK) Limited submitted to the licensing authority on 23/12/2025 17:01 GMT an application for a Modification

The procedure started on 09/01/2026 12:55 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-100466-PIP01-22-M02

Of 10/04/2026 16:42 BST

On the adopted decision for zilovetamab vedotin (MHRA-100466-PIP01-22-M02) 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 zilovetamab vedotin, Powder for concentrate for solution for infusion , INTRAVENOUS USE .

This decision is addressed to Merck Sharp & Dohme (UK) Limited, 120 Moorgate, London, UNITED KINGDOM, EC2M 6UR

ANNEX I

1. Waiver

1.1 Condition:

Not Applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Condition 1: Treatment of malignant neoplasms of haematopoietic and lymphoid tissue
Condition 2: Treatment of all conditions included in the category of malignant neoplasms (except nervous system, haematopoietic, and lymphoid tissue)

2.2 Indication(s) targeted by the PIP:

Condition 1: Treatment of patients with a relapsed or refractory solid or haematological malignancy identified based on the results of PIP study 1 as monotherapy or in combination with standard of care. Condition 2: Treatment of patients with a relapsed or refractory solid or haematological malignancy identified based on the results of PIP study 1 as monotherapy or in combination with standard of care.

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

For both conditions: The paediatric population from birth to less than 18 years of age

2.4 Pharmaceutical Form(s):

For both conditions: Powder for concentrate for solution for infusion

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	2	Same studies for both conditions Study 1 (MK-2140 Paediatric Study) Open label, two part trial to evaluate the recommended phase 2 dose, pharmacokinetics (PK), pharmacodynamics (PD), safety (part 1), and safety, activity and immunogenicity (Part 2) of zilovetamab vedotin in children from birth to less than 18 years of age with relapsed or refractory solid tumours or haematological or lymphoid malignancies for which all treatment options are exhausted (Part 1) and with relapsed or refractory B-Acute lymphoblastic leukaemia (B-ALL), diffuse large B cell lymphoma (DLBCL)/Burkitt lymphoma, Ewing sarcoma, or neuroblastoma (Part 2). Study 2 Randomised, controlled trial to evaluate safety, efficacy, immunogenicity of zilovetamab vedotin monotherapy or in combination with standard of care compared to standard of care in children from birth to less than 18 years of age with a malignancy identified based on data from Study 1.

Extrapolation, Modeling & Simulation Studies	1	Same study for both conditions Study 3 Modelling and simulation study, to support dose finding of zilovetamab vedotin in children from birth to less than 18 years of age with relapsed or refractory solid tumours or haematological malignancies.
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:	31/12/2035
Deferral of one or more studies contained in the paediatric investigation plan:	Yes