

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

MHRA-102362-PIP01-26

Scope of the Application

Active Substance(s)

Telisotuzumab adizutecan

Condition(s)

Treatment of all conditions included in the category of malignant neoplasms.

Pharmaceutical Form(s)

Powder for solution for infusion

Route(s) of Administration

Intravenous use

Name / Corporate name of the PIP applicant

AbbVie Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, AbbVie Ltd submitted to the licensing authority on 23/04/2026 12:12 BST an application for a Paediatric Investigation Plan

The procedure started on 12/05/2026 17:09 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

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-102362-PIP01-26

Of 17/08/2026 07:36 BST

On the adopted decision for Telisotuzumab adizutecan (MHRA-102362-PIP01-26) 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 Telisotuzumab adizutecan, Powder for solution for infusion , Intravenous use .

This decision is addressed to AbbVie Ltd, AbbVie House, Vanwall Road , Maidenhead, UNITED KINGDOM, SL6 4UB

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.
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2.2 Indication(s) targeted by the PIP:

Treatment of paediatric patients with locally advanced or metastatic solid tumours with a MET gene amplification that have progressed on or following prior systemic treatment
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2.3 Subset(s) of the paediatric population concerned by the paediatric development:

All subsets of the paediatric population from birth to less than 18 years of age

2.4 Pharmaceutical Form(s):

Powder for solution for infusion

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age-appropriate dose administration scheme.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	2	Study 2 (M25-279) Open-label, single arm trial (paediatric cohort) to evaluate the dose, pharmacokinetics (PK), pharmacodynamics (PD), safety, immunogenicity and activity of telisotuzumab adizutecan in children and adolescents from birth to less than 18 years of age with locally advanced or metastatic solid tumours, including central nervous system (CNS) tumours, with MET amplification who have progressed on or after minimum one prior line of standard-of-care therapy and/or have no satisfactory alternative treatment. Study 3 Randomised controlled trial to evaluate safety and efficacy of telisotuzumab adizutecan compared to standard of care in children and adolescents from birth to less than 18 years of age with solid tumours, including CNS tumours, with MET amplification and additional patient characteristics based on results from PIP study 2.
Extrapolation, Modeling & Simulation Studies	1	Study 4 Modelling and simulation analyses, to support and confirm the final dose recommendation of telisotuzumab adizutecan in children and adolescents 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 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:	29/02/2040
Deferral of one or more studies contained in the paediatric investigation plan:	Yes