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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral

MHRA-102057-PIP01-25

Scope of the Application

Active Substance(s)

Humanised IgG1 monoclonal antibody against PD-L1 conjugated to monomethyl auristatin E via a valinecitrulline linker; Fetrastobart vedotin

Condition(s)

Treatment of all conditions included in the category of malignant neoplasms (except central nervous system tumours)

Pharmaceutical Form(s)

Powder for concentrate for solution for infusion

Route(s) of Administration

Intravenous use

Name / Corporate name of the PIP applicant

Pfizer Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Pfizer Limited submitted to the licensing authority on 25/07/2025 18:28 BST an application for a Paediatric Investigation Plan

The procedure started on 02/09/2025 19:03 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.

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

gov.uk/mhra

Final Decision Letter

MHRA-102057-PIP01-25

Of 01/10/2026 10:24 BST

On the adopted decision for Humanised IgG1 monoclonal antibody against PD-L1 conjugated to monomethyl auristatin E via a valinecitrulline linker; Fetrastobart vedotin (MHRA-102057-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 Humanised IgG1 monoclonal antibody against PD-L1 conjugated to monomethyl auristatin E via a valinecitrulline linker; Fetrastobart vedotin, Powder for concentrate for solution for infusion , Intravenous use .

This decision is addressed to Pfizer Limited, Ramsgate Road, Sandwich, Kent, UNITED KINGDOM, CT13 9NJ

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 central nervous system tumours)

2.2 Indication(s) targeted by the PIP:

Treatment of all conditions included in the category of malignant neoplasms (except central nervous system tumours)

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):

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 formulation.
Non-Clinical Studies	2	Study 2 In vitro study to (1) confirm PD-L1 expression in paediatric tumours of interest by immunohistochemistry (IHC) and in cell lines of interest by quantitative flow cytometry, (2) evaluate in vitro cytotoxic potential of fetrastobart vedotin in PD-L1-expressing paediatric cancer cell lines and (3) identify in vivo models representative of selected paediatric tumours. Study 3 In vivo study to (1) select in vivo models with appropriate paediatric PD-L1 expression and (2) evaluate anti-tumour efficacy of fetrastobart vedotin in xenograft tumours models of paediatric indications of interest with diverse PD-L1 expression levels including undetectable levels, which are representative of anticipated heterogenous paediatric tumours.
Clinical Studies	2	Study 4 Open-label basket trial to evaluate dose, tolerability, and preliminary evidence of fetrastobart vedotin activity in paediatric patients with tumours selected based on the studies 2 and 3. Study 5 Randomised, controlled trial to evaluate efficacy and safety of fetrastobart vedotin compared to the appropriate standard of care (SOC) in a selected paediatric

		tumour type to be conducted based on results of Study 4.
Extrapolation, Modeling & Simulation Studies	1	Study 6 Use of population PK (PopPK) to predict initial paediatric doses of fetrastobart vedotin to be used in clinical studies.
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:	31/07/2040
Deferral of one or more studies contained in the paediatric investigation plan:	Yes