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 and grant a waiver

MHRA-102440-PIP01-26

Scope of the Application

Active Substance(s)

Surovatamig (formerly AZD0486)

Condition(s)

B-Lymphoblastic Leukaemia/lymphoma

Pharmaceutical Form(s)

Concentrate for solution for infusion, Powder for concentrate for solution for infusion

Route(s) of Administration

INTRAVENOUS

Name / Corporate name of the PIP applicant

AstraZeneca UK Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, AstraZeneca UK Limited submitted to the licensing authority on 24/04/2026 11:16 BST an application for a Paediatric Investigation Plan

The procedure started on 22/05/2026 14:42 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.

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

gov.uk/mhra

Final Decision Letter

MHRA-102440-PIP01-26

Of 08/10/2026 11:53 BST

On the adopted decision for Surovatamig (formerly AZD0486) (MHRA-102440-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 Surovatamig (formerly AZD0486) , Concentrate for solution for infusion, Powder for concentrate for solution for infusion , INTRAVENOUS .

This decision is addressed to AstraZeneca UK Limited , 2 Pancras Square, 8th Floor, London, UNITED KINGDOM, N1C 4AG

ANNEX I

1. Waiver

1.1 Condition:

Treatment of B-lymphoblastic leukaemia/lymphoma The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 28 days of age Pharmaceutical form(s): Concentrate for solution for infusion Powder for concentrate for solution for infusion Route(s) of administration: Intravenous use Reason for granting waiver: on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s)

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of B-lymphoblastic leukaemia/lymphoma

2.2 Indication(s) targeted by the PIP:

Treatment of refractory or relapsed B-cell acute lymphoblastic leukaemia

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

The paediatric population from 28 days to less than 18 years of age

2.4 Pharmaceutical Form(s):

Concentrate for solution for infusion; 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	Study 1 (B-ALL 1) Open-label, single arm trial to evaluate pharmacokinetics, pharmacodynamics, safety, activity, and immunogenicity of surovatamig monotherapy in children from 28 days to less than 18 years of age with refractory or relapsed B-cell acute lymphoblastic leukaemia (B-ALL). Study 2 (B-ALL 2) Open-label, randomised, active controlled trial to evaluate the safety and efficacy of surovatamig compared to standard of care in children from 28 days to less than 18 years of age with first relapse or refractory B-acute lymphoblastic leukaemia.
Extrapolation, Modeling & Simulation Studies	1	Study 3 Modelling and simulation study to determine the initial doses and to confirm or modify the posology of surovatamig monotherapy in children from 28 days to less than 18 years of age with refractory or relapsed B-cell acute lymphoblastic leukaemia.
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:	30/09/2034
Deferral of one or more studies contained in the paediatric investigation plan:	Yes