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-100556-PIP02-25

Scope of the Application

Active Substance(s)

Riliprubart

Condition(s)

Treatment of rejection of a transplanted kidney

Pharmaceutical Form(s)

Solution for injection/infusion

Route(s) of Administration

INTRAVENOUS USE

Name / Corporate name of the PIP applicant

Sanofi B.V.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Sanofi B.V. submitted to the licensing authority on 27/06/2025 17:14 BST an application for a Paediatric Investigation Plan

The procedure started on 24/07/2025 20:09 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 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-100556-PIP02-25

Of 12/01/2026 08:44 GMT

On the adopted decision for Riliprubart (MHRA-100556-PIP02-25) 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 Riliprubart, Solution for injection/infusion , INTRAVENOUS USE .

This decision is addressed to Sanofi B.V., Paasheuvelweg 25, Amsterdam, NETHERLANDS, 1105 BP

ANNEX I

1. Waiver

1.1 Condition:

Treatment of rejection of a transplanted kidney The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 years of age Pharmaceutical form(s): Solution for injection/infusion Route(s) of administration: INTRAVENOUS 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 rejection of a transplanted kidney

2.2 Indication(s) targeted by the PIP:

Treatment of antibody-mediated rejection in kidney transplant recipients

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

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

2.4 Pharmaceutical Form(s):

Solution for injection/infusion

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 1 Open-label, single-arm trial to evaluate pharmacokinetics and safety of riliprubart in paediatric patients from 6 years to less than 18 years of age who are kidney transplant recipients with active/ chronic active antibody-mediated rejection (AMR).
Extrapolation, Modeling & Simulation Studies	2	Study 2 Modelling and simulation analyses to evaluate the use of riliprubart for the treatment of rejection of transplanted kidney in paediatric patients from 6 years to less than 18 years of age. Extrapolation Plan Studies 1 and 2 are part of an extrapolation plan covering the paediatric population from 6 years 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:	No
Date of completion of the paediatric investigation plan:	30/06/2035
Deferral of one or more studies contained in the paediatric investigation plan:	Yes