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

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Decision Cover Letter

Decision of the licensing authority to:

grant a product specific waiver.

MHRA-102192-PIP01-25

Scope of the Application

Active Substance(s)

casdatifan

Condition(s)

Treatment of renal cell carcinoma (RCC)

Pharmaceutical Form(s)

Tablet

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Arcus Biosciences, Inc.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Arcus Biosciences, Inc. submitted to the licensing authority on 16/12/2025 21:48 GMT an application for a Paediatric Investigation Plan

The procedure started on 08/01/2026 17:32 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 grant a product specific 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-102192-PIP01-25

Of 09/03/2026 11:37 GMT

On the adopted decision for casdatifan (MHRA-102192-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:

Granting a waiver in all age groups for the listed condition(s).

This decision applies to a Paediatric Investigation Plan for casdatifan, Tablet , ORAL USE .

This decision is addressed to Arcus Biosciences, Inc., 3928 Point Eden Way, Hayward, UNITED STATES OF AMERICA, 94545

ANNEX I

1. Waiver

1.1 Condition:

Treatment of renal cell carcinoma (RCC) The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 18 years of age. Pharmaceutical form(s): Tablet Route(s) of administration: ORAL USE Reason for granting waiver: On the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies are not feasible

2. Paediatric Investigation Plan:

2.1 Condition(s):

Not applicable.

2.2 Indication(s) targeted by the PIP:

Not applicable.

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

Not applicable.

2.4 Pharmaceutical Form(s):

Not applicable.

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	Not applicable.	Not applicable.
Non-Clinical Studies	Not applicable.	Not applicable.
Clinical Studies	Not applicable.	Not applicable.
Extrapolation, Modeling & Simulation Studies	Not applicable.	Not applicable.
Other Studies	Not applicable.	Not applicable.
Other Measures	Not applicable.	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:	Not applicable.
Date of completion of the paediatric investigation plan:	
Deferral of one or more studies contained in the paediatric investigation plan:	Not applicable.