MHRA
10 South Colonnade
Canary Wharf
London
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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-101323-PIP02-24

Scope of the Application

Active Substance(s)

tulisokibart

Condition(s)

Treatment of Crohn's disease

Pharmaceutical Form(s)

Concentrate for solution for infusion; Solution for infusion; Age-appropriate dosage form for parenteral use

Route(s) of Administration

INTRAVENOUS USE; SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

Merck Sharp & Dohme (UK) Ltd.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Merck Sharp & Dohme (UK) Ltd. submitted to the licensing authority on 05/02/2024 16:42 GMT an application for a Paediatric Investigation Plan

The procedure started on 15/03/2024 14:33 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 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-101323-PIP02-24

Of 16/12/2024 13:47 GMT

On the adopted decision for tulisokibart (MHRA-101323-PIP02-24) 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 tulisokibart , Concentrate for solution for infusion; Solution for infusion; Age-appropriate dosage form for parenteral use , INTRAVENOUS USE; SUBCUTANEOUS USE .

This decision is addressed to Merck Sharp & Dohme (UK) Ltd., 120 Moorgate, London, UNITED KINGDOM, EC2M 6UR

ANNEX I

1. Waiver

1.1 Condition:

Treatment of Crohn's disease The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age. Pharmaceutical form(s): Concentrate for solution for infusion Solution for injection Age-appropriate dosage form for parenteral use Route(s) of administration: INTRAVENOUS USE SUBCUTANEOUS USE Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of Crohn's disease

2.2 Indication(s) targeted by the PIP:

Treatment of moderately to severe active Crohn's disease

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

The paediatric population from 2 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Concentrate for solution for infusion Solution for Injection Age-appropriate dosage form for parenteral use.

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age appropriate formulation for parenteral use.
Non-Clinical Studies	1	Study 2 Prenatal and postnatal development study of intravenous tulisokibart in rabbits with assessment of immune system parameters.
Clinical Studies	1	Study 3 Open-label study evaluating the efficacy, safety, and PK of tulisokibart in paediatric participants from 2 years to less than 18 years of age with moderately to severely active Crohn's disease.
Extrapolation, Modeling & Simulation Studies	2	Study 4 Population pharmacokinetic (PopPK) model to simulate tulisokibart exposures in paediatric participants to predict the paediatric doses in each cohort to be used in PIP study 3. Extrapolation plan Studies 3 and 4 are part of the extrapolation plan of efficacy data from adult and adolescent patients to the paediatric population with Crohn's disease.
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:	28/02/2037
Deferral of one or more studies contained in the paediatric investigation plan:	Yes