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-101111-PIP01-23

Scope of the Application

Active Substance(s)

Cendakimab (BMS-986355)

Condition(s)

Treatment of Eosinophilic Esophagitis (EoE)

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

Bristol-Myers Squibb Pharma EEIG

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Bristol-Myers Squibb Pharma EEIG submitted to the licensing authority on 12/09/2023 13:53 BST an application for a Paediatric Investigation Plan

The procedure started on 26/07/2024 14:51 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-101111-PIP01-23

Of 02/09/2024 13:10 BST

On the adopted decision for Cendakimab (BMS-986355) (MHRA-101111-PIP01-23) 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 Cendakimab (BMS-986355), Solution for injection , SUBCUTANEOUS USE .

This decision is addressed to Bristol-Myers Squibb Pharma EEIG, Plaza 254, Blanchardstown Corporate Park 2 , Dublin 15, IRELAND, D15 T867

ANNEX I

1. Waiver

1.1 Condition:

Treatment of eosinophilic oesophagitis The waiver applies / applied to: Paediatric Subset(s): the paediatric population from birth to less than 2 years of age Pharmaceutical form(s): Solution for injection Route(s) of administration: Subcutaneous 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 Reason for Refusing Waiver: Not Applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of eosinophilic oesophagitis

2.2 Indication(s) targeted by the PIP:

Treatment of eosinophilic oesophagitis

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

From 2 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Solution for injection

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: Randomized, double-blind, placebo-controlled study to evaluate efficacy, safety and tolerability of cendakimab in induction and maintenance in adolescents from 12 years to less than 18 years of age weighing more than 40 kg (and adults) with eosinophilic oesophagitis. (Study CC-93538-EE-001) Study 2: Open-label, non-comparative trial to evaluate pharmacokinetics, safety and tolerability of cendakimab in children from 2 years to less than 12 years of age with eosinophilic oesophagitis
Extrapolation, Modeling & Simulation Studies	2	Study 3: Modelling and simulation study to support the dose selection for children from 2 years to less than 12 years of age Study 4: Modelling and simulation study to support the dose selection for children from 2 years to less
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:	30/05/2030
Deferral of one or more studies contained in the paediatric investigation plan:	Yes