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

MHRA-100585-PIP01-22

Scope of the Application

Active Substance(s)

Adintrevimab

Condition(s)

Treatment of Coronavirus Disease 2019 (COVID-19), Prevention of Coronavirus Disease 2019 (COVID-19)

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

INTRAMUSCULAR USE

Name / Corporate name of the PIP applicant

Adagio Therapeutics Netherlands B.V.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Adagio Therapeutics Netherlands B.V. submitted to the licensing authority on 05/08/2022 06:41 BST an application for a

The procedure started on 02/09/2022 10:53 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

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-100585-PIP01-22

Of 19/12/2022 15:45 GMT

On the adopted decision for Adintrevimab (MHRA-100585-PIP01-22) 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 for Adintrevimab, Solution for injection , INTRAMUSCULAR .

This decision is addressed to Adagio Therapeutics Netherlands B.V., Naritaweg 165, Amsterdam, NETHERLANDS, 1043 BW

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of Coronavirus Disease 2019 (COVID-19) Prevention of Coronavirus Disease 2019 (COVID-19)

2.2 Indication(s) targeted by the PIP:

Treatment of confirmed COVID-19 in paediatric patients who have a susceptible variant, who do not require supplemental oxygen for COVID-19 and who are at high risk for progressing to severe

COVID-19. Pre- and post-exposure prophylaxis of symptomatic COVID-19 in paediatric patients exposed to a susceptible variant.

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

All subsets of the paediatric population from at least 29 weeks of gestational age 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	1	Study 1 In vitro assessment of adintrevimab activity against circulating and emerging SARS-CoV-2 variants.
Clinical Studies	4	Study 2 (ADG20-PREV-001, EVADE) Randomised, double-blind, placebo-controlled study to evaluate the efficacy and safety of adintrevimab compared with placebo in the prevention of symptomatic COVID-19 in adolescents (and adults) with no known history of SARS-CoV-2 and who are at risk of symptomatic COVD-19. Study 3 (Paediatric Prevention Study) Open-label, single-arm trial to evaluate the safety, and pharmacokinetics of adintrevimab for the prevention of SARS CoV-2 infection, including symptomatic COVID-19, in children. Study 4 (ADG20-TRMT-001, STAMP) Randomised, double-blind, placebo-controlled study to evaluate the efficacy and safety of adintrevimab compared with placebo in the treatment of ambulatory adolescents (and adults) with mild to moderate COVID-19. Study 5 (Paediatric Treatment Study) Open-label, single-arm study to evaluate of the safety and pharmacokinetics of adintrevimab for the treatment

		of children with mild or moderate COVID-19 who are at high risk of disease progression.
Extrapolation, Modeling & Simulation Studies	2	Study 6 Population PK model for adintrevimab dose prediction and confirmation in the prevention and treatment of COVID-19 in children from birth to less than 12 years of age. Study 7 PK bridging and extrapolation of safety and efficacy to support the use of a single dose of adintrevimab administered via the intramuscular route for treatment and prevention of COVID-19 from adults to paediatric patients from birth 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:	31/12/2026
Deferral of one or more studies contained in the paediatric investigation plan:	Yes