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

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan and to the deferral

MHRA-100490-PIP01-22-M01

Scope of the Application

Active Substance(s)

nirsevimab (MEDI8897)

Condition(s)

Prevention of lower respiratory tract infection caused by respiratory syncytial virus (RSV).

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

Intramuscular use

Name / Corporate name of the PIP applicant

AstraZeneca UK Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, AstraZeneca UK Limited submitted to the licensing authority on 30/03/2022 14:10 BST an application for a Modification

The procedure started on 04/07/2022 13:41 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 accept change(s) to the agreed paediatric investigation plan and to the 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-100490-PIP01-22-M01

Of 11/07/2022 17:10 BST

On the adopted decision for nirsevimab (MEDI8897) (MHRA-100490-PIP01-22-M01) 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 modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for nirsevimab (MEDI8897), Solution for injection , PARENTERAL .

This decision is addressed to AstraZeneca UK Limited, 600 Capability Green, Luton, UNITED KINGDOM, LU1 3LU

ANNEX I

1. Waiver

1.1 Condition:

Prevention of lower respiratory tract infection caused by respiratory syncytial virus (RSV). The waiver applies / applied to: Paediatric Subset(s): The paediatric population from 2 years to less than18 years of age Pharmaceutical form(s): Solution for injection Route(s) of administration: Intramuscular use Reason for granting waiver: on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of lower respiratory tract infection caused by respiratory syncytial virus (RSV).

2.2 Indication(s) targeted by the PIP:

Prevention of lower respiratory tract infection caused by respiratory syncytial virus (RSV) in all infants entering their first RSV season and children with Chronic Lung Disease or Congenital Heart Disease entering their first and second RSV season

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

The paediatric population from birth to less than 2 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	4	Study 1 (D5290C00002) Randomised, double-blind, placebo-controlled, single ascending dose study to evaluate safety and pharmacokinetic (PK) of MEDI8897 in preterm infants less than or equal to 35 weeks gestation and less than 12 months of chronological age, not eligible for palivizumab prophylaxis. Study 2 (D5290C00003) Randomised, double-blind, placebo-controlled, single-dose efficacy and safety study in healthy preterm infants less than or equal to 35 weeks gestation and less than or equal to 8 months of chronological age, not eligible for palivizumab prophylaxis. Study 3 (D5290C00004) Randomised, double-blind, placebo controlled, single-dose efficacy and safety study in healthy infants of greater than 35 weeks gestational age and less than or equal to 8 months of chronological age, including infants with a chronic underlying illness who are healthy at the time of enrolment. (MELODY) Study 4 (D5290C00005) Double-blind, palivizumab controlled, safety and PK bridging study with collection of efficacy data for trend toward

		efficacy in preterm infants who are eligible to receive palivizumab in their first RSV season or infants with chronic lung disease (CLD) or congenital heart disease (CHD) less than 2 years of age in their first and second RSV season. (MEDLEY)
Extrapolation, Modeling & Simulation Studies	2	Study 5 Modelling and simulation study to optimise appropriate intramuscular dose regimens that will result in a protective concentration against RSV during the dose interval and the remaining of the RSV season in infants and children less than or equal to 24 months of age at the start of the RSV season. Study 6 Extrapolation study to assess whether the efficacy of MEDI8897 from study 2 in preterm infants and from study 3 in term infants entering their first RSV season applies to the palivizumab eligible population.
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:	Yes
Date of completion of the paediatric investigation plan:	30/09/2023
Deferral of one or more studies contained in the paediatric investigation plan:	Yes