MHRA
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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-101177-PIP01-23

Scope of the Application

Active Substance(s)

Recombinant humanized IgG1, kappa light chain, long-acting monoclonal antibody ; (navenibart; STAR-0215)

Condition(s)

Treatment of hereditary angioedema

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

Astria Therapeutics, Inc.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Astria Therapeutics, Inc. submitted to the licensing authority on 11/09/2023 10:14 BST an application for a Paediatric Investigation Plan

The procedure started on 04/12/2023 09:16 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-101177-PIP01-23

Of 08/10/2024 07:05 BST

On the adopted decision for Recombinant humanized IgG1, kappa light chain, long-acting monoclonal antibody ; (navenibart; STAR-0215) (MHRA-101177-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 Recombinant humanized IgG1, kappa light chain, long-acting monoclonal antibody ; (navenibart; STAR-0215), Solution for injection , SUBCUTANEOUS USE .

This decision is addressed to Astria Therapeutics, Inc., 75 State Street, Suite 1400, Boston, UNITED STATES OF AMERICA, MA 02109

ANNEX I

1. Waiver

1.1 Condition:

Treatment of hereditary angioedema 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.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of hereditary angioedema

2.2 Indication(s) targeted by the PIP:

Routine prevention of recurrent attacks of hereditary angioedema in paediatric patients 2 years of age and older

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):

Solution for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 (STAR-0215-PIP Quality) Development of a lower strength of solution for injection appropriate for the paediatric population from 2 years to less than 12 years of age.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	2	Study 2 (STAR-0215-301) Randomised, double-blind, placebo-controlled trial to evaluate efficacy, safety and pharmacokinetics (PK) of recombinant humanized IgG1, kappa light chain, long-acting monoclonal antibody (STAR-0215) for prevention of angioedema attacks in adolescents from 12 years to less than 18 years of age (and adults) with hereditary angioedema. Study 3 (STAR-0215-303) Open-label trial to evaluate the safety, pharmacokinetics, pharmacodynamics and clinical activity of recombinant humanized IgG1, kappa light chain, long-acting monoclonal antibody (STAR-0215) in children from 2 years to less than 12 years of age with hereditary angioedema.
Extrapolation, Modeling & Simulation Studies	2	Study 4 (STAR-0215-PIP M&S-1) Population PK (popPK) model to inform dose selection and support

		extrapolation of efficacy to the target paediatric population. Study 5 (STAR-0215-PIP Extrapolation-1) Analysis of in-house data to support the use of STAR-0215 in the paediatric population from 2 years to less than 18 years of age with hereditary angioedema.
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:	31/12/2032
Deferral of one or more studies contained in the paediatric investigation plan:	Yes