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-101093-PIP01-23-M01

Scope of the Application

Active Substance(s)

Enspryng; SATRALIZUMAB

Condition(s)

Treatment of neuromyelitis optica.

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

Roche Products Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Roche Products Limited submitted to the licensing authority on 01/12/2023 14:54 GMT an application for a Modification

The procedure started on 18/03/2024 08:57 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 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-101093-PIP01-23-M01

Of 04/04/2024 11:11 BST

On the adopted decision for SATRALIZUMAB (MHRA-101093-PIP01-23-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 SATRALIZUMAB, Solution for injection , SUBCUTANEOUS USE .

This decision is addressed to Roche Products Limited, 6 Falcon Way, Shire Park, Welwyn Garden City, UNITED KINGDOM, AL7 1TW

ANNEX I

1. Waiver

1.1 Condition:

Treatment of neuromyelitis optica 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 the specific medicinal product does not represent a significant therapeutic benefit as clinical studies are not feasible.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of neuromyelitis optica.

2.2 Indication(s) targeted by the PIP:

Treatment of neuromyelitis optica spectrum disorders.

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 Development of solution for injection for subcutaneous use appropriate for the paediatric population from 2 years of age.
Non-Clinical Studies	1	Study 2 Reprotox enhanced pre- and postnatal development study in cynomolgus monkeys.
Clinical Studies	3	Study 3 Double-blind, randomised, placebo-controlled trial to evaluate pharmacokinetics, safety and efficacy of satralizumab as add-on to baseline immunosuppressant therapy in children from 12 years to less than 18 years of age (and in adults) with relapsing neuromyelitis optica and neuromyelitis optica spectrum disorders (NMO/NMOSD). Study 7 Open-label, uncontrolled trial to evaluate pharmacokinetics, safety and efficacy of satralizumab in adolescents from 12 years to less than 18 years of age (and adults) with neuromyelitis optica spectrum disorders (NMOSD). Study 4 Open-label, uncontrolled trial to evaluate pharmacokinetics, activity and safety of satralizumab in children from 2 years to less than 12 years of age with positive AQP4 IgG serostatus neuromyelitis optica spectrum disorders (NMOSD).

Extrapolation, Modeling & Simulation Studies	3	Study 5 Modelling and simulation study to evaluate the dose of satralizumab in the treatment of relapsing NMO/NMOSD in children from 2 years to less than 12 years of age. Study 8 Analysis of existing data on efficacy, safety and pharmacokinetics of satralizumab to evaluate the use of the product in the treatment of relapsing NMO/ NMOSD in children from 12 years to less than 18 years of age. Study 6 Analysis of existing data on efficacy, safety and pharmacokinetics of satralizumab to evaluate the use of the product in the treatment of NMOSD in children from 2 years to less than 12 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:	Yes
Date of completion of the paediatric investigation plan:	30/11/2027
Deferral of one or more studies contained in the paediatric investigation plan:	Yes