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-100123-PIP01-21-M01

Scope of the Application

Active Substance(s)

SARILUMAB

Condition(s)

Treatment of chronic idiopathic arthritis

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

Subcutaneous use

Name / Corporate name of the PIP applicant

sanofi-aventis recherche et développement

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, sanofi-aventis recherche et développement submitted to the licensing authority on 26/05/2021 23:21 BST an application for a Modification

The procedure started on 22/04/2022 07:40 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-100123-PIP01-21-M01

Of 10/05/2022 15:08 BST

On the adopted decision for SARILUMAB (MHRA-100123-PIP01-21-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 SARILUMAB, Solution for injection , Subcutaneous use .

This decision is addressed to sanofi-aventis recherche et développement, 1, avenue Pierre Brossolette , Chilly-Mazarin, France, 91385

ANNEX I

1. Waiver

1.1 Condition:

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, spondylarthritis, psoriatic arthritis and juvenile idiopathic arthritis) The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 1 year of age Pharmaceutical form(s): Solution for injection Route(s) of administration: Subcutaneous use Reason for granting waiver: on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, spondylarthritis, psoriatic arthritis and juvenile idiopathic arthritis)

2.2 Indication(s) targeted by the PIP:

Treatment of juvenile idiopathic arthritis

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

The paediatric population from 1 year 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 age/weight appropriate strength and presentation for subcutaneous use for paediatric population.
Non-Clinical Studies	0	Not applicable
Clinical Studies	2	Study 2 Open-label, two part trial including a 12-week ascending repeated dose-finding core phase and an extension phase to evaluate the pharmacokinetics and safety of sarilumab in children from 2 to less than 18 years of age with polyarticular course juvenile idiopathic arthritis (pJIA). Study 3 Deleted during procedure EMEA-001045-PIP01-10-M01 Study 4 Open-label, two part trial including a 12-week ascending repeated dose-finding study and a 144 week extension study to evaluate the pharmacokinetics and safety of sarilumab in children from 1 to less than 18 years of age with systemic juvenile idiopathic arthritis (sJIA). Study 5 Deleted during procedure EMEA-001045-PIP01-10-M01
Extrapolation, Modeling & Simulation Studies	2	Study 6 Extrapolation study to evaluate the use of sarilumab in children from 2 years to less than 18 years of age with polyarticular course juvenile idiopathic arthritis (pJIA). Study 7 Extrapolation study to evaluate the use of sarilumab in children from 1 year to less than 18

		years of age with systemic juvenile idiopathic arthritis (sJIA).
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:	30/04/2027
Deferral of one or more studies contained in the paediatric investigation plan:	Yes