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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-100218-PIP01-21

Scope of the Application

Active Substance(s)

DUPILUMAB

Condition(s)

Treatment of chronic spontaneous urticaria

Pharmaceutical Form(s)

Solution for injection in a pre-filled syringe

Route(s) of Administration

Subcutaneous use

Name / Corporate name of the PIP applicant

sanofi-aventis recherche & développement

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, sanofi-aventis recherche & développement submitted to the licensing authority on 04/10/2021 00:25 BST an application for a Paediatric Investigation Plan

The procedure started on 29/07/2022 14:48 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 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.

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

gov.uk/mhra

Final Decision Letter

MHRA-100218-PIP01-21

Of 12/08/2022 12:06 BST

On the adopted decision for DUPILUMAB (MHRA-100218-PIP01-21) 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 DUPILUMAB, Solution for injection in a pre-filled syringe , Subcutaneous use .

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

ANNEX I

1. Waiver

1.1 Condition:

Treatment of chronic spontaneous urticaria 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 in a pre-filled syringe Route(s) of administration: Subcutaneous 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):

Treatment of chronic spontaneous urticaria

2.2 Indication(s) targeted by the PIP:

Treatment of chronic spontaneous urticaria (CSU) in patients whose disease in not adequately controlled with H1-antihistamine and anti-IgE antibody treatment

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 in a pre-filled syringe

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable
Non-Clinical Studies	0	Not applicable
Clinical Studies	2	Study 1 (EFC16461) Double-blind, randomised, placebo- controlled, parallel-group trial to evaluate the safety and efficacy of dupilumab in adolescents from 12 years to less than 18 years of age (and adults) with chronic spontaneous urticaria (CSU) who remain symptomatic despite use of H1-antihistamine (Study A) or who remain symptomatic despite use of H1-antihistamine and anti-IgE antibody treatment (Study B). Study 2 Open label, uncontrolled trial to evaluate the pharmacokinetics, safety and activity of dupilumab in children from 2 years to less than 12 years of age with chronic spontaneous urticaria (CSU) who remain symptomatic despite use of H1-antihistamine.
Extrapolation, Modeling & Simulation Studies	1	Study 3 Extrapolation study to evaluate the use of dupilumab in the treatment of chronic spontaneous urticaria (CSU) 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:	30/06/2026
Deferral of one or more studies contained in the paediatric investigation plan:	Yes