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-101091-PIP01-23

Scope of the Application

Active Substance(s)

Borrelia outer surface protein A (OspA) serotypes (ST1-6) lipidated, fusion protein vaccine (VLA15 - PF-07307405)

Condition(s)

Prevention of Lyme disease

Pharmaceutical Form(s)

Suspension for injection in pre-filled syringe

Route(s) of Administration

INTRAMUSCULAR USE

Name / Corporate name of the PIP applicant

Pfizer Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Pfizer Limited submitted to the licensing authority on 14/07/2023 09:14 BST an application for a Paediatric Investigation Plan

The procedure started on 09/11/2023 16:50 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.

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

gov.uk/mhra

Final Decision Letter

MHRA-101091-PIP01-23

Of 18/12/2024 08:49 GMT

On the adopted decision for Borrelia outer surface protein A (OspA) serotypes (ST1-6) lipidated, fusion protein vaccine (VLA15 - PF-07307405) (MHRA-101091-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 Borrelia outer surface protein A (OspA) serotypes (ST1-6) lipidated, fusion protein vaccine (VLA15 - PF-07307405), Suspension for injection in pre-filled syringe , INTRAMUSCULAR USE .

This decision is addressed to Pfizer Limited, Ramsgate Road, Sandwich, Kent, UNITED KINGDOM, CT13 9NJ

ANNEX I

1. Waiver

1.1 Condition:

Prevention of Lyme disease The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 1 year of age Pharmaceutical form(s): Suspension for injection in pre-filled syringe Route(s) of administration: INTRAMUSCULAR 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):

Prevention of Lyme disease

2.2 Indication(s) targeted by the PIP:

Active immunisation for the prevention of Lyme disease caused by Borrelia species

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):

Suspension for injection in 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	4	Study 1 (C4601009) Randomised, placebo-controlled, observer-blind trial to evaluate safety, tolerability, and immunogenicity of a 6-valent OspA-based Lyme disease vaccine (VLA15) in healthy children from 1 year to less than 5 years of age. Study 2 (C4601003) Multicentre, placebo-controlled, randomised, observer-blind trial to evaluate the safety, efficacy, immunogenicity, and lot consistency of a 6-valent OspA-based Lyme disease vaccine (VLA15) in healthy participants from 5 years to less than 18 years of age (and adults). Study 3 (C4601012) Randomised, placebo-controlled, observer-blind trial to evaluate the safety of a 6-valent OspA-based Lyme disease vaccine (VLA15) in healthy children from 5 years to less than 18 years of age. Study 4 (VLA15-221) Randomised, observer-blind, placebo-controlled, multicentre trial to evaluate safety and immunogenicity of a 6-valent OspA-based Lyme disease vaccine (VLA15) in healthy children from

		5 years to less than 18 years of age (and adults).
Extrapolation, Modeling & Simulation Studies	0	Not applicable.
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:	30/04/2029
Deferral of one or more studies contained in the paediatric investigation plan:	Yes