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

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Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral

MHRA-101407-PIP01-24

Scope of the Application

Active Substance(s)

chikungunya virus virus-like particle

Condition(s)

Prevention of Chikungunya virus disease

Pharmaceutical Form(s)

Suspension for injection

Route(s) of Administration

INTRAMUSCULAR USE

Name / Corporate name of the PIP applicant

Bavarian Nordic A/S

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Bavarian Nordic A/S submitted to the licensing authority on 22/04/2024 22:45 BST an application for a Paediatric Investigation Plan

The procedure started on 04/06/2024 14:08 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

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-101407-PIP01-24

Of 02/09/2024 13:55 BST

On the adopted decision for chikungunya virus virus-like particle (MHRA-101407-PIP01-24) 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 chikungunya virus virus-like particle, Suspension for injection , INTRAMUSCULAR USE .

This decision is addressed to Bavarian Nordic A/S, Philip Heymans Alle 3, Hellerup, DENMARK, 2900

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of Chikungunya virus disease

2.2 Indication(s) targeted by the PIP:

Prevention of Chikungunya virus disease

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

All subsets of the paediatric population from birth to less than 18 years of age

2.4 Pharmaceutical Form(s):

Suspension for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	5	Study 1 (EBSI-CV-317-004) Randomised, placebo-controlled, double-blind safety and immunogenicity study of Chikungunya Virus Virus-Like Particle Vaccine/ aluminium hydroxide (PXVX0317) in adolescents from 12 years to less than 18 years of age (and adults). Study 2 (EBSI-CV-317-006) Randomised, double-blind, placebo-controlled, safety and immunologic non-inferiority study of PXVX0317 in children from 2 years to less than 12 years of age. Study 3 (EBSI-CV-317-009) Randomised, active comparator-controlled, open label safety and immunogenicity study of PXVX0317 in children from birth to less than 2 years of age. Study 4 (EBSI-CV-317-008) Randomised, double-blind, long-term immunogenicity study in adolescents from 12 years to less than 18 years of age (and adults) who were previously administered PXVX0317 vaccine in study EBSI-CV-317-004. Study 5 (EBSI-CV-317-007) Double blind, randomised, placebo-controlled, event-driven efficacy study to evaluate the efficacy, safety, and immunogenicity of an Adjuvanted Chikungunya Virus Virus-like Particle Vaccine (PXVX0317) for the prevention of Chikungunya Disease in adolescents from 12 years to less

		than 18 years of age (and adults). Vaccination will be performed only during a Chikungunya virus (CHIKV) outbreak.
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:	30/09/2030
Deferral of one or more studies contained in the paediatric investigation plan:	Yes