MHRA
10 South Colonnade
Canary Wharf
London
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United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

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

MHRA-101379-PIP01-24

Scope of the Application

Active Substance(s)

Broadly neutralizing anti-HIV human monoclonal antibody (VH3810109)

Condition(s)

Treatment of Human Immunodeficiency Virus (HIV-1) Infection

Pharmaceutical Form(s)

Solution for injection/infusion

Route(s) of Administration

SUBCUTANEOUS USE; INTRAVENOUS USE

Name / Corporate name of the PIP applicant

GlaxoSmithKline UK Ltd (on behalf of ViiV Healthcare UK Limited)

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, GlaxoSmithKline UK Ltd (on behalf of ViiV Healthcare UK Limited) submitted to the licensing authority on 07/03/2024 16:57 GMT an application for a Paediatric Investigation Plan

The procedure started on 27/03/2024 17:04 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.

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Final Decision Letter

MHRA-101379-PIP01-24

Of 15/07/2024 10:23 BST

On the adopted decision for Broadly neutralizing anti-HIV human monoclonal antibody (VH3810109) (MHRA-101379-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 Broadly neutralizing anti-HIV human monoclonal antibody (VH3810109), Solution for injection/infusion , SUBCUTANEOUS USE; INTRAVENOUS USE .

This decision is addressed to GlaxoSmithKline UK Ltd (on behalf of ViiV Healthcare UK Limited), 980 Great West Road , Brentford , UNITED KINGDOM, TW8 9GS

ANNEX I

1. Waiver

1.1 Condition:

Treatment of Human Immunodeficiency Virus (HIV-1) Infection 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/infusion Route(s) of administration: SUBCUTANEOUS USE INTRAVENOUS USE Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of Human Immunodeficiency Virus (HIV-1) Infection

2.2 Indication(s) targeted by the PIP:

For the treatment of HIV-1-infected children and adolescents from 2 years to less than 18 years of age to replace the current ARV regimen in those who are virologically suppressed (HIV-1 RNA 50 copies/mL) on a stable antiretroviral regimen, given with cabotegravir (as a separate injection given at the same visit).

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/infusion

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 Open-label, multiple-cohort study to evaluate VH3810109, administered IV or SC, in combination with cabotegravir (CAB) (as a separate injection given at the same visit) in HIV-1-infected (HIV-1 RNA <50 copies/ mL) paediatric patients from 12 years to less than 18 years of age (and adults) on an existing suppressive anti-retroviral therapy (ART). Study 2 Open-label, single arm study to evaluate VH3810109 in combination with cabotegravir (CAB) (as a separate injection given at the same visit) in HIV-1-infected (HIV-1 RNA <50 copies/mL) paediatric patients from 2 years to less than 12 years of age on an existing suppressive anti-retroviral therapy (ART).
Extrapolation, Modeling & Simulation Studies	2	Study 3 Population PK model to identify doses providing exposures of VH3810109 in paediatric patients from 2 years to less than 18 years of age that match the exposures that have been confirmed to be safe and

		efficacious in the adult programme and to support extrapolation of efficacy. Extrapolation Plan Studies 1, 2 and 3 are part of the extrapolation plan of efficacy data from adults to the paediatric population from 2 years to less than 18 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:	No
Date of completion of the paediatric investigation plan:	31/12/2030
Deferral of one or more studies contained in the paediatric investigation plan:	Yes