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 (EMEA-002535-PIP03-19) and to the deferral

MHRA-101596-PIP01-24-M01

Scope of the Application

Active Substance(s)

Ibrexafungerp

Condition(s)

Treatment of vulvovaginal candidiasis , Prevention of recurrent vulvovaginal candidiasis

Pharmaceutical Form(s)

Tablet

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

SCYNEXIS, Inc.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, SCYNEXIS, Inc. submitted to the licensing authority on 15/08/2024 09:56 BST an application for a Modification

The procedure started on 16/09/2024 09:26 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-101596-PIP01-24-M01

Of 04/11/2024 12:36 GMT

On the adopted decision for Ibrexafungerp (MHRA-101596-PIP01-24-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 Ibrexafungerp, Tablet , ORAL USE .

This decision is addressed to SCYNEXIS, Inc., 1 Evertrust Plaza, Jersey City, UNITED STATES OF AMERICA, 07302

ANNEX I

1. Waiver

1.1 Condition:

Condition 1: Treatment of vulvovaginal candidiasis The waiver applies / applied to: Paediatric Subset(s): Boys from birth to less than 18 years of age Pre-menarche girls Pharmaceutical form(s): Tablet Route(s) of administration: ORAL USE Reason for granting waiver: For boys from birth to less than 18 years of age: - 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). For pre-menarche girls: - on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments. Reason for Refusing Waiver: Not Applicable Condition 2: Prevention of recurrent vulvovaginal candidiasis The waiver applies / applied to: Paediatric Subset(s): Boys from birth to less than 18 years of age Pre-menarche girls Pharmaceutical form(s): Tablet Route(s) of administration: ORAL USE Reason for granting waiver: For boys from birth to less than 18 years of age: - 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). For pre-menarche girls: - 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):

Condition 1: Treatment of vulvovaginal candidiasis Condition 2: Prevention of recurrent vulvovaginal candidiasis

2.2 Indication(s) targeted by the PIP:

Condition 1: Treatment of vulvovaginal candidiasis Condition 2: Prevention of recurrent vulvovaginal candidiasis

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

For both Conditions: Girls from menarche to less than 18 years of age

2.4 Pharmaceutical Form(s):

For both Conditions: Tablet

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	(Same study for both conditions) Study 1 (SCY-078-120) Open-label study to evaluate pharmacokinetics, safety and tolerability of oral doses of ibrexafungerp in post-menarche girls with vaginitis.
Extrapolation, Modeling & Simulation Studies	1	(Same study for both conditions) Study 2 Population pharmacokinetics (PK) model to demonstrate similar PK in adults and adolescents.
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:	31/12/2021

Deferral of one or more studies contained in the paediatric investigation plan:	Yes