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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan (MHRA-100670-PIP01-22) and to the deferral

MHRA-100670-PIP01-22-M01

Scope of the Application

Active Substance(s)

ibrexafungerp citrate

Condition(s)

Treatment of invasive candidiasis

Pharmaceutical Form(s)

Tablet, Powder for solution for injection/infusion, Powder for oral suspension

Route(s) of Administration

ORAL USE; INTRAVENOUS 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 24/06/2024 08:52 BST an application for a Modification

The procedure started on 03/09/2024 08:29 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-100670-PIP01-22-M01

Of 16/09/2024 17:28 BST

On the adopted decision for ibrexafungerp citrate (MHRA-100670-PIP01-22-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 citrate, Tablet, Powder for solution for injection/infusion, Powder for oral suspension , ORAL USE; INTRAVENOUS 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:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of invasive candidiasis

2.2 Indication(s) targeted by the PIP:

Treatment of invasive candidiasis

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

The paediatric population from birth to less than 18 years of age

2.4 Pharmaceutical Form(s):

Tablet Powder for solution for injection / infusion Powder for oral suspension

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age-appropriate formulation to be used in children from birth to less than 12 years of age.
Non-Clinical Studies	2	Study 2 Dose range-finding juvenile toxicity study. Study 3 Definitive juvenile toxicity study.
Clinical Studies	2	Study 4 (SCY-078-209) Open-label, uncontrolled study to evaluate the pharmacokinetics, safety and tolerability of oral ibrexafungerp as antifungal prophylaxis in children and adolescents from 2 years to less than 18 years of age with haematological malignancies and neutropenia. Study 5 (SCY-078-210) Open-label, uncontrolled study to evaluate the pharmacokinetics, safety and tolerability of oral ibrexafungerp as antifungal prophylaxis in immunocompromised neonates and children.
Extrapolation, Modeling & Simulation Studies	1	Study 6 Population pharmacokinetic (PK) model to compare PK in adults and children 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:	31/10/2033

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