EMA/421548/2024

# European Medicines Agency decision

P/0347/2024

of 13 September 2024

on the acceptance of a modification of an agreed paediatric investigation plan for ibrexafungerp (citrate) (EMEA-002535-PIP04-21-M02) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

**Disclaimer**

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

**Only the English text is authentic.**

# European Medicines Agency decision

P/0347/2024

of 13 September 2024

on the acceptance of a modification of an agreed paediatric investigation plan for ibrexafungerp (citrate) (EMEA-002535-PIP04-21-M02) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0370/2022 issued on 9 September 2022,

Having regard to the application submitted by SCYNEXIS, Inc. on 22 May 2024 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 6 September 2024, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan and to the deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

[1] OJ L 378, 27.12.2006, p.1, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

***Article 1***

Changes to the agreed paediatric investigation plan for ibrexafungerp (citrate), tablet, powder for solution for injection or infusion, powder for oral solution, oral use, intravenous use , including changes to the deferral, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

***Article 2***

This decision is addressed to SCYNEXIS, Inc., 1 Evertrust Plaza, NJ07302 - Jersey City, United States.

EMA/PDCO/279439/2024
Amsterdam, 6 September 2024

# Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-002535-PIP04-21-M02

## Scope of the application

**Active substance(s):**

Ibrexafungerp (citrate)

**Invented name and authorisation status:**

See Annex II

**Condition(s):**

Treatment of invasive candidiasis

**Pharmaceutical form(s):**

Tablet

Powder for solution for injection or infusion

Powder for oral solution

**Route(s) of administration:**

Oral use

Intravenous use

**Name/corporate name of the PIP applicant:**

SCYNEXIS, Inc.

## Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, SCYNEXIS, Inc. submitted to the European Medicines Agency on 22 May 2024 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0370/2022 issued on 9 September 2022.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral.

The procedure started on 8 July 2024.

## Scope of the modification

Some timelines of the Paediatric Investigation Plan have been modified.

## Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan and to the deferral in the scope set out in the Annex I of this opinion.

   The Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

# Annex I

# The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

# 1. Waiver

Not applicable.

# 2. Paediatric investigation plan

## *2.1. Condition:*

Treatment of invasive candidiasis

### 2.1.1. Indication(s) targeted by the PIP

Treatment of invasive candidiasis

### 2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From birth to less than 18 years of age.

### 2.1.3. Pharmaceutical form(s)

Tablet

Powder for solution for injection or infusion

Powder for oral suspension

### 2.1.4. Measures

| Area | Description |
|---|---|
| Quality-related studies | **Study 1**<br><br>Development of an age-appropriate formulation for oral use suitable for children from birth to less than 12 years of age. |
| Non-clinical studies | **Study 2**<br><br>Dose range-finding juvenile toxicity study.<br><br>**Study 3**<br><br>Definitive juvenile toxicity study. |
| Clinical studies | **Study 4 (SCY-078-209)**<br><br>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.<br><br>**Study 5 (SCY-078-210)**<br><br>Open-label, uncontrolled study to evaluate the pharmacokinetics, safety and tolerability of oral ibrexafungerp as antifungal prophylaxis |

| | |
|---|---|
| | in immunocompromised neonates and children from birth to less than 2 years of age. |
| Extrapolation, modelling and simulation studies | **Study 6**<br><br>Population pharmacokinetic (PK) model to compare PK in adults and children and adolescents. |
| Other studies | Not applicable. |
| Other measures | Not applicable. |

# 3. Follow-up, completion and deferral of PIP

| | |
|---|---|
| Concerns on potential long term safety/efficacy issues in relation to paediatric use: | No |
| Date of completion of the paediatric investigation plan: | By October 2033 |
| Deferral for one or more measures contained in the paediatric investigation plan: | Yes |

# Annex II

# Information about the authorised medicinal product

***Information provided by the applicant:***

**The product is not authorised anywhere in the European Community.**