EMADOC-1700519818-1723829

European Medicines Agency decision

EMA/PE/0000225106

of 25 October 2024

on the acceptance of a modification of an agreed paediatric investigation plan for ibrexafungerp (EMA/PE/0000225106) 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.

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on the acceptance of a modification of an agreed paediatric investigation plan for ibrexafungerp (EMA/PE/0000225106) 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/0164/2020 issued on 17 April 2020 and the decision P/0240/2024 issued on 19 July 2024,

Having regard to the application submitted by Scynexis, Inc. on 12 August 2024 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 18 October 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.

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

[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 EMA/PE/0000225106, tablet, oral use, 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., One Evertrust Plaza, 07302- Jersey City, United States.

EMADOC-1700519818-1662140
Amsterdam, 18 October 2024

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

EMA/PE/0000225106

Scope of the application

Active substance(s):

Ibrexafungerp

Invented name and authorisation status:

See Annex II

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 opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Scynexis, Inc. submitted to the European Medicines Agency on 12 August 2024 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/0164/2020 issued on 17 April 2020 and the decision P/0240/2024 issued on 19 July 2024.

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

The procedure started on 16 September 2024.

Scope of the modification

Some measures and 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 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 and the subset(s) of the paediatric population and condition(s) covered by the waiver 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

1.1. Condition:

Treatment of vulvovaginal candidiasis

The waiver applies to:

- boys from birth to less than 18 years of age;
- tablet, oral use;
- 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);

and to:

- pre-menarche girls;
- tablet, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

1.2. Condition:

Prevention of recurrent vulvovaginal candidiasis

The waiver applies to:

- boys from birth to less than 18 years of age;
- tablet, oral use;
- 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);

and to:

- pre-menarche girls;
- tablet, oral use;
- 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:

Treatment of vulvovaginal candidiasis

2.1.1. Indication(s) targeted by the PIP

Treatment of vulvovaginal candidiasis

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

Girls from menarche to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Tablet

2.1.4. Measures

Area	Description
Quality-related studies	Not applicable.
Non-clinical studies	Not applicable.
Clinical studies	**Study 1:** Open-label study to evaluate pharmacokinetics, safety and tolerability of oral doses of ibrexafungerp in post-menarche girls with vaginitis.
Extrapolation, modelling and simulation studies	**Study 2:** Population pharmacokinetics (PK) model to demonstrate similar PK in adults and adolescents.
Other studies	Not applicable.
Other measures	Not applicable.

2.2. Condition:

Prevention of recurrent vulvovaginal candidiasis

2.2.1. Indication(s) targeted by the PIP

Prevention of recurrent vulvovaginal candidiasis

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

Girls from menarche to less than 18 years of age

2.2.3. Pharmaceutical form(s)

Tablet

2.2.4. Measures

Area	Description
Quality-related studies	Not applicable.
Non-clinical studies	Not applicable.
Clinical studies	**Study 1:** Open-label study to evaluate pharmacokinetics, safety and tolerability of oral doses of ibrexafungerp in post-menarche girls with vaginitis. *[Same study as Study 1 for condition "treatment of vulvovaginal candidiasis"]*
Extrapolation, modelling and simulation studies	**Study 2:** Population pharmacokinetics (PK) model to demonstrate similar PK in adults and adolescents. *[Same study as Study 2 for condition "treatment of vulvovaginal candidiasis"]*
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 December 2021
Deferral for one or more measures contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.