EMADOC-1700519818-2035407

European Medicines Agency decision

EMA/PE/0000237724

of 14 April 2025

on the acceptance of a modification of an agreed paediatric investigation plan for pimicotinib hydrochloride hydrate 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 pimicotinib hydrochloride hydrate 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/0373/2024 issued on 25 October 2024,

Having regard to the application submitted by Abbisko Therapeutics Co. Ltd. on 18 November 2024 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 28 February 2025, 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 pimicotinib hydrochloride hydrate, 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 Abbisko Therapeutics Co. Ltd., No 3 898 Lane Halei Road, Trade Zone, China, Pilot Free, 201203 - Shanghai, China.

EMADOC-1700519818-1808151
Amsterdam, 28 February 2025

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

EMA/PE/0000237724

Scope of the application

Active substance(s):

Pimicotinib hydrochloride hydrate

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of tenosynovial giant cell tumours

Pharmaceutical form(s):

Capsule, hard

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Abbisko Therapeutics Co. Ltd.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Abbisko Therapeutics Co. Ltd. submitted to the European Medicines Agency on 18 November 2024 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0373/2024 issued on 25 October 2024.

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

The procedure started on 2 January 2025.

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 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 tenosynovial giant cell tumours

The waiver applies to:

- the paediatric population from birth to less than 12 years of age;
- capsule, hard, oral use;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric investigation plan

2.1. Condition:

Treatment of tenosynovial giant cell tumours

2.1.1. Indication(s) targeted by the PIP

Treatment of tenosynovial giant cell tumours not amenable to surgery

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

From 12 years to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Capsule, hard

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1** Generation of data on the compatibility of mixing the content of the hard capsules of ABSK021-101 in common food and liquid.
Non-clinical studies	Not applicable.
Clinical studies	**Study 2** Open-label multicentre study to assess the safety, pharmacokinetics and antitumor activity of ABSK021 and to provide PK/pharmacodynamic data to support the extrapolation of efficacy from adults to adolescents from 12 to less than 18 years of age with tenosynovial giant cell tumour not amenable to surgery.

Modelling and simulation analyses	**Study 3** Modelling and simulation study to confirm and further define the dose and regimen of ABSK021 to be used in adolescents from 12 years to less than 18 years of age with tenosynovial giant cell tumour and to support the extrapolation of efficacy from adults with tenosynovial giant cell tumour.
Other studies	Not applicable.
Extrapolation plan	Study 2 (ABSK021-101) and study 3 are part of an extrapolation plan covering the paediatric population from 12 years to less than 18 years of age as agreed by the PDCO.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By August 2027
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.