EMADOC-1700519818-1810197

European Medicines Agency decision

EMA/PE/0000223498

of 3 January 2025

on the acceptance of a modification of an agreed paediatric investigation plan for infigratinib 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 infigratinib 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/0331/2021 issued on 13 August 2021,

Having regard to the application submitted by QED Therapeutics Inc. on 8 August 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 15 November 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 infigratinib 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 QED Therapeutics Inc., 1800 Owens Street Ste C1200, San Francisco, CA, 94158-2584, United States.

EMADOC-1700519818-1666201 Corr[1]
Amsterdam, 15 November 2024

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

EMA/PE/0000223498

Scope of the application

Active substance(s):

Infigratinib

Condition(s):

Treatment of achondroplasia

Pharmaceutical form(s):

Tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

QED Therapeutics Inc.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, QED Therapeutics Inc. submitted to the European Medicines Agency on 8 August 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/0331/2021 issued on 13 August 2021.

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.

[1] Correction 2 December 2024

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 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)

Waiver

Not applicable

1. Paediatric investigation plan

1.1. Condition:

Treatment of achondroplasia

1.1.1. Indication(s) targeted by the PIP

Treatment of achondroplasia

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

From birth to less than 18 years of age

1.1.3. Pharmaceutical form(s)

Tablet

1.1.4. Measures

Area	Description
Quality-related studies	**Study 1** Development of an age appropriate formulation for patients from birth
Non-clinical studies	Not applicable
Clinical studies	**Study 2 (Propel (QBGJ398-001))** Observational study to evaluate the natural history of children with achondroplasia (ACH) from birth to less than 18 years of age **Study 3 (Propel 2 (QBGJ398-201))** Open-label, dose finding trial to evaluate pharmacokinetics, safety and activity of infigratinibin children from 3 years to less than 12 years of age with achondroplasia **Study 4 (PROPEL 3 (QBGJ398-303))** Double-blind, randomised, placebo controlled trial to evaluate safety, efficacy and acceptability/palatability of infigratinib in children from 3 to less than 18 years of age with achondroplasia in terms of superiority of infigratinib over placebo

	Study 5 Open-label, long term extension study to provide long term safety and efficacy of infigratinib in patients with achondroplasia who previously participated in PIP studies 2, 3, 4 or 6 **Study 6** Two part trial, consisting of an open label dose finding part to evaluate pharmacokinetics, safety and activity, followed by a double blind, randomised, placebo controlled part to evaluate safety, acceptability/palatability and efficacy in terms of superiority of infigratinib over placebo in children from birth to less than 3 years of age with achondroplasia
Extrapolation, modelling and simulation studies	**Study 7 (QED/1/B)** Modelling and simulation study to support dose finding of the product in the treatment of achondroplasia in children from birth to less than 3 years of age **Study 8** Modelling and simulation study to evaluate the use of the product in children from 3 years to less than 18 years of age with achondroplasia
Other studies	Not applicable
Other measures	Not applicable

2. 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 February 2036
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.