



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMADOC-1700519818-1808237

European Medicines Agency decision

EMA/PE/0000225746

of 3 January 2025

on the acceptance of a modification of an agreed paediatric investigation plan for atogepant (Aquipta) 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 atogepant (Aquipta) 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 726/2004¹,

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 Agency²,

Having regard to the European Medicines Agency's decision P/0046/2020 issued on 29 January 2020,

Having regard to the application submitted by Abbvie Limited on 13 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 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 atogepant (Aquipta), 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 Abbvie Limited, Abbvie House, SL6 4UB - Maidenhead, United Kingdom.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMADOC-1700519818-1668647
Amsterdam, 15 November 2024

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA/PE/0000225746

Scope of the application

Active substance(s):

Atogepant

Invented name and authorisation status:

See Annex II

Condition(s):

Prevention of migraine headaches

Pharmaceutical form(s):

Tablet

Age appropriate oral solid formulation

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Abbvie Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Abbvie Limited submitted to the European Medicines Agency on 13 August 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/0046/2020 issued on 29 January 2020.

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

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 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 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:

Prevention of migraine headaches.

The waiver applies to:

- the paediatric population from birth to less than 6 years of age;
- tablet, age appropriate oral solid formulation, 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:

Prevention of migraine headaches

2.1.1. Indication(s) targeted by the PIP

Prevention of migraine headaches

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

From 6 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Tablet

Age appropriate oral solid formulation

2.1.4. Measures

Area	Description
Quality-related studies	Study 1 Development of lower strength tablet/capsule appropriate to the paediatric population from 6 to less than 12 year of age and for those unable to swallow existing dose form to administer dose higher than 20mg.
Non-clinical studies	Study 2 Definitive juvenile toxicity study to determine the safety of atogepant in juvenile rats (3101-XXX-052).
Clinical studies	Study 3 Randomized, double-blind, placebo-controlled, parallel group study to assess PK, efficacy, safety and tolerability of atogepant as compared to

	<p>placebo for the preventive treatment of episodic migraine in paediatric patients from 6 to less than 18 years of age (Study 3101-307-002).</p> <p>Study 4</p> <p>Randomized, double-blind, placebo-controlled, parallel group study to assess PK, efficacy, safety and tolerability of atogepant as compared to placebo for the preventive treatment of chronic migraine in paediatric patients from 12 years to less than 18 years of age (Study 3101-308-002).</p> <p>Study 5</p> <p>Open-label study to evaluate the long-term safety of daily administration of atogepant for preventive treatment of episodic migraine in paediatric patients from 6 to less than 18 years of age (3101-310-002).</p>
Extrapolation, modelling and simulation studies	<p>Study 6</p> <p>Development of Population PK model to support selection of initial paediatric dose(s) (3101-S03-000).</p>
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 March 2032
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:

Condition(s) and authorised indication(s)

1. Prevention of migraine headaches

Authorised indication(s):

- AQUIPTA is indicated for prophylaxis of migraine in adults who have at least 4 migraine days per month.
 - Invented name(s): AQUIPTA
 - Authorised pharmaceutical form(s): tablet
 - Authorised route(s) of administration: oral use
 - Authorised via centralised procedure