

EMA/25515/2024

European Medicines Agency decision

P/0011/2024

of 31 January 2024

on the acceptance of a modification of an agreed paediatric investigation plan for etripamil, (EMEA-002303-PIP01-17-M04) 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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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/0042/2019 issued on 29 January 2019, the decision P/0406/2020 issued on 23 October 2020, and the decision P/0349/2022 issued on 10 August 2022,

Having regard to the application submitted by Milestone Pharmaceuticals, Inc. on 8 September 2023 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 December 2023, 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 etripamil, nasal spray, solution, intranasal 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 Milestone Pharmaceuticals, Inc., 1111, Dr, Frederik-Philips Blvd., Suite 420, Montreal, Quebec, H4M 2X6 – Montreal, Canada.

EMA/PDCO/426342/2023
Amsterdam, 15 December 2023

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-002303-PIP01-17-M04

Scope of the application

Active substance(s):

Etripamil

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of supraventricular arrhythmia

Pharmaceutical form(s):

Nasal spray, solution

Route(s) of administration:

Intranasal use

Name/corporate name of the PIP applicant:

Milestone Pharmaceuticals, Inc.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Milestone Pharmaceuticals, Inc. submitted to the European Medicines Agency on 8 September 2023 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/0042/2019 issued on 29 January 2019, the decision P/0406/2020 issued on 23 October 2020, and the decision P/0349/2022 issued on 10 August 2022.

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

The procedure started on 16 October 2023.

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 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 supraventricular arrhythmia

The waiver applies to:

- the paediatric population from birth to less than 6 years of age;
- nasal spray, solution, intranasal 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 supraventricular arrhythmia

2.1.1. Indication(s) targeted by the PIP

Treatment of paroxysmal supraventricular tachycardia

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

From 6 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Nasal spray, solution

2.1.4. Measures

Area	Description
Quality-related studies	Not applicable.
Non-clinical studies	Not applicable.
Clinical studies	Study 1 Single dose, open label, 2-part sequential design PK, safety, and activity study of etripamil in paediatric patients from 6 years to less than 18 years of age with sustained, symptomatic paroxysmal supraventricular tachycardia (PSVT).
Extrapolation, modelling and simulation studies	Study 2 PK modelling and simulation study to optimize dosing of etripamil NS for use in paediatric patients from 6 years to less than 18 years of age.
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 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.