



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMADOC-1700519818-1976387

European Medicines Agency decision

EMA/PE/0000225778

of 20 March 2025

on the acceptance of a modification of an agreed paediatric investigation plan for sipavibart (Kavigale) 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.



European Medicines Agency decision

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on the acceptance of a modification of an agreed paediatric investigation plan for sipavibart (Kavigale) 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/0504/2023 issued on 29 December 2023,

Having regard to the application submitted by AstraZeneca AB on 21 October 2024 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 31 January 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 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 sipavibart (Kavigale), 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 AstraZeneca AB, 151 85 - Sodertalje, Sweden.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMADOC-1700519818-1976094Corr¹

Amsterdam, 31 January 2025

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA/PE/0000225778

Scope of the application

Active substance(s):

Sipavibart

Invented name and authorisation status:

See Annex II

Condition(s):

Prevention of coronavirus disease 2019 (COVID-19)

Pharmaceutical form(s):

Solution for injection/infusion

Route(s) of administration:

Intramuscular use

Intravenous use

Name/corporate name of the PIP applicant:

AstraZeneca AB

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, AstraZeneca AB submitted to the European Medicines Agency on 21 October 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/0504/2023 issued on 29 December 2023.

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

¹ 10 March 2025



The procedure started on 25 November 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 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

Not applicable

2. Paediatric investigation plan

2.1. Condition:

Prevention of coronavirus disease 2019 (COVID-19)

2.1.1. Indication(s) targeted by the PIP

Pre- exposure prophylaxis of Coronavirus disease 2019 (COVID-19) in children who are at risk of developing severe disease.

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

From birth to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Solution for injection/infusion

2.1.4. Measures

Area	Description
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	Study 1 (POLARIS) Open-label, single-dose study to evaluate the safety, pharmacodynamics and pharmacokinetics of sipavibartin paediatric participants from birth to less than 18 years of age (including premature infants born at least at 29 weeks gestational age (GA)) immunocompromised and/or at increased risk of developing severe COVID-19
Modelling and simulation studies	Study 2 Population PK model study for dosing confirmation of sipavibart across weight bands in children from birth to less than 18 years of age immunocompromised and/or at increased risk of developing severe COVID-19
Other studies	Not applicable
Extrapolation plan	Studies 1 and Study 2 are part of an extrapolation plan covering the paediatric population from birth 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:	No
Date of completion of the paediatric investigation plan:	By December 2028
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 coronavirus disease 2019 (COVID-19)

Authorised indication(s):

- KAVIGALE is indicated for the pre exposure prophylaxis of COVID 19 in adults and adolescents 12 years of age and older weighing at least 40 kg and who are immunocompromised due to a medical condition or receipt of immunosuppressive treatments.

KAVIGALE should be used in accordance with official recommendations where available and based on information on the activity of sipavibart against presently circulating viral variants (see sections 4.4 and 5.1).

- Invented name(s): Kavigale
- Authorised pharmaceutical form(s): Solution for injection/infusion (injection/infusion)
- Authorised route(s) of administration: Intramuscular injection or intravenous use
- Authorised via centralised procedure