EMA/347536/2023

European Medicines Agency decision

P/0362/2023

of 8 September 2023

on the agreement of a paediatric investigation plan for dexmedetomidine (EMEA-003283-PIP01-22) 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 agreement of a paediatric investigation plan for dexmedetomidine (EMEA-003283-PIP01-22) 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 application submitted by Cessatech A/S on 8 July 2022 under Article 16(1) of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 21 July 2023, in accordance with Article 17 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 agreement of a paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

Has adopted this decision:

Article 1

A paediatric investigation plan for dexmedetomidine, nasal spray, solution, intranasal use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

This decision is addressed to Cessatech A/S, Kanonbådsvej 2, 1437 – Copenhagen, Denmark.

[1] OJ L 378, 27.12.2006, p.1, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

EMA/PDCO/217745/2023
Amsterdam, 21 July 2023

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan

EMEA-003283-PIP01-22

Scope of the application

Active substance(s):

Dexmedetomidine

Invented name and authorisation status:

See Annex II

Condition(s):

Sedation

Pharmaceutical form(s):

Nasal spray, solution

Route(s) of administration:

Intranasal use

Name/corporate name of the PIP applicant:

Cessatech A/S

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Cessatech A/S submitted for agreement to the European Medicines Agency on 8 July 2022 an application for a paediatric investigation plan for the above mentioned medicinal product.

The procedure started on 12 September 2022.

Supplementary information was provided by the applicant on 21 April 2023. The applicant proposed modifications to the paediatric investigation plan.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 17(1) of said Regulation.

   The Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed 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:

Sedation

2.1.1. Indication(s) targeted by the PIP

For sedation of non-intubated paediatric patients prior to and/or during diagnostic (or surgical) procedures requiring sedation, i.e. procedural/awake sedation.

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

From birth to less than 18 years of age

Pharmaceutical form(s)

Nasal spray, solution

2.1.3. Measures

Area	Description
Quality-related studies	**Study 1** Development of an age-appropriate preservative-free nasal spray for use in neonates and children from birth to less than 18 years of age.
Non-clinical studies	Not applicable
Clinical studies	**Study 2 (CT002-01)** Open-label, randomised, active-controlled non-inferiority trial to evaluate pharmacokinetics, safety and efficacy of dexmedetomidine compared to intranasal midazolam in children from 1 year to less than 18 years of age who require sedation in connection with a routine MRI procedure. **Study 3 (CT002-02)** Open-label, non-comparative trial to evaluate pharmacokinetics, safety and activity of dexmedetomidine in neonates and infants from birth to less than 1 year of age who require sedation in connection with a routine MRI procedure.
Modelling and simulation studies	**Study 4 (CT002-03)** Modelling and simulation population pharmacokinetic (popPK) study, to evaluate the use of intranasal dexmedetomidine in the sedation of children from birth to less than 18 years of age who are undergoing a routine MRI procedure.

Other studies	Not applicable
Extrapolation plan	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 October 2026
Deferral for one or more measures contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.