



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/591617/2019

European Medicines Agency decision P/0368/2019

of 8 November 2019

on the acceptance of a modification of an agreed paediatric investigation plan for sodium thiosulfate (STS), (EMA-002147-PIP02-17-M01) 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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency²,

Having regard to the European Medicines Agency's decision P/0312/2018 issued on 12 September 2018,

Having regard to the application submitted by Fennec Pharmaceuticals, Inc. on 3 September 2019 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 18 October 2019, 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.

² OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for sodium thiosulfate (STS), intravenous use, solution for infusion, 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 Fennec Pharmaceuticals, Inc., 68 T.W. Alexander Drive, 27709 - Research Triangle Park, North Carolina, USA.

EMA/PDCO/497815/2019
Amsterdam, 18 October 2019

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-002147-PIP02-17-M01

Scope of the application

Active substance(s):

Sodium thiosulfate (STS)

Condition(s):

Prevention of platinum-induced ototoxic hearing loss

Pharmaceutical form(s):

Solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Fennec Pharmaceuticals, Inc.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Fennec Pharmaceuticals, Inc. submitted to the European Medicines Agency on 3 September 2019 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/0312/2018 issued on 12 September 2018.

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

The procedure started on 15 October 2019.

Scope of the modification

Some measures 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 in the scope set out in the Annex I of this opinion.

The Norwegian Paediatric Committee member 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 annex 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 platinum-induced ototoxic hearing loss

The waiver applies to:

- preterm and term newborn infants from birth to less than 1 month of age;
- solution for infusion for intravenous use;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric investigation plan

2.1. Condition:

Prevention of platinum-induced ototoxic hearing loss

2.1.1. Indication(s) targeted by the PIP

Prevention of platinum-induced ototoxic hearing loss for standard risk hepatoblastoma (SR-HB)

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

From 1 month to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for infusion

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable
Non-clinical studies	0	Not applicable
Clinical studies	2	Study 1 Multi-centre open label randomised trial of the efficacy of sodium thiosulphate in reducing ototoxicity in patients receiving cisplatin chemotherapy for standard risk hepatoblastoma (SIOPEL-6) Study 2 Randomised study of sodium thiosulfate for the prevention of cisplatin-induced ototoxicity in children (ACCL0431)

Extrapolation, modelling and simulation studies	1	Study 3 Population based PK model (PopPK) for Extrapolation/Interpolation (LAPP-17040)
Other studies	0	Not applicable
Other measures	0	Not applicable

3. 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 2019
Deferral for one or more measures contained in the paediatric investigation plan:	No