EMA/705997/2021

European Medicines Agency decision

P/0563/2021

of 31 December 2021

on the agreement of a paediatric investigation plan and on the granting of a deferral for tosatoxumab (EMEA-002506-PIP03-21) 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

P/0563/2021

of 31 December 2021

on the agreement of a paediatric investigation plan and on the granting of a deferral for tosatoxumab (EMEA-002506-PIP03-21) 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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the application submitted by Aridis Pharmaceuticals Inc on 18 January 2021 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 12 November 2021, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation,

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 and on the granting of a deferral.

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

(3) It is therefore appropriate to adopt a decision granting a deferral.

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

Has adopted this decision:

Article 1

A paediatric investigation plan for tosatoxumab, solution for infusion, intravenous 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

A deferral for tosatoxumab, solution for infusion, intravenous 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 granted.

Article 3

This decision is addressed to Aridis Pharmaceuticals Inc, 983 University Avenue, Building B, CA 95032-7637 - Los Gatos, USA.

EMA/PDCO/469613/2021
Amsterdam, 12 November 2021

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

EMEA-002506-PIP03-21

Scope of the application

Active substance(s):

Tosatoxumab

Condition(s):

Treatment of Staphylococcus aureus pneumonia

Pharmaceutical form(s):

Solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Aridis Pharmaceuticals Inc

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Aridis Pharmaceuticals Inc submitted for agreement to the European Medicines Agency on 18 January 2021 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 23 February 2021.

Supplementary information was provided by the applicant on 16 July 2021. 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;
   - to grant a deferral in accordance with Article 21 of said Regulation.

   The Norwegian Paediatric Committee member 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 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

Not applicable

2. Paediatric investigation plan

2.1. Condition:

Treatment of Staphylococcus aureus pneumonia

2.1.1. Indication(s) targeted by the PIP

Treatment of Staphylococcus aureus pneumonia in addition to standard of care (SOC)

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 infusion

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Generation of data on the compatibility of tosatoxumab (AR-301) with paediatric administration systems: IV bag and syringes for IV infusion
Non-clinical studies	0	Not applicable
Clinical studies	2	**Study 2** Randomized, double-blind, placebo-controlled, study of pharmacokinetics (PK), safety and efficacy of tosatoxumab (AR-301) as adjunct therapy to standard of care (SOC) in the treatment of paediatric patients from 12 years to less than 18 years of age with pneumonia caused by Staphylococcus aureus (AR-301-003a) **Study 3** Open label, single arm study of pharmacokinetics (PK) and safety of tosatoxumab (AR-301) as adjunct therapy to standard of care (SOC) in the treatment of paediatric patients from birth to less than 12 years of age with pneumonia caused by Staphylococcus aureus (AR-301-004)

Extrapolation, modelling and simulation studies	2	**Study 4** Population PK model for characterisation of pharmacokinetics of tosatoxumab in children, adolescents (and adults) (AR-301-005 PopPK) **Study 5** Extrapolation study to evaluate the use of tosatoxumab in adjunct therapy to standard of care antibiotics in the treatment of bacterial pneumonia in children from birth to less than 18 years of age with a documented diagnosis of pneumonia due to Staphylococcus aureus (AR-301-005 extrapolation plan)
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:	No
Date of completion of the paediatric investigation plan:	By July 2028
Deferral for one or more measures contained in the paediatric investigation plan:	Yes