EMA/156109/2018

European Medicines Agency decision

P/0103/2018

of 19 March 2018

on the agreement of a paediatric investigation plan and on the granting of a deferral for plazomicin (sulfate) (EMEA-001639-PIP02-17) 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 726/2004[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 Achaogen Inc. on 12 June 2017 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 23 February 2018, 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.

Has adopted this decision:

Article 1

A paediatric investigation plan for plazomicin (sulfate), concentrate for 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.

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

Article 2

A deferral for plazomicin (sulfate), concentrate for 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 Achaogen Inc., 1 Tower Place, Suite 300, CA 94080 - South San Francisco, United States.

EMA/PDCO/827363/2017
London, 23 February 2018

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

EMEA-001639-PIP02-17

Scope of the application

Active substance(s):

Plazomicin (sulfate)

Condition(s):

Treatment of complicated urinary tract infections

Treatment of infections due to *Enterobacteriaceae*

Pharmaceutical form(s):

Concentrate for solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Achaogen Inc.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Achaogen Inc. submitted for agreement to the European Medicines Agency on 12 June 2017 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 18 July 2017.

Supplementary information was provided by the applicant on 11 December 2017. The applicant proposed modifications to the paediatric investigation plan.

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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 complicated urinary tract infections

2.1.1. Indication(s) targeted by the PIP

Treatment of complicated urinary tract infections

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)

Concentrate for 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** Prospective, open-label, single- and multiple-dose, pharmacokinetic, safety and tolerability study of intravenous plazomicin in paediatric subjects from birth to less than 18 years of age who are receiving systemic antibiotic therapy for suspected or confirmed systemic infection. **Study 2** Prospective study to determine the safety, tolerability, and pharmacokinetics, of plazomicin in paediatric subjects from birth (gestational age ≥ 26 weeks) up to 44 weeks of post-menstrual age.
Extrapolation, modelling and simulation studies	2	**Study 3** Population pharmacokinetic (PK) modelling and PK/pharmacodynamic (PD) probability of target attainment (PTA) analysis for dose selection across paediatric age groups for the treatment of complicated urinary tract infections or of infections caused by *Enterobacteriaceae*.

Area	Number of measures	Description
		Study 4 Extrapolation study of the clinical efficacy and safety data of plazomicin from the adult programme to paediatric patients from birth to less than 18 years of age with complicated urinary tract infections or with infections caused by *Enterobacteriaceae* based on pop PK-PD modelling study (Study 3).
Other studies	0	Not applicable
Other measures	0	Not applicable

2.2. Condition:

Treatment of infections due to *Enterobacteriaceae*

2.2.1. Indication(s) targeted by the PIP

Treatment of infections due to *Enterobacteriaceae* in patients with limited treatment options

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

From birth to less than 18 years of age

2.2.3. Pharmaceutical form(s)

Concentrate for solution for infusion

2.2.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable
Non-clinical studies	0	Not applicable
Clinical studies	2	**Study 1** Prospective, open-label, single and multiple-dose, pharmacokinetic, safety and tolerability study of intravenous plazomicin in paediatric subjects from birth to less than 18 years of age who are receiving systemic antibiotic therapy for suspected or confirmed systemic infection **Study 2**

		Prospective study to determine the safety, tolerability, and pharmacokinetics, of plazomicin in paediatric subjects from birth (gestational age ≥ 26 weeks) up to 44 weeks of post-menstrual age
Extrapolation, modelling and simulation studies	2	**Study 3** Population pharmacokinetic (PK) modelling and PK/pharmacodynamic (PD) probability of target attainment (PTA) analysis for dose selection across paediatric age groups for the treatment of complicated urinary tract infections or of infections caused by *Enterobacteriaceae* **Study 4** Extrapolation study of the clinical efficacy and safety data of plazomicin from the adult programme to paediatric patients from birth to less than 18 years of age with infections based on pop PK-PD modelling study (Study 4).
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 August 2022
Deferral for one or more measures contained in the paediatric investigation plan:	Yes