



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/354130/2017

European Medicines Agency decision

P/0169/2017

of 3 July 2017

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for omadacycline (EMA-000560-PIP02-15) 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 application submitted by Paratek UK Limited on 21 December 2015 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 19 May 2017, in accordance with Article 18 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation and Article 13 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 and on the granting of a waiver.
- (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.
- (4) It is therefore appropriate to adopt a decision granting a waiver.

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 omadacycline, powder for concentrate for solution for infusion, film-coated tablet, granules, intravenous use, oral 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 omadacycline, powder for concentrate for solution for infusion, film-coated tablet, granules, intravenous use, oral 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

A waiver for omadacycline, powder for concentrate for solution for infusion, film-coated tablet, granules, intravenous use, oral 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 4

This decision is addressed to Paratek UK Limited, 20-22 Bedford Row, WC1R 4JS - London, United Kingdom.

EMA/PDCO/171065/2017

London, 19 May 2017

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

EMA-000560-PIP02-15

Scope of the application

Active substance(s):

Omadacycline

Condition(s):

Treatment of acute bacterial skin and skin structure infections (ABSSSI)

Pharmaceutical form(s):

Powder for concentrate for solution for infusion

Film-coated tablet

Granules

Route(s) of administration:

Intravenous use

Oral use

Name / corporate name of the PIP applicant:

Paratek UK Limited

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Paratek UK Limited submitted for agreement to the European Medicines Agency on 21 December 2015 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 2 February 2016.

Supplementary information was provided by the applicant on 23 February 2017. 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 18 of said Regulation;
- to grant a deferral in accordance with Article 21 of said Regulation;
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population.

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 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

Treatment of acute bacterial skin and skin structure infections (ABSSSI)

The waiver applies to:

- the paediatric population from birth to less than 8 years;
- powder for concentrate for solution for infusion, film-coated tablet, granules, intravenous use, oral use;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric investigation plan

2.1. Condition

Treatment of acute bacterial skin and skin structure infections (ABSSSI)

2.1.1. Indication(s) targeted by the PIP

Treatment of acute bacterial skin and skin structure infections (ABSSSI)

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

From 8 years to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Powder for concentrate for solution for infusion

Film-coated tablet

Granules

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	Study 1 (same study as study 1 in PIP EMEA-000560-PIP03-15) Development of age-appropriate solid oral formulation.
Non-clinical studies	0	Not applicable.
Clinical studies	2	Study 2 (same study as study 2 in PIP EMEA-000560-PIP03-15) Open-label, single-dose, cross-over study to compare the safety, tolerability and pharmacokinetics of intravenous (IV) and oral (tablet and coated granule) omadacycline in children and adolescents 8 to less than 18 years of age.

		Study 3 Randomised, investigator blinded, open-label study to compare the safety and efficacy of omadacycline with a comparator antibiotic for treatment of acute bacterial skin and skin structure infections (ABSSSI) in children 8 to less than 18 years of age.
Extrapolation, modelling and simulation studies	1	Study 4 (same study as study 4 in PIP EMEA-000560-PIP03-15) Modelling and simulation study for dose selection in all planned clinical studies.
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 March 2024
Deferral for one or more measures contained in the paediatric investigation plan:	Yes