EMA/514764/2018

European Medicines Agency decision

P/0269/2018

of 16 August 2018

on the acceptance of a modification of an agreed paediatric investigation plan for omadacycline (EMEA-000560-PIP03-15-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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on the acceptance of a modification of an agreed paediatric investigation plan for omadacycline (EMEA-000560-PIP03-15-M01) 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 European Medicines Agency's decision P/0168/2017 issued on 3 July 2017,

Having regard to the application submitted by Paratek UK Limited on 4 June 2018 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 27 July 2018, 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 omadacycline, powder for concentrate for solution for infusion, film-coated tablet, granules, intravenous use, oral use, 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 covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/0169/2017 issued on 3 July 2017, including subsequent modifications thereof.

Article 3

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

EMA/PDCO/412825/2018
London, 27 July 2018

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-000560-PIP03-15-M01

Scope of the application

Active substance(s):

Omadacycline

Condition(s):

Treatment of bacterial pneumonia

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 22 of Regulation (EC) No 1901/2006 as amended, Paratek UK Limited submitted to the European Medicines Agency on 4 June 2018 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0168/2017 issued on 3 July 2017.

The application for modification proposed introduction of a cross reference to another agreed paediatric investigation plan for the same product.

The procedure started on 26 June 2018.

Scope of the modification

Introduction of a cross reference to all indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals in Treatment of acute bacterial skin and skin structure infections (ABSSSI), covered by a separate paediatric investigation plan for the same product as set out in the European Medicines Agency's decision P/0169/2017 issued on 3 July 2017.

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 introduction of a cross reference to all indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals in condtion(s) Treatment of acute bacterial skin and skin structure infections (ABSSSI), covered by a separate agreed paediatric investigation plan as set out in the European Medicines Agency's decision P/0169/2017 issued on 3 July 2017.

   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

Treatment of bacterial pneumonia

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 bacterial pneumonia

2.1.1. Indication(s) targeted by the PIP

Treatment of community acquired bacterial pneumonia

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-PIP02-15) 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-PIP02-15) 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 community acquired bacterial pneumonia 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-PIP02-15) 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