EMA/464831/2014

European Medicines Agency decision

P/0223/2014

of 5 September 2014

on the acceptance of a modification of an agreed paediatric investigation plan for dalbavancin (EMEA-000016-PIP01-07-M03) 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 European Medicines Agency's decision P/31/2008 issued on 19 June 2008, decision P/0057/2013 issued on 26 March 2013, and decision P/0245/2013 of 4 October 2013,

Having regard to the application submitted by Durata Therapeutics International B.V. on 28 April 2014 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 18 July 2014, 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 and to the deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the 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

Changes to the agreed paediatric investigation plan for dalbavancin, powder for concentrate for solution for infusion, intravenous use, including changes to the deferral, 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 Durata Therapeutics International B.V., Spaces Zuidas II, Barbara Strozzilaan 101, 1083HN – Amsterdam, The Netherlands.

Done at London, 5 September 2014

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/266364/2014 corr

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

EMEA-000016-PIP01-07-M03

Scope of the application

Active substance(s):

Dalbavancin

Condition(s):

Treatment of skin and soft tissue infections

Pharmaceutical form(s):

Powder for concentrate for solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Durata Therapeutics International B.V.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Durata Therapeutics International B.V. submitted to the European Medicines Agency on 28 April 2014 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/31/2008 issued on 19 June 2008, decision P/0057/2013 issued on 26 March 2013, and decision P/0245/2013 of 4 October 2013.

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

The procedure started on 21 May 2014.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

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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 and to the deferral 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 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.

London, 18 July 2014

On behalf of the Paediatric Committee
Dr Dirk Mentzer, Chairman
(Signature on file)

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 skin and soft tissue infections

2.1.1. Indication(s) targeted by the PIP

Treatment of complicated skin and soft tissue infections caused by susceptible Gram positive bacteria

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)

Powder for concentrate for solution for infusion

2.1.4. Measures

Area	Number of studies	Description
Quality-related studies	1	**Study 1** Development of a vial with smaller content and/or a lower strength appropriate for a paediatric population.
Non-clinical studies	2	**Study 2** Dose Range Finding Study with Dalbavancin in Neonatal Rat. **Study 3** Definitive Juvenile Rat Toxicology Study of Dalbavancin.
Clinical studies	4	**Study 4** Paediatric Pharmacokinetic study: Determination of pharmacokinetics of dalbavancin in paediatric patients aged 12 to less than 18 years for selection of dosing in a Phase 3 therapeutic study for complicated skin and soft tissue infections. **Study 5** Paediatric Pharmacokinetic study: Determination of pharmacokinetics of dalbavancin in paediatric patients aged 3 months to less than 12 years for selection of dosing in a Phase 3 therapeutic study for complicated skin and soft tissue infections.

		Study 6 Paediatric Pharmacokinetic study: Determination of pharmacokinetics of dalbavancin in paediatric patients aged less than 3 months for selection of dosing in a Phase 3 therapeutic study for complicated skin and soft tissue infections. **Study 7** Paediatric Safety and Efficacy study: Determination of safety and efficacy of dalbavancin in complicated skin and soft tissue infections in patients aged from birth to less than 18 years of age requiring hospitalization and intravenous antibiotic therapy.
Extrapolation, modelling and simulation studies	0	Not applicable.
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 December 2016
Deferral for one or more measures contained in the paediatric investigation plan:	Yes