EMA/364959/2015

European Medicines Agency decision

P/0138/2015

of 10 July 2015

on the acceptance of a modification of an agreed paediatric investigation plan for dalbavancin (Xydalba), (EMEA-000016-PIP01-07-M04) 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, the decision P/0057/2013 issued on 26 March 2013, the decision P/0245/2013 issued on 4 October 2013, and the decision P/0223/2014 issued on 5 September 2014,

Having regard to the application submitted by Durata Therapeutics International B.V. on 2 March 2015 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 22 May 2015, 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 (Xydalba), 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, 10 July 2015

For the European Medicines Agency
Jordi Llinares Garcia
Head of Division (ad interim)
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/154769/2015 Corr
London, 22 May 2015

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

EMEA-000016-PIP01-07-M04

Scope of the application

Active substance(s):

Dalbavancin

Invented name:

Xydalba

Condition(s):

Treatment of acute bacterial skin and skin structure infections

Authorised indication(s):

See Annex II

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.

Information about the authorised medicinal product:

See Annex II

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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 2 March 2015 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, the decision P/0057/2013 issued on 26 March 2013, the decision P/0245/2013 issued on 4 October 2013, and the decision P/0223/2014 issued on 5 September 2014.

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

The procedure started on 24 March 2015.

Scope of the modification

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

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 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 annexes 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 acute bacterial skin and skin structure infections

2.1.1. Indication(s) targeted by the PIP

Treatment of acute bacterial skin and skin structure 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 acute bacterial skin and skin structure 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 acute bacterial skin and skin structure 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 acute bacterial skin and skin structure infections. **Study 7** Paediatric Safety and Efficacy study: Determination of safety and efficacy of dalbavancin in acute bacterial skin and skin structure 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 June 2017
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s)

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

Authorised indication(s):

- Xydalba is indicated for the treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults (see sections 4.4 and 5.1).
  Consideration should be given to official guidance on the appropriate use of antibacterial agents.

Authorised pharmaceutical form(s)

Powder for concentrate for solution for infusion (powder for concentrate)

Authorised route(s) of administration

Intravenous use