EMA/625765/2021

European Medicines Agency decision

P/0522/2021

of 3 December 2021

on the acceptance of a modification of an agreed paediatric investigation plan for dalbavancin hydrochloride (Xydalba), (EMEA-000016-PIP01-07-M08) 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, the decision P/0223/2014 issued on 5 September 2014, the decision P/0138/2015 issued on 10 July 2015, the decision P/0056/2016 issued on 18 March 2016, the decision P/0113/2018 issued on 11 April 2018 and the decision P/0377/2019 issued on 4 December 2019,

Having regard to the application submitted by Allergan Pharmaceuticals International Limited on 12 July 2021 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 15 October 2021, 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 hydrochloride (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 Allergan Pharmaceuticals International Limited, Clonshaugh Business & Technology Park, D17 E400 – Dublin, Ireland.

EMA/PDCO/415692/2021
Amsterdam, 15 October 2021

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

EMEA-000016-PIP01-07-M08

Scope of the application

Active substance(s):

Dalbavancin hydrochloride

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:

Allergan Pharmaceuticals International Limited

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Allergan Pharmaceuticals International Limited submitted to the European Medicines Agency on 12 July 2021 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, the decision P/0223/2014 issued on 5 September 2014, the decision P/0138/2015 issued on 10 July 2015, the decision P/0056/2016 issued on 18 March 2016, the decision P/0113/2018 issued on 11 April 2018 and the decision P/0377/2019 issued on 4 December 2019.

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

The procedure started on 17 August 2021.

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 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

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	0	***Study 1*** *Study deleted with EMEA-000016-PIP01-07-M06*
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 for the determination of pharmacokinetics of dalbavancin in paediatric patients aged 12 to less than 18 years for selection of dosing for a Phase 3 study for children with acute bacterial skin and skin structure infections **Study 5** Paediatric pharmacokinetic study for the determination of pharmacokinetics of dalbavancin in paediatric patients aged 3 months to less than 12 years for selection of dosing for a Phase 3 study in children with acute bacterial skin and skin structure infections

		Study 6 Paediatric pharmacokinetic study for the determination of pharmacokinetics of dalbavancin in paediatric patients aged less than 3 months with suspected or confirmed bacterial infections for selection of dosing for a phase 3 study in children with late-onset sepsis **Study 7** Paediatric safety and efficacy study for the 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 ***Study 8*** *Study deleted in EMEA-000016-PIP01-07-M06*
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 2023
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