EMA/512491/2023

European Medicines Agency decision

P/0467/2023

of 1 December 2023

on the acceptance of a modification of an agreed paediatric investigation plan for dalbavancin hydrochloride (Xydalba), (EMEA-000016-PIP01-07-M09) 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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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 Union procedures for the authorisation and supervision of medicinal products for human 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, the decision P/0377/2019 issued on 4 December 2019, and the decision P/0522/2021 issued on 3 December 2021,

Having regard to the application submitted by AbbVie Ltd on 28 June 2023 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 13 October 2023, 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, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

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, 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 AbbVie Ltd, Abbvie House, Vanwall Business Park, Vanwall Road, SL6 4UB – Maidenhead, United Kingdom.

EMA/PDCO/322742/2023 [1] [2]
Amsterdam, 13 October 2023

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

EMEA-000016-PIP01-07-M09

Scope of the application

Active substance(s):

Dalbavancin hydrochloride

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of acute bacterial skin and skin structure infections

Pharmaceutical form(s):

Powder for concentrate for solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

AbbVie Ltd

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, AbbVie Ltd submitted to the European Medicines Agency on 28 June 2023 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, the decision P/0377/2019 issued on 4 December 2019, and the decision P/0522/2021 issued on 3 December 2021.

[1] 10 November 2023.
[2] 30 November 2023.

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

The procedure started on 14 August 2023.

Scope of the modification

Some measures 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 in the scope set out in the Annex I of this opinion.

   The Paediatric Committee member of Norway 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 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	Description
Quality-related studies	***Study 1*** *Study deleted with EMEA-000016-PIP01-07-M06*
Non-clinical studies	**Study 2** Dose range finding study with dalbavancin in neonatal rat **Study 3** Definitive juvenile rat toxicology study of dalbavancin
Clinical studies	**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	Not applicable
Other studies	Not applicable
Other measures	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

Information provided by the applicant:

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