EMA/602322/2022

European Medicines Agency decision

P/0242/2022

of 8 July 2022

on the acceptance of a modification of an agreed paediatric investigation plan for daprodustat (EMEA-001452-PIP01-13-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 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/0191/2014 issued on 6 August 2014, decision P/0025/2018 issued on 30/01/2018, and decision P/0047/2021 issued on 27 January 2021,

Having regard to the application submitted by GlaxoSmithKline Trading Services Limited on 18 February 2022 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 20 May 2022, 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 and to the waiver.

(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 and to the waiver.

[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 daprodustat, tablet, dispersible tablet, oral use, including changes to the deferral and to the waiver, 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 GlaxoSmithKline Trading Services Limited, 12 River Walk, Citywest Business Campus, D24 YK11 – Dublin, Ireland.

EMA/PDCO/133268/2022 Corr
Amsterdam, 20 May 2022

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

EMEA-001452-PIP01-13-M04

Scope of the application

Active substance(s):

Daprodustat

Condition(s):

Treatment of anaemia due to chronic disorders

Pharmaceutical form(s):

Tablet

Dispersible tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

GlaxoSmithKline Trading Services Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, GlaxoSmithKline Trading Services Limited submitted to the European Medicines Agency on 18 February 2022 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/0191/2014 issued on 6 August 2014, the decision P/0025/2018 issued on 30/01/2018 and the decision P/0047/2021 issued on 27 January 2021.

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

The procedure started on 21 March 2022.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified. The deferral has been removed. The scope of the waiver has 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 and to the waiver 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 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 anaemia due to chronic disorders

The waiver applies to:

- the paediatric population from birth to less than 3 months of age;
- tablet, dispersible tablet, oral use;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric investigation plan

2.1. Condition:

Treatment of anaemia due to chronic disorders

2.1.1. Indication(s) targeted by the PIP

Treatment of anaemia associated with chronic kidney disease (CKD)

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 3 months to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Tablet

Dispersible tablet

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1** Development of dispersible tablets.
Non-clinical studies	**Study 2** Dose range finding study in juvenile rats. **Study 3** Definitive toxicity study in juvenile rats.
Clinical studies	**Study 4** *This study was deleted as a result of procedure EMEA-001452-PIP01-13-M03.*

	Study 5 *This study was deleted as a result of procedure EMEA-001452-PIP01-13-M04.* **Study 6** *This study was deleted as a result of procedure EMEA-001452-PIP01-13-M04.* **Study 7** *This study was deleted as a result of procedure EMEA-001452-PIP01-13-M04.* **Study 8** *This study was deleted as a result of procedure EMEA-001452-PIP01-13-M04.* **Study 9** Open-label basket trial to evaluate pharmacokinetics and safety of daprodustat in paediatric patients from 3 months to less than 18 years of age with anaemia associated with CKD requiring or not requiring dialysis. *This study was added as a result of procedure EMEA-001452-PIP01-13-M04.* **Study 10** Observational basket cohort study to characterise the use of erythropoiesis-stimulating agent (ESA) therapies in paediatric patients from 3 months to less than 18 years of age with anaemia associated with CKD requiring or not requiring dialysis. *This study was added as a result of procedure EMEA-001452-PIP01-13-M04.*
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 or efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By June 2028
Deferral for one or more measures contained in the paediatric investigation plan:	No