EMA/29826/2018

European Medicines Agency decision

P/0025/2018

of 30 January 2018

on the acceptance of a modification of an agreed paediatric investigation plan for N-[(1,3-dicyclohexyl-6-hydroxy-2,4-dioxo-1,2,3,4-tetrahydro-5-pyrimidinyl)carbonyl]glycine (GSK1278863) (EMEA-001452-PIP01-13-M01) 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/0191/2014 issued on 6 August 2014,

Having regard to the application submitted by GlaxoSmithKline Trading Services Limited on 25 September 2017 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 15 December 2017, 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 N-[(1,3-dicyclohexyl-6-hydroxy-2,4-dioxo-1,2,3,4-tetrahydro-5-pyrimidinyl)carbonyl]glycine (GSK1278863), oral solution, oral suspension, tablet, oral 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 GlaxoSmithKline Trading Services Limited, Building 10, Stockley Park West, UB11 1BU - Uxbridge, United Kingdom.

EMA/PDCO/647470/2017
London, 15 December 2017

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

EMEA-001452-PIP01-13-M01

Scope of the application

Active substance(s):

N-[(1,3-dicyclohexyl-6-hydroxy-2,4-dioxo-1,2,3,4-tetrahydro-5-pyrimidinyl)carbonyl]glycine (GSK1278863)

Condition(s):

Treatment of anaemia due to chronic disorders

Pharmaceutical form(s):

Oral solution

Oral suspension

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 25 September 2017 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 application for modification proposed changes to the agreed paediatric investigation plan and to the deferral.

The procedure started on 17 October 2017.

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 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 1 year of age;
- oral solution, oral suspension, 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 renal disease

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

From 1 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Oral solution

Oral suspension

Tablet

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1:** Development of an oral solution or oral suspension.
Non-clinical studies	2	**Study 2:** Dose range finding study in juvenile rats. **Study 3:** Definitive toxicity study in juvenile rats.
Clinical studies	5	**Study 4:** Relative bioavailability study of oral solution or oral suspension in adults.

		Study 5: Open-label, single-arm sequential cohort trial to evaluate pharmacokinetics and safety of GSK1278863 in children from 1 to less than 18 years of age who are undergoing dialysis. **Study 6:** Open-label, single-arm sequential cohort trial to evaluate pharmacokinetics and safety of GSK1278863 in children from 1 to less than 18 years of age who are NOT undergoing dialysis. **Study 7:** Open-label, randomised, dose-titration, active controlled trial to evaluate efficacy and safety of GSK1278863 in children from 1 to less than 18 years of age with anaemia who are undergoing dialysis. **Study 8:** Open-label, randomised, dose-titration, active controlled trial to evaluate efficacy and safety of GSK1278863 in children from 1 to less than 18 years of age with anaemia who are NOT undergoing dialysis.
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 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:	Yes