

EMA/689628/2015

European Medicines Agency decision

P/0289/2015

of 27 November 2015

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for 4-Amino-2-butoxy-8-[3-(pyrrolidin-1-ylmethyl)benzyl]-7,8-dihydropteridin-6(5H)-one (GS-9620) (EMEA-001745-PIP01-14) 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 726/2004¹,

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 Agency²,

Having regard to the application submitted by Gilead Sciences International Ltd. on 12 February 2015 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 9 October 2015, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation and Article 13 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver.
- (2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.
- (3) It is therefore appropriate to adopt a decision granting a deferral.
- (4) It is therefore appropriate to adopt a decision granting a waiver.

¹ OJ L 378, 27.12.2006, p.1.

² OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

A paediatric investigation plan for 4-Amino-2-butoxy-8-[3-(pyrrolidin-1-ylmethyl)benzyl]-7,8-dihydropteridin-6(5H)-one (GS-9620), film-coated tablet, tablet, age-appropriate oral formulation, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for 4-Amino-2-butoxy-8-[3-(pyrrolidin-1-ylmethyl)benzyl]-7,8-dihydropteridin-6(5H)-one (GS-9620), film-coated tablet, tablet, age-appropriate oral formulation, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

A waiver for 4-Amino-2-butoxy-8-[3-(pyrrolidin-1-ylmethyl)benzyl]-7,8-dihydropteridin-6(5H)-one (GS-9620), film-coated tablet, tablet, age-appropriate oral formulation, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 4

This decision is addressed to Gilead Sciences International Ltd., Flowers Building, Granta Park, CB216GT – Cambridge, United Kingdom.

Done at London, 27 November 2015

For the European Medicines Agency
Zaïde Frias
Head of Division
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/502359/2015

London, 9 October 2015

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMEA-001745-PIP01-14

Scope of the application

Active substance(s):

4-Amino-2-butoxy-8-[3-(pyrrolidin-1-ylmethyl)benzyl]-7,8-dihydropteridin-6(5H)-one (GS-9620)

Condition(s):

Treatment of chronic viral hepatitis B

Pharmaceutical form(s):

Film-coated tablet

Tablet

Age-appropriate oral formulation

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Gilead Sciences International Ltd.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Gilead Sciences International Ltd. submitted for agreement to the European Medicines Agency on 12 February 2015 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 24 March 2015.

Supplementary information was provided by the applicant on 17 July 2015.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report :
 - to agree the paediatric investigation plan in accordance with Article 18 of said Regulation;
 - to grant a deferral in accordance with Article 21 of said Regulation;
 - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed 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 chronic viral hepatitis B

The waiver applies to:

- the paediatric population from birth to less than 2 years of age;
- film-coated tablet, tablet, age-appropriate oral formulation, oral use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric investigation plan

2.1. Condition

Treatment of chronic viral hepatitis B

2.1.1. Indication(s) targeted by the PIP

Treatment of chronic viral hepatitis B in children who are virally suppressed on treatment with oral antiviral drugs

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

From 2 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Film-coated tablet

Tablet

Age-appropriate oral formulation

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	2	<p>Study 1</p> <p>Development of an age-appropriate strength of a solid formulation for use in children from 6 to less than 12 years of age.</p> <p>Study 2</p> <p>Development of an age-appropriate oral dosage form for use in children from 2 to less than 6 years of age and in older children who are unable to swallow tablets.</p>

Non-clinical studies	0	Not applicable.
Clinical studies	2	<p>Study 3</p> <p>Open-label, randomised, single-dose crossover trial to evaluate the relative bioavailability of the GS-9620 age-appropriate oral formulation compared to the film-coated tablet in healthy adult subjects.</p> <p>Study 4</p> <p>Open-label, historical controlled trial to evaluate PK, safety and efficacy of GS-9620 in children from 2 to less than 18 years of age with chronic viral hepatitis B infection.</p>
Extrapolation, modelling and simulation studies	1	<p>Study 5</p> <p>Population PK model to support paediatric dosing.</p>
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:	No
Date of completion of the paediatric investigation plan:	By December 2022
Deferral for one or more measures contained in the paediatric investigation plan:	Yes