EMA/627431/2021

European Medicines Agency decision

P/0468/2021

of 12 November 2021

on the acceptance of a modification of an agreed paediatric investigation plan for sotrovimab (EMEA-002899-PIP01-20-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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on the acceptance of a modification of an agreed paediatric investigation plan for sotrovimab (EMEA-002899-PIP01-20-M01) in accordance with Regulation (EC) 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 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/0240/2021 issued on 17 June 2021,

Having regard to the application submitted by GlaxoSmithKline Trading Services Ltd on 9 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 sotrovimab, concentrate for solution for infusion, solution for injection/infusion, intravenous use, intramuscular 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 Ltd, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland.

EMA/PDCO/408100/2021 corr
Amsterdam, 15 October 2021

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

EMEA-002899-PIP01-20-M01

Scope of the application

Active substance(s):

Sotrovimab

Condition(s):

Treatment of coronavirus disease 2019 (COVID-19)

Pharmaceutical form(s):

Concentrate for solution for infusion

Solution for injection/infusion

Route(s) of administration:

Intravenous use

Intramuscular use

Name/corporate name of the PIP applicant:

GlaxoSmithKline Trading Services Ltd

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, GlaxoSmithKline Trading Services Ltd submitted to the European Medicines Agency on 9 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/0240/2021 issued on 17 June 2021.

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.

   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 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

Not applicable

2. Paediatric investigation plan

2.1. Condition:

Treatment of coronavirus disease 2019 (COVID-19)

2.1.1. Indication(s) targeted by the PIP

Treatment of paediatric patients with COVID-19 who are at risk of progressing to severe disease

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)

Concentrate for solution for infusion

Solution for injection/infusion

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 4** Age-appropriate formulation strength for intramuscular (IM) use in children from birth to less than 12 years of age and 40 kg. *This measure was added with procedure EMEA-002899-PIP01-20-M01*
Non-clinical studies	0	Not applicable
Clinical studies	1	**Study 1 (215226)** Open-label, non-comparator, multicentre study to describe pharmacokinetics (PK), pharmacodynamics (viral load) and safety following a single intravenous or intramuscular dose of sotrovimab in paediatric participants from 32 weeks gestational age (GA) with mild to moderate COVID-19 at high risk of progression.
Extrapolation, modelling and simulation studies	2	**Study 2** Population PK (PopPK) model for dosing prediction and confirmation in paediatric patients from 32 weeks of gestational age (GA) (at birth) to less than 18 years of age.

		Study 3 PK bridging and extrapolation of safety and virology data to support the use of sotrovimab for the treatment of mild, moderate COVID-19 disease in children from 32 weeks GA (at birth) to less than 18 years of age.
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 October 2024
Deferral for one or more measures contained in the paediatric investigation plan:	Yes