EMA/365940/2020

European Medicines Agency decision
P/0266/2020

of 15 July 2020

on the acceptance of a modification of an agreed paediatric investigation plan for recombinant human monoclonal antibody to GM-CSF (otilimab) (EMEA-001882-PIP02-16-M02) 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/0272/2017 issued on 4 October 2017 and the decision P/0287/2019 issued on 16 August 2019,

Having regard to the application submitted by GlaxoSmithKline Trading Services Limited on 20 February 2020 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 29 May 2020, 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.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for recombinant human monoclonal antibody to GM-CSF (otilimab), solution for injection, subcutaneous 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 GlaxoSmithKline Trading Services Limited, 12 Riverwalk, Citywest Business Campus, 24 – Dublin, Ireland.

EMA/PDCO/138552/2020 Corr
Amsterdam, 29 May 2020

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

EMEA-001882-PIP02-16-M02

Active substance(s):

Recombinant human monoclonal antibody to GM-CSF (otilimab)

Condition(s):

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylarthritis and juvenile idiopathic arthritis)

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous 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 20 February 2020 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/0272/2017 issued on 4 October 2017 and the decision P/0287/2019 issued on 16 August 2019.

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

The procedure started on 31 March 2020.

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 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 chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylarthritis and juvenile idiopathic arthritis)

The waiver applies to:

- the paediatric population from birth to less than 1 year of age;
- solution for injection, subcutaneous use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric investigation plan

2.1. Condition:

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylarthritis and juvenile idiopathic arthritis)

2.1.1. Indication(s) targeted by the PIP

Otilimab in combination with methotrexate is indicated for the treatment of active polyarticular Juvenile Idiopathic Arthritis (JIA) in patients 2 years of age and older

Otilimab in combination with methotrexate is indicated for the treatment of active systemic JIA in patients 1 year of age and older

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)

Solution for injection

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable
Non-clinical studies	1	**Study 1** Enhanced pre- and postnatal development study (PPND) in primates to determine normal development of the offspring and pharmacology of Granulocyte macrophage colony-stimulating factor (GM-CSF) on growth, clinical behaviour, respiratory function

Clinical studies	2	**Study 2** Pharmacokinetic, efficacy and safety study of otilimab in combination with methotrexate (MTX) in children aged 2 to less than 18 years of age with active polyarticular juvenile idiopathic arthritis (pJIA) **Study 3** Pharmacokinetic, efficacy and safety study of otilimab in combination with MTX in children aged 1 to less than 18 years of age with active systemic JIA (sJIA)
Extrapolation, modelling and simulation studies	1	**Study 4** Analysis of PK data from adult RA population combined with all PK data from paediatric subjects enrolled into PIP2 (Study 2, PIP2) and PIP3 (Study 3, PIP3)

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 January 2029
Deferral for one or more measures contained in the paediatric investigation plan:	Yes