EMA/112003/2013

European Medicines Agency decision

P/0053/2013

of 20 March 2013

on the acceptance of a modification of an agreed paediatric investigation plan for vedolizumab (EMEA-000645-PIP01-09-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 vedolizumab (EMEA-000645-PIP01-09-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/145/2010 issued on 30 July 2010,

Having regard to the application submitted by Takeda Global Research & Development Centre (Europe) Ltd on 10 December 2012 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 8 February 2013, 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 vedolizumab, powder for concentrate for solution for infusion, intravenous 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 Takeda Global Research & Development Centre (Europe) Ltd, 61 Aldwych, London WC2B 4AE, United Kingdom.

Done at London, 20 March 2013

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/54912/2013

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

EMEA-000645-PIP01-09-M01

Scope of the application

Active substance(s):

Vedolizumab

Condition(s):

Treatment of Crohn's disease

Treatment of ulcerative colitis

Pharmaceutical form(s):

Powder for concentrate for solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Takeda Global Research & Development Centre (Europe) Ltd

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Takeda Global Research & Development Centre (Europe) Ltd submitted to the European Medicines Agency on 10 December 2012 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/145/2010 issued on 30 July 2010.

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

The procedure started on 16 January 2013.

Scope of the modification

The standard term for the pharmaceutical form was modified.

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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.

London, 8 February 2013

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

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

1. Waiver

1.1. Condition: Treatment of Crohn's disease

The waiver applies to:

- children from birth to less than 4 years,
- for powder for concentrate for solution for infusion, intravenous use,
- on the grounds that the specific medicinal product is likely to be unsafe.

1.2. Condition: Treatment of ulcerative colitis

The waiver applies to:

- children from birth to less than 4 years,
- for powder for concentrate for solution for infusion, intravenous use,
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric Investigation Plan

2.1. Condition: Treatment of Crohn's disease

2.1.1. Indication(s) targeted by the PIP

Treatment of moderately to severely active Crohn's disease.

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

- From 4 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Powder for concentrate for solution for infusion.

2.1.4. Measures

Area	Number of measures	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	2	Measure 1 Dose-ranging study to determine the pharmacokinetics, pharmacodynamics, safety, and tolerability of vedolizumab in paediatric patients with inflammatory bowel disease.

Area	Number of measures	Description
		Measure 2 Randomised, double-blind, placebo-controlled two-dose, three-arm, multicentre study of the induction and maintenance of clinical response and remission by vedolizumab in paediatric patients with moderate to severe Crohn's disease.

2.2. Condition: Treatment of ulcerative colitis

2.2.1. Indication(s) targeted by the PIP

Treatment of moderately to severely active ulcerative colitis.

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

From 4 to less than 18 years of age.

2.2.3. Pharmaceutical form(s)

Powder for concentrate for solution for infusion.

2.2.4. Measures

Area	Number of measures	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	2	Measure 1 Dose-ranging study to determine the pharmacokinetics, pharmacodynamics, safety, and tolerability of vedolizumab in paediatric patients with inflammatory bowel disease – Same study as for condition Crohn's disease. Measure 3 Randomised, double-blind, placebo-controlled two-dose, three-arm, multicentre study of the induction and maintenance of clinical response and remission by vedolizumab in paediatric patients with moderate to severe ulcerative colitis.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By September 2021
Deferral for one or more measures contained in the paediatric investigation plan:	Yes