EMA/771133/2017

European Medicines Agency decision

P/0397/2017

of 19 December 2017

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for brazikumab (EMEA-001929-PIP01-16) 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 agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for brazikumab (EMEA-001929-PIP01-16) 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 application submitted by MedImmune Ltd (Affiliate of AstraZeneca AB) on 18 March 2016 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 10 November 2017, in accordance with Article 17 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 brazikumab, solution for injection, solution for infusion, subcutaneous use, intravenous 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 brazikumab, solution for injection, solution for infusion, subcutaneous use, intravenous 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 brazikumab, solution for injection, solution for infusion, subcutaneous use, intravenous 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 Allergan Limited, Marlow International Parkway, SL71YL - Marlow, United Kingdom.

EMA/PDCO/254990/2016
London, 10 November 2017

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

EMEA-001929-PIP01-16

Scope of the application

Active substance(s):

Brazikumab

Condition(s):

Treatment of Crohn's disease

Treatment of ulcerative colitis

Pharmaceutical form(s):

Solution for injection

Solution for infusion

Route(s) of administration:

Subcutaneous use

Intravenous use

Name/corporate name of the PIP applicant:

Allergan Limited

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Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, MedImmune Ltd (Affiliate of AstraZeneca AB) submitted for agreement to the European Medicines Agency on 18 March 2016 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 26 April 2016.

Supplementary information was provided by the applicant on 21 August 2017. The applicant proposed modifications to the paediatric investigation plan.

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 17(1) 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 Crohn's disease

The waiver applies to:

- the paediatric population from birth to less than 2 years;
- solution for injection, solution for infusion, subcutaneous, intravenous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

1.2. Condition

Treatment of ulcerative colitis

The waiver applies to:

- the paediatric population from birth to less than 2 years;
- solution for injection, solution for infusion, subcutaneous, intravenous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric investigation plan

2.1. Condition

Treatment of Crohn's disease

2.1.1. Indication(s) targeted by the PIP

Treatment of Crohn's disease

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

From 2 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for injection

Solution for infusion

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable.

Non-clinical studies	0	Not applicable.
Clinical studies	2	**Study 1** Open-label, multiple-ascending repeat-dose study to evaluate the safety and tolerability, pharmacokinetics, and pharmacodynamics, of brazikumab in children and adolescents from 2 to less than 18 years with Crohn's disease and ulcerative colitis. **Study 2** Open-label, repeat-dose safety and efficacy study, with a reference tumour necrosis factor alpha antagonist (anti-TNF-alpha) arm, in children and adolescents from 2 to less than 18 years with Crohn's disease receiving brazikumab every 4 weeks for 48 weeks.
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

2.2. Condition

Treatment of ulcerative colitis

2.2.1. Indication(s) targeted by the PIP

Treatment of ulcerative colitis

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

From 2 years to less than 18 years of age

2.2.3. Pharmaceutical form(s)

Solution for injection

Solution for infusion

2.2.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	0	Not applicable.

Clinical studies	2	**Study 1** *As for condition treatment of Crohn's disease.* **Study 3** Open-label, repeat-dose safety and efficacy study, with a reference tumour necrosis factor alpha antagonist (anti-TNF-alpha) arm, in children and adolescents from 2 to less than 18 years with ulcerative colitis receiving brazikumab every 4 weeks for 48 weeks.
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/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By July 2030
Deferral for one or more measures contained in the paediatric investigation plan:	Yes