EMA/139282/2016

European Medicines Agency decision

P/0066/2016

of 18 March 2016

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for romosozumab (EMEA-001075-PIP04-15) 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 application submitted by Amgen Europe B.V. on 13 March 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 29 January 2016, 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 romosozumab, solution for injection, subcutaneous 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 romosozumab, solution for injection, subcutaneous 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 romosozumab, solution for injection, subcutaneous 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 Amgen Europe B.V., Minervum 7061, 4817-ZK Breda -The Netherlands.

Done at London, 18 March 2016

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

EMA/PDCO/779084/2015
London, 29 January 2016

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

EMEA-001075-PIP04-15

Scope of the application

Active substance(s):

Romosozumab

Condition(s):

Treatment of osteoporosis

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Amgen Europe B.V.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Amgen Europe B.V. submitted for agreement to the European Medicines Agency on 13 March 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 21 April 2015.

Supplementary information was provided by the applicant on 06 November 2015

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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)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population.

   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 osteoporosis

The waiver applies to:

The request for the waiver applied to:

- the paediatric population from birth to less than 5 years;
- solution for injection, subcutaneous use;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric investigation plan

2.1. Condition:

Treatment of osteoporosis

2.1.1. Indication(s) targeted by the PIP

Osteogenesis imperfecta

Glucocorticoid induced osteoporosis

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

Osteogenesis imperfecta: from 5 years to less than 18 years of age

Glucocorticoid induced osteoporosis: from 10 years 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	1	**Study 1** Development of an age appropriate pharmaceutical form.
Non-clinical studies	0	Not applicable.
Clinical studies	4	**Study 2** Randomised, double-blind, placebo-controlled, ascending multiple dose study to evaluate the safety, pharmacokinetics (PK) and pharmacodynamics (PD) of romosozumab in paediatric patients from 5 to less than 18 years of age with osteogenesis imperfecta (OI). **Study 3** Randomised, double-blind, placebo controlled study to evaluate the efficacy and safety of romosozumab in children with osteoporosis imperfecta (OI) in paediatric patients from 5 to less than 18 years of age. **Study 4** Randomised, double-blind, placebo-controlled, ascending multiple dose study to evaluate the safety, pharmacokinetics (PK) and

Area	Number of measures	Description
		pharmacodynamics (PD) of romosozumab in paediatric patients from 10 to less than 18 of age with glucocorticoid induced osteoporosis (GIOP). **Study 5** Randomised, double-blind, placebo-controlled study to evaluate the efficacy and safety of romosozumab compared to placebo in paediatric patients from 10 to less than 18 years of age with glucocorticoid-induced osteoporosis (GIOP).

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By May 2027
Deferral for one or more measures contained in the paediatric investigation plan:	Yes