EMA/621656/2019

European Medicines Agency decision

P/0395/2019

of 4 December 2019

on the granting of a product specific waiver for a fully humanized immunoglobulin G4 proline, alanine, alanine (IgG4 PAA) based bispecific antibody directed against cluster of differentiation 3 (CD3) receptor complex and G Protein Coupled Receptor Family C Group 5 Member D (GPRC5D) (JNJ-64407564) (EMEA-002615-PIP01-19) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 Janssen-Cilag International N.V. on 12 July 2019 under Article 13 of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 18 October 2019 in accordance with Article 13 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee has given an opinion on the granting of a product specific waiver.

(2) It is therefore appropriate to adopt a decision granting a waiver.

Has adopted this decision:

Article 1

A waiver for a fully humanized immunoglobulin G4 proline, alanine, alanine (IgG4 PAA) based bispecific antibody directed against cluster of differentiation 3 (CD3) receptor complex and G Protein Coupled Receptor Family C Group 5 Member D (GPRC5D) (JNJ-64407564), solution for injection / 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 2

This decision is addressed to Janssen-Cilag International N.V., Turnhoutseweg 30, B-2340 Beerse, Belgium.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

EMA/PDCO/467330/2019
Amsterdam, 18 October 2019

Opinion of the Paediatric Committee on the granting of a product-specific waiver

EMEA-002615-PIP01-19

Scope of the application

Active substance(s):

A fully humanized immunoglobulin G4 proline, alanine, alanine (IgG4 PAA) based bispecific antibody directed against cluster of differentiation 3 (CD3) receptor complex and G Protein Coupled Receptor Family C Group 5 Member D (GPRC5D) (JNJ-64407564)

Condition(s):

Treatment of multiple myeloma

Pharmaceutical form(s):

Solution for injection / infusion

Route(s) of administration:

Subcutaneous use

Intravenous use

Name/corporate name of the PIP applicant:

Janssen-Cilag International N.V.

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Janssen-Cilag International N.V. submitted to the European Medicines Agency on 12 July 2019 an application for a product-specific waiver on the grounds set out in Article 11 of said Regulation for the above mentioned medicinal product.

The procedure started on 20 August 2019.

Opinion

1. The Paediatric Committee, having assessed the waiver application in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to grant a product-specific waiver for all subsets of the paediatric population and the above mentioned condition(s) in accordance with Article 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended occurs only in adult populations.

   The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The grounds for the granting of the waiver are set out in 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

Grounds for the granting of the waiver

1. Waiver

1.1. Condition:

Treatment of multiple myeloma

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- solution for injection / infusion, subcutaneous use and intravenous 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).