



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/284200/2015

## European Medicines Agency decision

P/0106/2015

of 13 May 2015

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for humanised monoclonal antibody IgG2 recognising the interleukin-31 receptor A (CIM331) (EMA-001624-PIP01-14) 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<sup>1</sup>,

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<sup>2</sup>,

Having regard to the application submitted by Chugai Pharma Europe Ltd. on 9 April 2014 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 17 April 2015, 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.

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<sup>1</sup> OJ L 378, 27.12.2006, p.1.

<sup>2</sup> OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

**Article 1**

A paediatric investigation plan for humanised monoclonal antibody IgG2 recognising the interleukin-31 receptor A (CIM331), powder for 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 humanised monoclonal antibody IgG2 recognising the interleukin-31 receptor A (CIM331), powder for 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 humanised monoclonal antibody IgG2 recognising the interleukin-31 receptor A (CIM331), powder for 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 Chugai Pharma Europe Ltd., Mulliner House, Flanders Road, Turnham Green, W4 1NN – London, United Kingdom.

Done at London, 13 May 2015

For the European Medicines Agency  
Jordi Llinares Garcia  
Head of Division (ad interim)  
Human Medicines Research and Development Support  
(Signature on file)

EMA/PDCO/82509/2015

London, 17 April 2015

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

EMA-001624-PIP01-14

### Scope of the application

**Active substance(s):**

Humanised monoclonal antibody IgG2 recognising the interleukin-31 receptor A (CIM331)

**Condition(s):**

Treatment of atopic dermatitis

**Pharmaceutical form(s):**

Powder for solution for injection

**Route(s) of administration:**

Subcutaneous use

**Name / corporate name of the PIP applicant:**

Chugai Pharma Europe Ltd.

### Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Chugai Pharma Europe Ltd. submitted for agreement to the European Medicines Agency on 9 April 2014 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 May 2014.

Supplementary information was provided by the applicant on 26 January 2015. 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 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)(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 Icelandic and the Norwegian Paediatric Committee members agree 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 atopic dermatitis

The waiver applies to:

- the paediatric population from birth to less than 2 years;
- powder for solution for injection, subcutaneous use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

## 2. Paediatric investigation plan

### 2.1. Condition:

Treatment of atopic dermatitis

#### 2.1.1. Indication(s) targeted by the PIP

Treatment of atopic dermatitis

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

From 2 to less than 18 years of age.

#### 2.1.3. Pharmaceutical form(s)

Powder for solution for injection

#### 2.1.4. Measures

| Area                    | Number of measures | Description                                                                                                                                                                                      |
|-------------------------|--------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Quality-related studies | 1                  | <b>Study 1</b><br>Development of age-appropriate pharmaceutical form.                                                                                                                            |
| Non-clinical studies    | 1                  | <b>Study 2</b><br>Study to evaluate the effects on pre- and postnatal development in cynomolgus monkeys and to assess the systemic exposure in dams and offspring along with milk concentrations |
| Clinical studies        | 7                  | <b>Study 3</b><br>Placebo-controlled, randomized, multicentre, study to evaluate efficacy and safety of CIM331.                                                                                  |

| Area                                            | Number of measures | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-------------------------------------------------|--------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                 |                    | <p><b>Study 4</b></p> <p>Placebo-controlled, randomized, multicentre, study to evaluate efficacy and safety of CIM331.</p> <p><b>Study 5</b></p> <p>Single arm, open label, long-term study to evaluate efficacy and safety of CIM331.</p> <p><b>Study 6</b></p> <p>Single arm, open label, long-term study to evaluate efficacy and safety of CIM331.</p> <p><b>Study 7</b></p> <p>Randomised, double-blind, placebo-controlled, multicentre, single dose study to evaluate systemic exposure and tolerability profile of CIM331.</p> <p><b>Study 8</b></p> <p>Single arm, open label, repeat dose extension study</p> <p><b>Study 9</b></p> <p>Single arm, open label, long-term study</p> |
| Extrapolation, modelling and simulation studies | 1                  | <p><b>Study 10</b></p> <p>1-compartment model with 1st order absorption (PK)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 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: | Yes         |
| Date of completion of the paediatric investigation plan:                              | By May 2022 |
| Deferral for one or more measures contained in the paediatric investigation plan:     | Yes         |