EMA/71529/2021

# European Medicines Agency decision

P/0078/2021

of 17 March 2021

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for bimekizumab (EMEA-002189-PIP04-20) 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.**

# European Medicines Agency decision

P/0078/2021

of 17 March 2021

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for bimekizumab (EMEA-002189-PIP04-20) 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 UCB Biopharma SRL on 15 May 2020 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 2021, 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 bimekizumab, 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 bimekizumab, 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 bimekizumab, 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 covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/0193/2018 issued on 17 July 2018, including subsequent modifications thereof.

***Article 5***

This decision is addressed to UCB Biopharma SRL, Allée de la Recherche 60, 1070 – Brussels, Belgium.

EMA/PDCO/584259/2020 Corr
Amsterdam, 29 January 2021

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

EMEA-002189-PIP04-20

## Scope of the application

**Active substance(s):**

Bimekizumab

**Condition(s):**

Treatment of hidradenitis suppurativa

**Pharmaceutical form(s):**

Solution for injection

**Route(s) of administration:**

Subcutaneous use

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

UCB Biopharma SRL

## Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, UCB Biopharma SRL submitted for agreement to the European Medicines Agency on 15 May 2020 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 6 July 2020.

Supplementary information was provided by the applicant on 23 October 2020. 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 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) 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 hidradenitis suppurativa

The waiver applies to:

- the paediatric population prior to onset of puberty (Tanner stage less than 2);
- solution for injection, subcutaneous 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).

# 2. Paediatric investigation plan

## *2.1. Condition:*

Treatment of hidradenitis suppurativa

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

Treatment of moderate to severe hidradenitis suppurativa (acne inversa) in adolescents, and in children with Tanner stage ≥2

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

From onset of puberty (Tanner stage 2) 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 | 0 | Not applicable. |
| Non-clinical studies | 0 | Not applicable. |
| Clinical studies | 1 | **Study 1 (HS0006)**<br>Open-label study in paediatric patients up to 18 years of age at Tanner pubertal stage 2 or greater with moderate to severe hidradenitis suppurativa to provide pharmacokinetic (PK) data to support the extrapolation of efficacy of bimekizumab from adults, with an extension period to evaluate safety. |

| Area | Number of measures | Description |
|---|---|---|
| Extrapolation, modelling and simulation studies | 1 | **Study 2**<br>Modelling and simulation study for bimekizumab in paediatric patients up to 18 years of age at Tanner pubertal stage 2 or greater with moderate to severe hidradenitis suppurativa. |
| 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 November 2030 |
| Deferral for one or more measures contained in the paediatric investigation plan: | Yes |