EMA/21184/2023

European Medicines Agency decision

P/0037/2023

of 31 January 2023

on the refusal of a modification of an agreed paediatric investigation plan and on the granting of a product-specific waiver for lanadelumab (Takhzyro), (EMEA-001864-PIP03-19-M01) 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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0476/2020 issued on 1 December 2020,

Having regard to the application submitted by Takeda Pharmaceuticals International AG Ireland Branch on 9 September 2022 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 16 December 2022, in accordance with Article 22 of Regulation (EC) No 1901/2006 and of its own motion in accordance with Article 12 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 refusal of changes to the agreed paediatric investigation plan and to the deferral and on the granting of a product-specific waiver.

(2) It is therefore appropriate to adopt a decision on the refusal of changes to the agreed paediatric investigation plan, including changes to the deferral.

(3) It is therefore appropriate to adopt a decision granting a product-specific waiver.

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

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for lanadelumab (Takhzyro), solution for injection, subcutaneous use, including changes to the deferral, 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, are hereby refused.

Article 2

A product-specific waiver for lanadelumab (Takhzyro), solution for injection, subcutaneous use, the details of which are set out in the opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to Takeda Pharmaceuticals International AG Ireland Branch, Block 2 Miesian Plaza, 50-58 Baggot Street Lower, D02 HW68 - Dublin 2, Ireland.

EMA/PDCO/773920/2022
Amsterdam, 16 December 2022

Opinion of the Paediatric Committee on the refusal of a modification of an agreed Paediatric Investigation Plan and on the granting of a product-specific waiver

EMEA-001864-PIP03-19-M01

Scope of the application

Active substance(s):

Lanadelumab

Invented name and authorisation status:

See Annex II

Condition(s):

Prevention of attacks of idiopathic non-histaminergic angioedema

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Takeda Pharmaceuticals International AG Ireland Branch

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Takeda Pharmaceuticals International AG Ireland Branch submitted to the European Medicines Agency on 9 September 2022 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/0476/2020 issued on 1 December 2020.

The application for modification proposed changes to the agreed paediatric investigation plan and to the waiver.

The procedure started on 17 October 2022.

Scope of the modification

The waiver has been extended to cover all subsets of the paediatric population.

Opinion

The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to refuse the changes proposed by the applicant regarding the paediatric investigation plan and the scope of the waiver and in accordance with Article 12 of Regulation (EC) No 1901/2006 as amended,

And in accordance with Article 12 of Regulation (EC) No 1901/2006 as amended, recommends to grant a product-specific waiver of its own motion for all subsets of the paediatric population 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 Paediatric Committee members of Liechtenstein and Norway agree with the above-mentioned recommendation of the Paediatric Committee.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes 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:

Prevention of attacks of idiopathic non-histaminergic angioedema

The waiver applies to:

- the paediatric population from birth to less than 18 years of age;
- 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).

Annex II

Information about the authorised medicinal product

Information provided by the applicant

Condition(s) and authorised indication(s):

1. Prevention of hereditary angioedema attacks

Authorised indication(s):

- Takhzyro is indicated for routine prevention of recurrent attacks of hereditary angioedema (HAE) in patients aged 12 years and older.

Authorised pharmaceutical form(s):

Solution for injection.

Authorised route(s) of administration:

Subcutaneous use