EMADOC-1700519818-2035629

# European Medicines Agency decision

EMEA-002183-PIP03-23

of 14 April 2025

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for imlifidase 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

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on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for imlifidase in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 application submitted by Hansa Biopharma AB on 30 June 2023 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 28 February 2025, 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, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

***Article 1***

A paediatric investigation plan for imlifidase, 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 imlifidase, 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 imlifidase, 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/0229/2018 issued on 30 July 2018, including subsequent modifications thereof.

***Article 5***

This decision is addressed to Hansa Biopharma AB, Scheelevagen 22, Lunds Allhelgonafors, 223 63 - Lund Skane Lan, Sweden.

EMADOC-1700519818-1761008 Corr[1]
Amsterdam, 28 February 2025

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

EMEA-002183-PIP03-23

## Scope of the application

**Active substance(s):**

Imlifidase

**Invented name and authorisation status:**

See Annex II

**Condition(s):**

Treatment of glomerulonephritis and nephrotic syndrome

**Pharmaceutical form(s):**

Powder for concentrate for solution for infusion

**Route(s) of administration:**

Intravenous use

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

Hansa Biopharma AB

## Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Hansa Biopharma AB submitted for agreement to the European Medicines Agency on 30 June 2023 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 14 August 2023.

[1] 7 April 2025.

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Supplementary information was provided by the applicant on 24 October 2024. 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 13 of said Regulation and concluded in accordance with Article 11(1)(c) of Regulation (EC) No 1901/2006 as amended, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

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

2. The measures and timelines of the agreed paediatric investigation plan 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 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:*

Treatment of glomerulonephritis and nephrotic syndrome

The waiver applies to:

- the paediatric population from birth to less than 1 year of age;
- powder for concentrate for solution for infusion, intravenous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

# 2. Paediatric investigation plan

## *2.1. Condition:*

Treatment of glomerulonephritis and nephrotic syndrome

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

Treatment of anti–glomerular basement membrane (anti-GBM) disease

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

From one year to less than 18 years of age.

### 2.1.3. Pharmaceutical form(s)

Powder for concentrate for solution for infusion.

### 2.1.4. Measures

| Area | Description |
|---|---|
| Quality-related studies | Not applicable |
| Non-clinical studies | Not applicable |
| Clinical studies | Study 1<br>Open-label, controlled, randomised, multi-centre trial comparing imlifidase and standard-of-care with standard-of-care alone in the treatment of severe anti-GBM antibody disease (Goodpasture disease) in paediatric patients from one year to less than 18 years of age (and adults) |
| Modelling and simulation analyses | Study 2<br>PK/PD modelling and simulation analyses in support of dose determination and extrapolation of efficacy of imlifidase in paediatric |

| | |
|---|---|
| | patients from one year to less than 18 years of age with severe anti-GBM antibody disease (Goodpasture disease). |
| Other studies | Not applicable |
| Extrapolation plan | Studies 1,2 are part of an extrapolation plan covering the paediatric population from 1 year to less than 18 years of age, as agreed by the PDCO. |

# 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 June 2030 |
| Deferral for one or more measures contained in the paediatric investigation plan: | Yes |

# Annex II

# Information about the authorised medicinal product

# Information about the authorised medicinal product

## Condition(s) and authorised indication(s):

1. Prevention of graft rejection following solid organ transplantation.

Authorised indication(s):

- Desensitisation treatment of highly sensitised adult kidney transplant patients with positive crossmatch against an available deceased donor. The use of Idefirix should be reserved for patients unlikely to be transplanted under the available kidney allocation system including prioritisation programmes for highly sensitised patients.

## Authorised pharmaceutical form(s):

- Powder for concentrate for solution for infusion (powder for concentrate)

## Authorised route(s) of administration:

- Intravenous use