

EMA/287380/2023

European Medicines Agency decision P/0247/2023

of 14 July 2023

on the agreement of a paediatric investigation plan and on the granting of a deferral for spesolimab (Spevigo), (EMA-002475-PIP03-22) 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 726/2004¹,

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 Agency²,

Having regard to the application submitted by Boehringer Ingelheim International GmbH on 8 August 2022 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 26 May 2023, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 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.
- (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.

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 spesolimab (Spevigo), solution for injection, solution for 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 agreed.

Article 2

A deferral for spesolimab (Spevigo), solution for injection, solution for 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 3

This decision covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/0195/2020 issued on 15 May 2020, including subsequent modifications thereof.

Article 4

This decision is addressed to Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 - Ingelheim am Rhein, Germany.

EMA/PDCO/88989/2023 Corr¹
Amsterdam, 26 May 2023

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

EMA-002475-PIP03-22

Scope of the application

Active substance(s):

Spesolimab

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of Netherton syndrome

Pharmaceutical form(s):

Solution for injection

Solution for infusion

Route(s) of administration:

Subcutaneous use

Intravenous use

Name/corporate name of the PIP applicant:

Boehringer Ingelheim International GmbH

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Boehringer Ingelheim International GmbH submitted for agreement to the European Medicines Agency on 8 August 2022 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 12 September 2022.

¹ 12 July 2023

Supplementary information was provided by the applicant on 20 February 2023.

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.

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 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 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

Not applicable

2. Paediatric investigation plan

2.1. Condition:

Treatment of Netherton syndrome

2.1.1. Indication(s) targeted by the PIP

Treatment of patients with Netherton syndrome

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

From birth to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for injection

Solution for infusion

2.1.4. Measures

Area	Description
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	Study 1 (1368-0104) Double-blind, randomised, placebo-controlled trial to evaluate pharmacokinetics, safety, and efficacy of spesolimab in children from 12 years to less than 18 years of age (and adults) with Netherton syndrome. Study 2 (1368-NS-Ped1) Open-label non-randomised uncontrolled trial to evaluate safety, pharmacokinetics and immunogenicity of spesolimab in children from birth to less than 12 years of age with Netherton syndrome.
Modelling and simulation studies	Study 3 Modelling and simulation study to evaluate the adequacy of dose of spesolimab in the treatment of Netherton syndrome in children from 12 years to less than 18 years of age with Netherton syndrome. Study 4

	Modelling and simulation study to inform the design of Study 2 (spesolimab in the treatment of Netherton syndrome in children from birth to less than 12 years of age with Netherton syndrome) Study 5 Modelling and simulation study to evaluate the adequacy of dose of spesolimab in the treatment of Netherton syndrome in children from birth to less than 12 years of age with Netherton syndrome.
Other studies	Not applicable
Extrapolation plan	Studies 1, 2 ,3, 4, 5 are part of an extrapolation plan covering the paediatric population from birth to less than 12 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 September 2033
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Condition(s) and authorised indication(s)

1. Treatment of Generalised Pustular Psoriasis (GPP)

Authorised indication(s):

Spevigo is indicated for the treatment of flares in adult patients with generalised pustular psoriasis (GPP) as monotherapy.

- Invented name(s): Spevigo
- Authorised pharmaceutical form(s): concentrate for solution for infusion (sterile concentrate)
- Authorised route(s) of administration: intravenous infusion
- Authorised via centralised procedure