EMA/555066/2023

European Medicines Agency decision

P/0516/2023

of 29 December 2023

on the agreement of a paediatric investigation plan and on the granting of a waiver for 3-(4-acetamidophenyl)-2-(S)-methoxypropionic acid, or (S)-3-(4-acetamidophenyl)-2-methoxypropanoic acid (N-Acetyl-GED-0507-34-LEVO) (EMEA-002674-PIP01-19) 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[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 Nogra Pharma Limited on 29 November 2019 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 10 November 2023, in accordance with Article 17 of Regulation (EC) No 1901/2006 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 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 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 3-(4-acetamidophenyl)-2-(S)-methoxypropionic acid, or (S)-3-(4-acetamidophenyl)-2-methoxypropanoic acid (N-Acetyl-GED-0507-34-LEVO), gel, cutaneous 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 waiver for 3-(4-acetamidophenyl)-2-(S)-methoxypropionic acid, or (S)-3-(4-acetamidophenyl)-2-methoxypropanoic acid (N-Acetyl-GED-0507-34-LEVO), gel, cutaneous 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 is addressed to Nogra Pharma Limited, 33 Sir John Rogerson's Quay, Dublin 2, D02 XK09 – Dublin, Ireland.

EMA/PDCO/374135/2023
Amsterdam, 10 November 2023

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

EMEA-002674-PIP01-19

Scope of the application

Active substance(s):

3-(4-acetamidophenyl)-2-(S)-methoxypropionic acid, or (S)-3-(4-acetamidophenyl)-2-methoxypropanoic acid (N-Acetyl-GED-0507-34-LEVO)

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of acne vulgaris

Pharmaceutical form(s):

Gel

Route(s) of administration:

Cutaneous use

Name/corporate name of the PIP applicant:

Nogra Pharma Limited

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Nogra Pharma Limited submitted for agreement to the European Medicines Agency on 29 November 2019 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 6 January 2020.

Supplementary information was provided by the applicant on 1 August 2023. 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 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 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 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 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 Acne Vulgaris

The waiver applies to:

- the paediatric population from birth to less than 9 years of age;
- gel, cutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies are not feasible.

2. Paediatric investigation plan

2.1. Condition:

Treatment of acne vulgaris

2.1.1. Indication(s) targeted by the PIP

Treatment of acne vulgaris in children and adolescents from 9 years to less than 18 years of age.

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

From 9 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Gel

2.1.4. Measures

Area	**Description**
Quality-related studies	Not applicable
Non-clinical studies	Study 1 (A2293) Definitive juvenile toxicity study over 13 weeks in the minipig Study 2 (A3462) Definitive juvenile toxicity study over 39 weeks in the minipig
Clinical studies	Study 3 (NAC-GED-0507-ACN-01-18) 3-arm (N-Acetyl-GED-0507-34-LEVO gel 2%, 5% and vehicle) multicentre, randomized, parallel-group, vehicle-controlled, double-blind efficacy and safety study in patients from 12 years to less than 18 years of age (and adults) with facial acne vulgaris. Study 4 (NAC-GED-0507-ACN-01-23-A)

	Multicentre, randomized, parallel-group, vehicle-controlled, double-blind efficacy and safety study of N-Acetyl-GED-0507-34-LEVO gel in patients from 9 years to less than 18 years of age (and adults) with acne vulgaris. Study 5 (NAC-GED-0507-ACN-01-23-B) Multicentre, randomized, parallel-group, vehicle-controlled, double-blind efficacy and safety study of N-Acetyl-GED-0507-34-LEVO gel in patients from 9 years to less than 18 years of age (and adults) with acne vulgaris. Study 6 (NAC-GED-0507-ACN-01-23-LT) Multicentre, open-label, non-comparative safety and activity study with up to 52 Weeks of treatment with N-Acetyl-GED-0507-34-LEVO gel on the face and trunk in patients from 9 years to less than 18 years of age (and adults) with acne vulgaris.
Modelling and simulation studies	Not applicable
Other studies	Not applicable
Extrapolation plan	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 October 2026
Deferral for one or more measures contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.