EMA/178739/2024

European Medicines Agency decision

P/0170/2024

of 6 May 2024

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for tanimilast (EMEA-003393-PIP01-23) 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 Chiesi Farmaceutici S.p.A. on 20 January 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 22 March 2024, 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 tanimilast, inhalation powder, inhalation 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 tanimilast, inhalation powder, inhalation 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 tanimilast, inhalation powder, inhalation 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 is addressed to Chiesi Farmaceutici S.p.A., via Palermo 26/A, 43122 Parma, Italy.

EMA/PDCO/13892/2024
Amsterdam, 22 March 2024

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

EMEA-003393-PIP01-23

Scope of the application

Active substance(s):

Tanimilast

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of asthma

Pharmaceutical form(s):

Inhalation powder

Route(s) of administration:

Inhalation use

Name/corporate name of the PIP applicant:

Chiesi Farmaceutici S.p.A.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Chiesi Farmaceutici S.p.A. submitted for agreement to the European Medicines Agency on 20 January 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 27 February 2023.

Supplementary information was provided by the applicant on 18 December 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 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 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 asthma

The waiver applies to:

- the paediatric population from birth to less than 6 years of age;
- inhalation powder, inhalation use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric investigation plan

2.1. Condition:

Treatment of asthma

2.1.1. Indication(s) targeted by the PIP

Add-on maintenance treatment for asthmatic patients (aged 6 years to <12 years) inadequately controlled (symptomatic) despite medium/high-dose inhaled corticosteroids / long acting β2 agonist (ICS / LABA) combinations.

Add-on maintenance treatment for asthmatic patients (aged 12 years to <18 years) inadequately controlled (symptomatic) despite medium/high-dose ICS combinations (ICS / LABA with or without long acting muscarinic antagonist (LAMA)).

Alternative stand-alone treatment for asthmatic patients (aged 6 years to <18 years) well controlled on daily low dose ICS

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

From 6 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Inhalation powder

2.1.4. Measures

Area	Description
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	**Study 1** Open label, non-randomised, single dose PK/PD study in adolescent asthmatic patients from 12 to less than 18 years

	of age (and adults) to evaluate the pharmacokinetic profile of tanimilast after oral inhalation with NEXThaler device. **Study 2** Randomised, double-blind, placebo-controlled, 3-arm parallel group multinational, multicentre study to assess the efficacy of two doses of tanimilast compared to placebo as add-on background therapy [add-on to maintenance medium dose Inhaled corticosteroids/ Long acting β2 agonist (ICS / LABA) combination with or without Long acting muscarinic antagonist (LAMA) therapy] in reducing the rate of severe asthma exacerbations over the 52-week period of treatment in adolescents from 12 years to less than 18 years of age (and adults) with uncontrolled asthma on medium dose ICS/LABA ± LAMA combination therapy. **Study 3** Randomised, double-blind, placebo-controlled, 3-arm parallel group multinational, multicentre study to assess the efficacy of two doses of tanimilast compared to placebo as add-on background therapy [add-on to maintenance high dose Inhaled corticosteroids/ Long acting β2 agonist (ICS / LABA) combination with or without Long acting muscarinic antagonist (LAMA) therapy] in reducing the rate of severe asthma exacerbations over the 52-week period of treatment in adolescents from 12 years to less than 18 years of age (and adults) with uncontrolled asthma on high dose ICS/LABA ± LAMA combination therapy. **Study 4** Pharmacokinetic study to evaluate the pharmacokinetic profile of tanimilast after oral inhalation of one or two doses with NEXThaler device in asthmatic children from 6 years to less than 12 years of age. **Study 5** 52 week, double-blind, randomised, placebo controlled, multinational, multicentre, 2-arm, parallel group efficacy and safety trial comparing tanimilast to placebo on top of standard of care therapy in terms of rate of severe asthma exacerbations over 52 weeks in children from 6 years to less than 12 years of age with uncontrolled asthma despite treatment with medium-high ICS dose (per GINA guidelines) combined with LABA. **Study 6** Randomised, double-blind, , placebo-controlled, 3-arm parallel group efficacy and safety study in children and adolescents from 6 years to less than 18 years of age with

	mild asthma that is well-controlled on a stable, low-dose inhaled corticosteroids (ICS) to compare the use of tanimilast against ICS and placebo.
Modelling and simulation analyses	**Study 7** Population PK study to support use of tanimilast in children and adolescents with asthma.
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 September 2035
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:

The product is not authorised anywhere in the European Community.