EMA/215516/2019

European Medicines Agency decision

P/0129/2019

of 17 April 2019

on the acceptance of a modification of an agreed paediatric investigation plan for inebilizumab (EMEA-001911-PIP01-15-M02) 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

P/0129/2019

of 17 April 2019

on the acceptance of a modification of an agreed paediatric investigation plan for inebilizumab (EMEA-001911-PIP01-15-M02) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0344/2016 issued on 2 December 2016 and the decision P/0136/2018 issued on 7 May 2018,

Having regard to the application submitted by Viela Bio on 20 November 2018 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 1 March 2019, in accordance with Article 22 of Regulation (EC) No 1901/2006,

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 acceptance of changes to the agreed paediatric investigation plan.

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

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

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for inebilizumab, solution for infusion, intravenous use, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Viela Bio, One MedImmune Way, 20878 – Gaithersburg, United States.

EMA/PDCO/836830/2018
London, 1 March 2019

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-001911-PIP01-15-M02

Scope of the application

Active substance(s):

Inebilizumab

Condition(s):

Treatment of neuromyelitis optica spectrum disorders

Pharmaceutical form(s):

Solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Viela Bio

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Viela Bio submitted to the European Medicines Agency on 20 November 2018 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0344/2016 issued on 2 December 2016 and the decision P/0136/2018 issued on 7 May 2018.

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

The procedure started on 3 January 2019.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Scope of the modification

Some timelines of the Paediatric Investigation Plan have been modified.

Opinion

1. 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 agree to changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion.

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

2. The measures and timelines of the 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 annex 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 neuromyelitis optica spectrum disorders

The waiver applies to:

- the paediatric population from birth to less than 2 years of age;
- solution for infusion, intravenous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

2. Paediatric investigation plan

2.1. Condition:

Treatment of neuromyelitis optica spectrum disorders

2.1.1. Indication(s) targeted by the PIP

Maintenance treatment of patients with neuromyelitis optica spectrum disorders (NMOSD)

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

From 2 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for infusion

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of an age-appropriate IV formulation for the paediatric population from 2 years of age of age based on posology / dosing schedule established from the modelling and simulation study
Non-clinical studies	1	**Study 2** Reprotox: enhanced pre- and postnatal development in mice
Clinical studies	1	**Study 3** Open-label, uncontrolled trial to evaluate PK/PD and safety of inebilizumab in children from 2 to less than 18 years of age with neuromyelitis optica spectrum disorders

Extrapolation, modelling and simulation studies	2	**Study 4** Modelling and simulation study to determine the dose of inebilizumab in the treatment of neuromyelitis optica spectrum disorders in children from 2 to less than 18 years of age **Study 5** Analysis of existing data on efficacy, safety, pharmacodynamics and pharmacokinetics of inebilizumab to evaluate the use of the product in the treatment of neuromyelitis optica spectrum disorders in children from 2 to less than 18 years of age
Other studies	0	Not applicable
Other measures	0	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By May 2024
Deferral for one or more measures contained in the paediatric investigation plan:	Yes