EMA/18865/2021

European Medicines Agency decision

P/0057/2021

of 27 January 2021

on the acceptance of a modification of an agreed paediatric investigation plan for pitolisant (Wakix), (EMEA-001176-PIP01-11-M06) 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 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/0194/2012 issued on 24 August 2012, the decision P/0200/2013 issued on 2 September 2013, the decision P/0135/2016 issued on 20 May 2016, the decision P/0188/2018 issued on 17 July 2018, the decision P/0167/2020 issued on 27 April 2020 and the decision P/0298/2020 issued on 12 August 2020,

Having regard to the application submitted by Bioprojet Pharma on 11 September 2020 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 11 December 2020, 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 and to the deferral.

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

[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 pitolisant (Wakix), film-coated tablet, oral use, including changes to the deferral, 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 Bioprojet Pharma, 9 rue Rameau, 75002 - Paris, France.

EMA/PDCO/495392/2020
Amsterdam, 11 December 2020

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

EMEA-001176-PIP01-11-M06

Scope of the application

Active substance(s):

Pitolisant

Invented name:

Wakix

Condition(s):

Treatment of narcolepsy

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Film-coated tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Bioprojet Pharma

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Bioprojet Pharma submitted to the European Medicines Agency on 11 September 2020 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/0194/2012 issued on 24 August 2012, the decision P/0200/2013 issued on 2 September 2013, the decision P/0135/2016 issued on 20 May 2016, the decision P/0188/2018 issued on 17 July 2018, the decision P/0167/2020 issued on 27 April 2020 and the decision P/0298/2020 issued on 12 August 2020.

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

The procedure started on 13 October 2020.

Scope of the modification

Some measures and 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 and to the deferral 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 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 narcolepsy

The waiver applies to:

- all subsets of the paediatric population from birth to less than 6 years of age;
- film-coated tablet, oral use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric Investigation Plan

2.1. Condition:

Treatment of narcolepsy

2.1.1. Indication(s) targeted by the PIP

Treatment of narcolepsy with or without cataplexy

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

From 6 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Film-coated tablet

2.1.4. Measures

Area	Number of measures	Description
Quality	1	**Measure 1** Development of 2 tablets' strengths of 4.5 mg and 18 mg.
Non-clinical	1	**Measure 2** Neonatal and juvenile (pre and post weaning) toxicity study in the rat by the intraperitoneal route. (AB04616)
Clinical	2	**Measure 3** Multi-centre, single dose trial to evaluate pharmacokinetics of pitolisant in children from 6 to less than 18 years with narcolepsy. (P11-11) **Measure 4** Double blind, multicentre, randomised, placebo controlled trial to evaluate safety and efficacy of pitolisant in children from 6 to less than 18 years with narcolepsy with/without cataplexy. (P11-06)

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 January 2022
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of narcolepsy

Authorised indication(s):

- Treatment of narcolepsy with or without cataplexy in adults

Authorised pharmaceutical form(s):

Film-coated tablet

Authorised route(s) of administration:

Oral use