EMA/765283/2016

European Medicines Agency decision

P/0351/2016

of 2 December 2016

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for pimavanserin (EMEA-001688-PIP03-16) 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 application submitted by ACADIA Pharmaceuticals Inc. on 8 August 2016 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 11 November 2016, in accordance with Article 18 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.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

A paediatric investigation plan for pimavanserin, film-coated tablet, oral 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 pimavanserin, film-coated tablet, oral 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 pimavanserin, film-coated tablet, oral 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 2

This decision is addressed to ACADIA Pharmaceuticals Inc., 3611 Valley Centre Drive, Suite 300, 92130 - San Diego, California, USA.

EMA/PDCO/693447/2016 corr
London, 11 November 2016

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

EMEA-001688-PIP03-16

Scope of the application

Active substance(s):

Pimavanserin

Condition(s):

Treatment of schizophrenia and other psychotic disorders

Pharmaceutical form(s):

Film-coated tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

ACADIA Pharmaceuticals Inc.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, ACADIA Pharmaceuticals Inc. submitted for agreement to the European Medicines Agency on 8 August 2016 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 13 September 2016.

Supplementary information was provided by the applicant on 19 October 2016. The applicant proposed modifications to the paediatric investigation plan.

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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 18 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)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population.

   The Norwegian Paediatric Committee member 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 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 schizophrenia and other psychotic disorders

The waiver applies to:

- the paediatric population from birth to less than 13 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.

2. Paediatric investigation plan

2.1. Condition:

Treatment of schizophrenia and other psychotic disorders

2.1.1. Indication(s) targeted by the PIP

Treatment of schizophrenia

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

From 13 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-related studies	0	Not applicable.
Non-clinical studies	0	Not applicable.

Clinical studies	5	**Study 1** Pharmacokinetics, safety and tolerability study of pimavanserin in adolescents 13 to less than 18 years of age with a confirmed diagnosis of schizophrenia who are currently stable **Study 2** Randomised, double-blind, placebo-controlled, 6-week study evaluating the efficacy and safety of adjunctive pimavanserin in adolescents from 13 to less than18 years of age with a confirmed diagnosis of schizophrenia who have a suboptimal response to aripiprazole therapy **Study 3** 2-year open-label study evaluating the safety of adjunctive pimavanserin in adolescents from 13 to less than 18 years of age with a confirmed diagnosis of schizophrenia who have a suboptimal response to aripiprazole therapy **Study 5** Randomised, double-blind, placebo-controlled, 6-week study evaluating the efficacy and safety of pimavanserin monotherapy in adolescents from 13 to less than 18 years of age with a confirmed diagnosis of schizophrenia **Study 6** 2-year open-label study evaluating the safety of pimavanserin monotherapy in adolescents from 13 to less than 18 years of age with a confirmed diagnosis of schizophrenia
Extrapolation, modelling and simulation studies	2	**Study 4** Extrapolation study based on data from pimavanserin adult and paediatric studies and literature to support the maintenance of antipsychotic effect of adjunctive pimavanserin in adolescent schizophrenia **Study 7** Extrapolation study based on data from pimavanserin adult and paediatric studies and literature to support the maintenance of antipsychotic effect of pimavanserin monotherapy in adolescent schizophrenia
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:	No
Date of completion of the paediatric investigation plan:	By September 2029
Deferral for one or more measures contained in the paediatric investigation plan:	Yes