European Medicines Agency

Doc. Ref. EMEA/695125/2009
P/233/2009

EUROPEAN MEDICINES AGENCY DECISION

of 27 November 2009

on the acceptance of a modification of an agreed Paediatric Investigation Plan for asenapine maleate (EMEA-000228-PIP01-08-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006, as amended.

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THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

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 as amended 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 decision P/29/2009 of the European Medicines Agency on 23 February 2009,

Having regard to the application submitted by N.V. Organon on 7 August 2009 under Article 22 of Regulation (EC) No 1901/2006 as amended proposing changes to the agreed Paediatric Investigation Plan,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 16 October 2009, in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended,

Having regard to Article 25 of Regulation (EC) No 1901/2006 as amended,

WHEREAS:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to an agreed Paediatric Investigation Plan,

(2) It is therefore appropriate to adopt a Decision on the acceptance of changes to an 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 asenapine maleate, sublingual tablets, 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, are hereby accepted.

Article 2

This decision, that supersedes previous decision of the European Medicines Agency P/29/2009, as far as the agreed changes to the PIP for asenapine maleate, are concerned, is addressed to N.V. Organon, Kloosterstraat 6, 5349 AB – Oss, The Netherlands.

Done at London, 27 November 2009

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

Doc. Ref. EMEA/PDCO/628331/2009
EMEA-000228-PIP01-08-M01

OPINION OF THE PAEDIATRIC COMMITTEE ON THE ACCEPTANCE OF A MODIFICATION OF AN AGREED PAEDIATRIC INVESTIGATION PLAN

Scope of the application

Active substance(s):
Asenapine maleate

Condition(s):
Schizophrenia
Bipolar I disorder

Pharmaceutical form(s):
Sublingual tablets

Route(s) of administration:
Oral use

Name/corporate name of the PIP applicant:
N.V. Organon

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, N.V. Organon submitted to the EMEA on 7 August 2009 an application for modification of the agreed paediatric investigation plan as set out in the EMEA decision P/29/2009 of 23 February 2009. The application for modification proposed changes.

The procedure started on 20 August 2009.

Scope of the modification

Changes in the timelines and details of studies to be performed for the condition Schizophrenia.

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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 the changes proposed by the applicant regarding the measures and the timelines of the paediatric investigation plan.

The Icelandic and the Norwegian Paediatric Committee members agree 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 Agency, together with its annex and appendix.

London, 16 October 2009

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

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

A. CONDITION(S)

Schizophrenia
Bipolar I disorder

B. WAIVER

- **Condition**

Schizophrenia

The waiver applies to:

- Preterm newborn infants
- Term newborn infants from birth to less than 28 days
- Infants and toddlers from 28 days to less than 24 months
- Children from 2 to less than 12 years
- for sublingual tablet for 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 subsets.

- **Condition**

Bipolar I disorder

The waiver applies to:

- Preterm newborn infants
- Term newborn infants from birth to less than 28 days
- Infants and toddlers from 28 days to less than 24 months
- Children from 2 to less than 12 years
- for sublingual tablet for 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 subsets.

C.1. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Schizophrenia

- **Proposed PIP indication**

Treatment of schizophrenia

- **Subset(s) of the paediatric population concerned by the paediatric development**

From 12 to less than 18 years.

- **Formulation(s)**

Sublingual tablets 2.5mg and 5mg for oral use

- **Studies**

Area	Number of studies	Description
Quality	1	Development of the 2.5mg sublingual tablet
Non-clinical	0	Not applicable
Clinical	3	1. An 8 weeks, placebo-controlled, double-blind, randomized, fixed-dose efficacy and safety study in adolescent subjects with schizophrenia. 2. A 52 weeks, active-controlled, double-blind, randomized flexible dose, efficacy and safety study in adolescent subjects with schizophrenia. 3. A 104 weeks, open-label, flexible dose, long-term safety study in adolescent subjects with schizophrenia.

C.2. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Bipolar I disorder

- **Proposed PIP indication**

Treatment of manic episodes associated with bipolar I disorder

- **Subset(s) of the paediatric population concerned by the paediatric development**

From 12 to less than 18 years.

- **Formulation(s)**

Sublingual tablets 2.5mg, 5mg and 10 mg for oral use

- **Studies**

Area	Number of studies	Description
Quality	0	Not applicable
Non-clinical	0	Not applicable
Clinical	2	1. A 3 weeks placebo-controlled, double-blind, randomized, fixed-dose study in adolescent subjects with acute mania associated with Bipolar I Disorder to evaluate safety and efficacy. 2. Extension of the 3 weeks study for 49 weeks.

Measures to address long term follow-up of potential safety issues and efficacy in relation to paediatric use:	**Yes**
Date of completion of the paediatric investigation plan:	**By June 2018**
Deferral for some or all studies contained in the paediatric investigation plan:	**Yes**