EMA/670593/2011

European Medicines Agency decision

P/178/2011

of 26 August 2011

on the acceptance of a modification of an agreed paediatric investigation plan for asenapine (maleate) (Sycrest), (EMEA-000228-PIP01-08-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.

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on the acceptance of a modification of an agreed paediatric investigation plan for asenapine (maleate) (Sycrest), (EMEA-000228-PIP01-08-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/29/2009 issued on 23 February 2009, and the decision P/233/2009 issued on 27 November 2009,

Having regard to the application submitted by N.V. Organon on 28 April 2011 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 15 July 2011, 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 waiver.

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

Changes to the agreed paediatric investigation plan for asenapine (maleate) (Sycrest), sublingual tablets, oral use, including changes to the waiver, 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 N.V. Organon, Kloosterstraat 6, 5349 AB Oss, The Netherlands.

Done at London, 26 August 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director
(Signature on file)

EMA/PDCO/497205/2011

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

EMEA-000228-PIP01-08-M02

Scope of the application

Active substance(s):

Asenapine (maleate)

Invented name:

Sycrest

Condition(s):

Treatment of bipolar I disorder

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Sublingual tablets

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

N.V. Organon

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, N.V. Organon submitted to the European Medicines Agency on 28 April 2011 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/29/2009 issued on 23 February 2009, and the decision P/233/2009 issued on 27 November 2009.

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

The procedure started on 18 May 2011.

Scope of the modification

The agreed measures related to schizophrenia have been removed from the paediatric investigation plan.

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 waiver 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(es) and appendix.

London, 15 July 2011

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

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

1. Waiver

1.1. Condition: Treatment of bipolar I disorder

The waiver applies to:

- All subsets of the paediatric population from birth to less than 12 years of age;
- 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 subset(s).

2. Paediatric Investigation Plan

2.1. Condition: Treatment of bipolar I disorder

2.1.1. Indication(s) targeted by the PIP

Treatment of manic episodes associated with bipolar I disorder

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

From 12 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Sublingual tablets for oral use

2.1.4. Studies

Area	Number of studies	Description
Quality	1	**Study 1:** Development of the 2.5mg sublingual tablet
Non-clinical	0	Not applicable.
Clinical	2	**Study 2:** 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. **Study 3:** Extension of the 3 weeks study for 49 weeks.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By June 2018
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):

Treatment of bipolar I disorder

Authorised indications: Treatment of moderate to severe manic episodes associated with bipolar I disorder in adults

EU Number	Invented name	Strength	Pharmaceutical form	Route of administration	Packaging	Package size
EU/1/10/640/001	Sycrest	5 mg	Sublingual tablet	Oral use	blister (alu/alu)	20 tablets
EU/1/10/640/002	Sycrest	5 mg	Sublingual tablet	Oral use	blister (alu/alu)	60 tablets
EU/1/10/640/003	Sycrest	5 mg	Sublingual tablet	Oral use	blister (alu/alu)	100 tablets
EU/1/10/640/004	Sycrest	10 mg	Sublingual tablet	Oral use	blister (alu/alu)	20 tablets
EU/1/10/640/005	Sycrest	10 mg	Sublingual tablet	Oral use	blister (alu/alu)	60 tablets
EU/1/10/640/006	Sycrest	10 mg	Sublingual tablet	Oral use	blister (alu/alu)	100 tablets