EMA/473688/2015

European Medicines Agency decision

P/0163/2015

of 7 August 2015

on the acceptance of a modification of an agreed paediatric investigation plan for etravirine (Intelence), (EMEA-000222-PIP01-08-M08) 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/10/2009 issued on 27 January 2009, the decision P/257/2009 issued on 23 December 2009, the decision P/110/2010 issued on 6 July 2010, the decision P/43/2011 issued on 11 February 2011, the decision P/129/2011 issued on 8 June 2011, the decision P/273/2011 issued on 28 October 2011, the decision P/0205/2012 issued on 7 September 2012, and the decision P/0162/2013 issued on 29 July 2013,

Having regard to the application submitted by Janssen-Cilag International NV on 27 March 2015 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 19 June 2015, 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 and on the refusal of changes 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 deferral and on the refusal of 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 etravirine (Intelence), tablet, oral use, including changes to the deferral, refusing 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 Janssen-Cilag International NV, Turnhoutseweg 30, 2340 - Beerse, Belgium.

Done at London, 7 August 2015

For the European Medicines Agency
Jordi Llinares Garcia
Head of Division (ad interim)
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/218200/2015
London, 19 June 2015

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

EMEA-000222-PIP01-08-M08

Scope of the application

Active substance(s):

Etravirine

Invented name:

Intelence

Condition(s):

Treatment of Human Immunodeficiency Virus Infection

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Janssen-Cilag International NV

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, Janssen-Cilag International NV submitted to the European Medicines Agency on 27 March 2015 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/10/2009 issued on 27 January 2009, the decision P/257/2009 issued on 23 December 2009, the decision P/110/2010 issued on 6 July 2010, the decision P/43/2011 issued on 11 February 2011, the decision P/129/2011 issued on 8 June 2011, the decision P/273/2011 issued on 28 October 2011, the decision P/0205/2012 issued on 7 September 2012, and the decision P/0162/2013 issued on 29 July 2013.

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

The procedure started on 21 April 2015.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified. The date of completion of the Paediatric Investigation Plan has 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 and to refuse the change 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 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 Human immunodeficiency virus infection

The waiver applies to:

- the paediatric population from birth to less than 2 months;
- for tablets for oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan

2.1. Condition

Treatment of Human immunodeficiency virus infection

2.1.1. Indication(s) targeted by the PIP

Treatment of HIV-1 infection in antiretroviral treatment-experienced adolescents and children from 2 months to less than 18 years of age

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

From 2 months to less than 18 years

2.1.3. Pharmaceutical form(s)

Tablet

2.1.4. Studies

Area	Number of studies	Description
Quality	1	**Study 1** Development of a 25 mg scored tablet
Non-clinical	0	Not applicable.
Clinical	2	**Study 2** Open-label trial to evaluate the safety, tolerability and antiviral activity of etravirine in antiretroviral experienced HIV-1 infected children and adolescents from 6 years to less than 18 years of age. (TMC125-C213) **Study 3** Open-label trial to evaluate the safety, tolerability, pharmacokinetics and antiretroviral activity of etravirine in antiretroviral experienced HIV-1 infected children aged from 2 months to less than 6 years of age. (TMC125-TiDP35-C234/IMPAACT P1090)

3. Follow-up, completion and deferral of PIP

Concerns on potential long term issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By October 2019
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 Human Immunodeficiency Virus infection

Authorised indications:

- INTELENCE, in combination with a boosted protease inhibitor and other antiretroviral medicinal products, is indicated for the treatment of human immunodeficiency virus type 1 (HIV 1) infection in antiretroviral treatment experienced adult patients and in antiretroviral treatment experienced paediatric patients from 6 years of age (see sections 4.4, 4.5 and 5.1);
- the indication in adults is based on week 48 analyses from 2 Phase III trials in highly pre treated patients where INTELENCE was investigated in combination with an optimised background regimen (OBR) which included darunavir/ritonavir. The indication in paediatric patients is based on 48 week analyses of a single arm, Phase II trial in antiretroviral treatment experienced paediatric patients (see section 5.1).

Authorised pharmaceutical form(s)

Tablet

Authorised route(s) of administration

Oral use