EMA/463333/2010

European Medicines Agency decision

P/138/2010

of 30 July 2010

on the acceptance of a modification of an agreed paediatric investigation plan for darunavir (Prezista), (EMEA-000038-PIP01-07-M03) 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/49/2008 issued on 20 July 2008 and decision P/5/2009 issued on 27 January 2009,

Having regard to the application submitted by Janssen-Cilag International NV on 21 April 2010 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 June 2010, 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.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the 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 darunavir (Prezista), film-coated tablet and oral suspension, oral use, 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, 30 July 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/370650/2010

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

EMEA-000038-PIP01-07-M03

Scope of the application

Active substance(s):

Darunavir

Invented name:

Prezista

Condition(s):

Human immunodeficiency virus-infection

Pharmaceutical form(s):

Film-coated tablet

Oral suspension

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 21 April 2010 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/49/2008 issued on 20 July 2008 and decision P/5/2009 issued on 27 January 2009.
The application for modification proposed changes to the deferral.

The procedure started on 20 May 2010.

Scope of the modification

Timelines for some clinical measures 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 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, 11 June 2010

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

1. Condition(s)

Human immunodeficiency virus infection

2. Waiver

2.1. Condition

Human immunodeficiency virus infection

The waiver applies to:

- Neonates, infants and children below 3 years of age for darunavir
- for film-coated tablets (75 mg – 150 mg - 300 mg – 400 mg – 600 mg and oral suspension for oral use
- on the grounds that the specific medicinal product is likely to be unsafe.

3. Paediatric Investigation Plan

3.1. Condition to be investigated

Human immunodeficiency virus infection

3.1.1. Indication targeted by the PIP

Treatment of human immunodeficiency virus (HIV-1) infection in pediatric patients when coadministered with low-dose ritonavir and in combination with other antiretroviral (ARV) medicinal products.

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

From 3 to less than 18 years of age.

3.1.3. Pharmaceutical form(s)

In addition to the currently authorised 300 mg film-coated tablets, and the proposed 400 and 600 mg film-coated tablets, development of age appropriate formulations: 75-mg and 150-mg film-coated tablet and oral suspension formulation (100 mg/ml).

3.1.4. Studies

Area	Subarea	Number	Description
Formulation			Development of age appropriate formulations: Film-coated tablets 75 mg Film coated tablets 150 mg Oral suspension 100 mg/ml
	Bioequivalence		Measure to conclude on the relative bioavailability of the oral suspension and the tablets.
Clinical	Pharmacokinetic,	3	Phase II, randomised, open-label trial, to

	efficacy and safety		investigate pharmacokinetics, safety, tolerability and antiviral activity of darunavir with low dose ritonavir in treatment-experienced HIV-1 infected children and adolescents from 6 years to less than 18 years
			Phase II, open-label trial to evaluate pharmacokinetics, safety, tolerability and antiviral activity of darunavir with low dose ritonavir in treatment-experienced HIV-1 infected children between from 3 years and to less than 6 years of age
			Phase II, open-label trial to evaluate safety, tolerability and antiviral activity of darunavir with low dose ritonavir in treatment-naïve adolescents from 12 to less than 18 years of age.

4. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues and efficacy in relation to paediatric use:	**No**
Date of completion of the paediatric investigation plan:	By November 2011
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

EU Number	Invented name	Strength	Pharma-ceutical Form	Route of Administration	Packaging	Package size
EU/1/06/380/001	Prezista	300 mg	Film-coated tablet	Oral use	bottle (HDPE)	120 tablets
EU/1/06/380/002	Prezista	600 mg	Film-coated tablet	Oral use	bottle (HDPE)	60 tablets
EU/1/06/380/003	Prezista	400 mg	Film-coated tablet	Oral use	bottle (HDPE)	60 tablets
EU/1/06/380/004	Prezista	150 mg	Film-coated tablet	Oral use	bottle (HDPE)	240 tablets
EU/1/06/380/005	Prezista	75 mg	Film-coated tablet	Oral use	bottle (HDPE)	480 tablets