

EMA/603159/2011

European Medicines Agency decision P/199/2011

of 4 August 2011

on the agreement of a paediatric investigation plan and on the granting of a waiver for lopinavir / ritonavir (Kaletra), (EMA-001005-PIP01-10) 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 726/2004¹,

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 Agency²,

Having regard to the application submitted by Abbott Laboratories Limited on 2 July 2010 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 15 July 2011, in accordance with Article 18 of Regulation (EC) No 1901/2006, 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 waiver.
- (2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.
- (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 lopinavir / ritonavir (Kaletra), oral solution, soft capsules, film-coated 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, is hereby agreed.

Article 2

A waiver for lopinavir / ritonavir (Kaletra), oral solution, soft capsules, film-coated 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, is hereby granted.

Article 3

This decision is addressed to Abbott Laboratories Limited, Abbott House, Vanwall Business Park, Vanwall Road, SL6 4XE Maidenhead, Berkshire, United Kingdom.

Done at London, 4 August 2011

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



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/511433/2011

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

EMEA-001005-PIP01-10

Scope of the application

Active substance(s):

Lopinavir / ritonavir

Invented name:

Kaletra

Condition(s):

Treatment of human immunodeficiency virus (HIV-1) infection

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Oral Solution

Soft capsules

Film-coated tablets

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Abbott Laboratories Limited

Information about the authorised medicinal product:

See Annex II



Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Abbott Laboratories Limited submitted for agreement to the European Medicines Agency on 2 July 2010 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 12 August 2010.

Supplementary information was provided by the applicant on 14 April 2011. The applicant proposed modifications to the paediatric investigation plan and withdrew its request for a deferral.

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 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)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population, Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

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(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 human immunodeficiency virus (HIV-1) infection

The waiver applies to:

- All subsets of the paediatric population from 2 to less than 18 years of age;
- for soft capsule, oral solution, and film-coated tablets for oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as the needs are already covered.

The waiver applies to:

- All subsets of the paediatric population from birth to less than 14 days of age;
- for soft capsule, oral solution, and film-coated tablets for oral use;
- on the grounds that the specific medicinal product is likely to be unsafe.

The waiver applies to:

- All subsets of the paediatric population from 14 days to less than 2 years of age;
- for soft capsule and film-coated tablets for oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit.

Paediatric Investigation Plan

1.2. Condition: Treatment of human immunodeficiency virus (HIV-1) infection

1.2.1. Indication(s) targeted by the PIP

Treatment of human immunodeficiency virus (HIV-1) infection

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

From 14 days to less than 2 years of age.

1.2.3. Pharmaceutical form(s)

Oral solution

1.2.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable
Clinical	3	Study 1: open-label, multicentre trial of lopinavir/ritonavir (LPV/r) based combination retroviral therapy in HIV-1 infected infants less than 6 months of age to evaluate pharmacokinetics and safety. Study 2: Open-label, randomised, non-inferiority, three arm, regimen-comparison, multicentre trial to evaluate whether early antiretroviral therapy given over a limited period of time in children from 6 weeks to less than 13 weeks of age, infected with HIV-1 would delay progression of disease compared to those treated when the immune system begins to decline. Study 3: Open label, randomized, multicentre trial to compare rates of treatment failure at 24 weeks in HIV-1 infected children from 6 to less than 37 months who have or have not been exposed to single-dose nevirapine (sdNVP) for prevention of mother-to-child transmission (PMTCT).

2. Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By March 2013
Deferral for one or more studies contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of human immunodeficiency virus (VIH-1) infection

Authorised indications: Treatment of human immunodeficiency virus (HIV-1) in infected adults, adolescents and children above the age of 2 years, in association with other antiretroviral medicinal products

EU Number	Invented name	Strengt h	Pharma ceutical form	Route of administrati on	Packagi ng	Content (concen tration)	Package size
EU/1/01/172/001	Kaletra	133.3 /33.3 mg	Capsule, soft	Oral use	bottle (HDPE)		180 capsules
EU/1/01/172/002	Kaletra	133.3 /33.3 mg	Capsule, soft	Oral use	blister (PVC)		180 capsules
EU/1/01/172/003	Kaletra	(80 mg + 20 mg) / ml	Oral solution	Oral use	bottle (PET)	60 ml	5 bottles + 5 x 5 ml syringes
EU/1/01/172/004	Kaletra	200 mg / 50 mg	Film-coated tablet	Oral use	bottle (HDPE)		120 tablets
EU/1/01/172/005	Kaletra	200 mg / 50 mg	Film-coated tablet	Oral use	blister (PVC)		120 tablets
EU/1/01/172/006	Kaletra	100 mg / 25mg	Film-coated tablet	Oral use	bottle (HDPE)		60 tablets
EU/1/01/172/007	Kaletra	200 mg / 50 mg	Film-coated tablet	Oral use	bottle (HDPE)		360 (3 x 120) tablets
EU/1/01/172/008	Kaletra	200 mg / 50 mg	Film-coated tablet	Oral use	blister (PVC)		120 (10 x 12) tablets