EMA/584816/2019

European Medicines Agency decision

P/0359/2019

of 4 November 2019

on the acceptance of a modification of an agreed paediatric investigation plan for lurasidone (hydrochloride) (Latuda) (EMEA-001230-PIP01-11-M05) 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/0145/2012 issued on 23 July 2012, the decision P/0269/2013 issued on 30 October 2013, the decision P/0214/2016 issued on 12 August 2016, the decision P/0257/2017 issued on 4 September 2017 and the decision P/0160/2018 issued on 15 June 2018,

Having regard to the application submitted by AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO - A.C.R.A.F. S.p.A. on 1 July 2019 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 18 October 2019, 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 lurasidone (hydrochloride) (Latuda), film-coated tablet, 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 AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO - A.C.R.A.F. S.p.A., Viale Amelia 70, 00181 – Rome, Italy.

EMA/PDCO/410113/2019
Amsterdam, 18 October 2019

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

EMEA-001230-PIP01-11-M05

Scope of the application

Active substance(s):

Lurasidone (hydrochloride)

Invented name:

Latuda

Condition(s):

Treatment of schizophrenia

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Film-coated tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO - A.C.R.A.F. S.p.A.

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO - A.C.R.A.F. S.p.A. submitted to the European Medicines Agency on 1 July 2019 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/0145/2012 issued on 23 July 2012, the decision P/0269/2013 issued on 30 October 2013, the decision P/0214/2016 issued on 12 August 2016, the decision P/0257/2017 issued on 4 September 2017and the decision P/0160/2018 issued on 15 June 2018.

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

The procedure started on 20 August 2019.

Scope of the modification

Some measures of the Paediatric Investigation Plan 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 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

1. Waiver

1.1. Condition

Treatment of schizophrenia

The waiver applies to:

- all subsets of the paediatric population from birth to less than 13 years of age;
- for film-coated 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 schizophrenia

2.1.1. Indication(s) targeted by the PIP

Treatment of schizophrenia

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

From 13 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Film-coated tablet

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	3	**Study 1** Open-label, multicentre, single and multiple fixed ascending dose study to evaluate pharmacokinetics, safety, and tolerability of lurasidone in the paediatric population (D1050300). **Study 2** Randomised, parallel, double-blind, placebo-controlled, fixed-dose regimen, multicentre, study to evaluate the efficacy and safety of lurasidone in adolescent patients with schizophrenia (D1050301).

		Study 3 A 104-week, flexible-dose, open-label multicentre extension study to evaluate the long-term safety and effectiveness of lurasidone in adolescent patients with schizophrenia (D1050302). ***Study 4*** *Deleted in procedure EMEA-001230-PIP01-11-M04*

3. Follow-up, completion and deferral of PIP

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

1. Treatment of schizophrenia

Authorised indication(s):

- treatment of schizophrenia in adults aged 18 years and over

Authorised pharmaceutical form(s)

Film-coated tablet

Authorised route(s) of administration

Oral use