EMA/266656/2022

European Medicines Agency decision

P/0200/2022

of 10 June 2022

on the acceptance of a modification of an agreed paediatric investigation plan for loxapine (Adasuve), (EMEA-001115-PIP01-10-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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/220/2011 issued on 30 September 2011, the decision P/0219/2013 issued on 6 September 2013, the decision P/0088/2014 issued on 4 April 2014, the decision P/0145/2015 issued on 10 July 2015, the decision P/0050/2016 issued on 18 March 2016, the decision P/0327/2016 issued on 2 December 2016, the decision P/0295/2018 issued on 12 September 2018 and the decision P/0385/2019 issued on 4 December 2019,

Having regard to the application submitted by Ferrer Internacional, S.A. on 30 December 2021 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 22 April 2022, 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.

(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.

[1] OJ L 378, 27.12.2006, p.1, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for loxapine (Adasuve), inhalation powder, pre-dispensed, inhalation use, including changes to the deferral, 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 Ferrer Internacional, S.A., 549 5th floor Avenida Diagonal, 08029 – Barcelona, Spain.

EMA/PDCO/36483/2022
Amsterdam, 22 April 2022

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

EMEA-001115-PIP01-10-M08

Scope of the application

Active substance(s):

Loxapine

Invented name:

Adasuve

Condition(s):

Treatment of schizophrenia

Treatment of bipolar disorder

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Inhalation powder, pre-dispensed

Route(s) of administration:

Inhalation use

Name/corporate name of the PIP applicant:

Ferrer Internacional, S.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, Ferrer Internacional, S.A. submitted to the European Medicines Agency on 30 December 2021 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/220/2011 issued on 30 September 2011, the decision P/0219/2013 issued on 6 September 2013, the decision P/0088/2014 issued on 4 April 2014, the decision P/0145/2015 issued on 10 July 2015, the decision P/0050/2016 issued on 18 March 2016, the decision P/0327/2016 issued on 2 December 2016, the decision P/0295/2018 issued on 12 September 2018 and the decision P/0385/2019 issued on 4 December 2019.

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

The procedure started on 21 February 2022.

Scope of the modification

Some timelines 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 and to the deferral 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 schizophrenia

The waiver applies to:

- all subsets of the paediatric population from birth to less than 13 years of age;
  - inhalation powder, pre-dispensed, inhalation 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).

1.2. Condition:

Treatment of bipolar disorder

The waiver applies to:

- all subsets of the paediatric population from birth to less than 10 years of age;
  - inhalation powder, pre-dispensed, inhalation 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

Rapid control of agitation in patients with 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)

Inhalation powder, pre-dispensed

2.1.4. Measures

Area	Number of measures	Description
Quality	0	Not applicable
Non-clinical	1	**Study 1** Single-dose inhalation developmental tolerability and toxicokinetic study in rats
Clinical	2	**Study 2** Open-label safety, tolerability and pharmacokinetic study of loxapine inhalation powder in children and adolescents with any condition warranting chronic use of an antipsychotic medication **Study 3** A multicenter, randomised, double-blind, placebo- and active-controlled efficacy and safety study of loxapine inhalation powder for the treatment of agitation in children and adolescents with schizophrenia or bipolar I disorder (FCD-ADA-1701)

2.2. Condition

Treatment of bipolar disorder

2.2.1. Indication(s) targeted by the PIP

Rapid control of agitation in patients with bipolar disorder

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

From 10 to less than 18 years of age

2.2.3. Pharmaceutical form(s)

Inhalation powder, pre-dispensed

2.2.4. Measures

Same as the studies specified for the condition: treatment of schizophrenia

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 February 2025
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):

- ADASUVE is indicated for the rapid control of mild-to-moderate agitation in adult patients with schizophrenia or bipolar disorder.

2. Treatment of bipolar disorder

Authorised indication(s):

- ADASUVE is indicated for the rapid control of mild-to-moderate agitation in adult patients with schizophrenia or bipolar disorder.

Authorised pharmaceutical form(s):

Inhalation powder, pre-dispensed

Authorised route(s) of administration:

Inhalation use