EMA/762994/2017

European Medicines Agency decision

P/0362/2017

of 1 December 2017

on the acceptance of a modification of an agreed paediatric investigation plan for lumicitabine (EMEA-001758-PIP01-15-M02) 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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on the acceptance of a modification of an agreed paediatric investigation plan for lumicitabine (EMEA-001758-PIP01-15-M02) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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/0081/2016 issued on 18 March 2016 and the decision P/0029/2017 issued on 27 January 2017,

Having regard to the application submitted by Janssen Cilag International NV on 19 July 2017 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 13 October 2017, 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 lumicitabine, powder for 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.

EMA/PDCO/488611/2017
London, 13 October 2017

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

EMEA-001758-PIP01-15-M02

Scope of the application

Active substance(s):

Lumicitabine

Condition(s):

Treatment of lower respiratory tract disease caused by human respiratory syncytial virus

Pharmaceutical form(s):

Powder for oral suspension

Route(s) of administration:

Oral use

Gastric use

Name/corporate name of the PIP applicant:

Janssen Cilag International NV

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 19 July 2017 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0081/2016 issued on 18 March 2016 and the decision P/0029/2017 issued on 27 January 2017.

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

The procedure started on 15 August 2017.

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 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 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

Not applicable.

2. Paediatric investigation plan

2.1. Condition

Treatment of lower respiratory tract disease caused by human respiratory syncytial virus

2.1.1. Indication(s) targeted by the PIP

Treatment of lower respiratory tract disease caused by human respiratory syncytial virus (RSV)

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

From birth to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Powder for oral suspension

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of an age-appropriate formulation, i.e. powder for oral suspension.
Non-clinical studies	2	**Study 2** Juvenile toxicity study in rats. **Study 3** Juvenile toxicity study in dogs.
Clinical studies	5	**Study 4** Randomized, double-blind, placebo-controlled, single (Part 1) and multiple (Part 2) ascending dose study in otherwise healthy infants and neonates hospitalized with RSV infection to evaluate safety and PK. **Study 5** Randomized, double-blind, placebo-controlled PK, efficacy and safety study in infants and children (28 days-36 months old), whether otherwise healthy or with underlying comorbidities.

		Study 6 deleted in EMEA-001758-PIP01-15-M01. **Study 7** Randomised, double-blind, placebo-controlled, efficacy and safety study in otherwise healthy newborns, infants and children (0-36 months old) hospitalized with RSV infection. **Study 8** Randomised, double-blind, placebo-controlled, efficacy and safety study in newborns, infants, and children (0-36 months old) with underlying comorbidities hospitalized with RSV infection. **Study 9** Randomised, double-blind, placebo-controlled efficacy and safety study in newborns, infants, children, whether otherwise healthy (0-12 months old) or with underlying comorbidities (0-36 months old) who are outpatients and at risk for severe complications of RSV infection. **Study 10** deleted in EMEA-001758-PIP01-15-M01.
Extrapolation, modelling and simulation studies	2	**Study 11** Modelling and simulation study for dose selection in all planned clinical studies. **Study 12** Extrapolation study to estimate efficacy of lumicitabine for treatment of RSV lower respiratory tract infection in immunocompromised children 3-18 years of age.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By June 2023
Deferral for one or more measures contained in the paediatric investigation plan:	Yes