EMA/244252/2017

European Medicines Agency decision

P/0118/2017

of 5 May 2017

on the acceptance of a modification of an agreed paediatric investigation plan for 3-[[5-chloro-1-[3-(methylsulfonyl)propyl]-1H-indol-2-yl]methyl]-1-(2,2,2-trifluoroethyl)-1,3-dihydro-2H-imidazo[4,5-c]pyridine-2-one (JNJ-53718678) (EMEA-001838-PIP01-15-M01) 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 3-[[5-chloro-1-[3-(methylsulfonyl)propyl]-1H-indol-2-yl]methyl]-1-(2,2,2-trifluoroethyl)-1,3-dihydro-2H-imidazo[4,5-c]pyridine-2-one (JNJ-53718678) (EMEA-001838-PIP01-15-M01) 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/0223/2016 issued on 12 August 2016,

Having regard to the application submitted by Janssen-Cilag International NV on 4 January 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 24 March 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 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.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for 3-[[5-chloro-1-[3-(methylsulfonyl)propyl]-1H-indol-2-yl]methyl]-1-(2,2,2-trifluoroethyl)-1,3-dihydro-2H-imidazo[4,5-c]pyridine-2-one (JNJ-53718678), oral solution, oral 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 Janssen-Cilag International NV, Turnhoutseweg 30, 2340 – Beerse, Belgium.

EMA/PDCO/26580/2017
London, 24 March 2017

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

EMEA-001838-PIP01-15-M01

Scope of the application

Active substance(s):

3-[[5-chloro-1-[3-(methylsulfonyl)propyl]-1H-indol-2-yl]methyl]-1-(2,2,2-trifluoroethyl)-1,3-dihydro-2H-imidazo[4,5-c]pyridine-2-one (JNJ-53718678)

Condition(s):

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

Pharmaceutical form(s):

Oral solution

Route(s) of administration:

Oral 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 4 January 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/0223/2016 issued on 12 August 2016.

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

The procedure started on 24 January 2017.

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Scope of the modification

Some measures and 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 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 (RSV)

2.1.1. Indication(s) targeted by the PIP

Treatment of lower respiratory tract disease caused by human 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)

Oral solution

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of an age-appropriate formulation, i.e. oral solution.
Non-clinical studies	2	**Study 2** Juvenile rat toxicity study. **Study 3** Juvenile toxicity study in minipigs.
Clinical studies	7	**Study 4** Double-blind, placebo-controlled (except for the 1st cohort within each age group which is open-label), randomized multiple ascending dose study to assess preliminary safety, tolerability, pharmacokinetics, antiviral effect, and pharmacodynamics of multiple doses of orally administered JNJ-53718678 in otherwise healthy infants and children hospitalized with RSV infection, aged 1 month to 24 months. **Study 5** Double-blind, placebo-controlled, dose finding study in hospitalized children less than or equal to 3 years of age with RSV infection, whether otherwise healthy or with underlying comorbidities.

		Study 6 Double-blind, placebo-controlled, randomized study to assess the efficacy and safety of JNJ-53718678 as compared to placebo in otherwise healthy children less than three years of age hospitalized with RSV infection. **Study 7** Double-blind, placebo-controlled, randomized study to assess the efficacy and safety of JNJ-53718678 as compared to placebo in children who have risk factors for severe disease due to RSV infection. **Study 8** Double-blind, placebo-controlled, randomized study to assess the efficacy and safety of JNJ-53718678 as compared to placebo in outpatients diagnosed with RSV infection who are otherwise healthy or have risk factors for severe disease. **Study 9** Observational study to assess the long-term sequelae of RSV-related disease in patients previously enrolled into study 5. **Study 10** Observational study to assess the long-term sequelae of RSV-related disease in patients previously enrolled into studies 6, 7, and 8.
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 JNJ-53718678 for treatment of RSV lower respiratory tract infection in immunocompromised children from birth to less than 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 2026
Deferral for one or more measures contained in the paediatric investigation plan:	Yes