EMA/4727/2021

European Medicines Agency decision

P/0030/2021

of 27 January 2021

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]pyridin-2-one) (JNJ-53718678) (EMEA-001838-PIP01-15-M03) 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/0223/2016 issued on 12 August 2016, the decision P/0118/2017 issued on 5 May 2017, and the decision P/0081/2019 of 22 March 2019,

Having regard to the application submitted by Janssen-Cilag International NV on 8 September 2020 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 11 December 2020, 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]pyridin-2-one) (JNJ-53718678), powder and solvent for oral suspension, 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/517355/2020
Amsterdam, 11 December 2020

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

EMEA-001838-PIP01-15-M03

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]pyridin-2-one) (JNJ-53718678)

Condition(s):

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

Pharmaceutical form(s):

Powder and solvent for oral suspension

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 8 September 2020 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 decision P/0118/2017 issued on 5 May 2017, and the decision P/0081/2019 of 22 March 2019.

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

The procedure started on 13 October 2020.

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 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)

Powder and solvent 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 and solvent for oral suspension.
Non-clinical studies	2	**Study 2 (TOX11122)** Juvenile rat toxicity study. **Study 3 (TOX11123)** Juvenile toxicity study in minipigs.
Clinical studies	4	**Study 4 (53718678RSV1005)** 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, pharmaco-kinetics, 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 (53718678RSV2002) 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 (53718678RSV3001)** Double-blind, placebo-controlled, randomized study to assess the efficacy and safety of JNJ-53718678 as compared to placebo in otherwise healthy children and children who have (a) risk(s) factor for severe disease due to RSV infection less than or equal to five years of age hospitalized with RSV infection. **Study 7** Deleted in procedure EMEA-001838-PIP01-15-M03 **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** Deleted in procedure EMEA-001838-PIP01-15-M02 **Study 10** Deleted in procedure EMEA-001838-PIP01-15-M02.
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 December 2027
Deferral for one or more measures contained in the paediatric investigation plan:	Yes