EMA/501690/2016

European Medicines Agency decision

P/0223/2016

of 12 August 2016

on the agreement of a paediatric investigation plan and on the granting of a deferral 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) 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 agreement of a paediatric investigation plan and on the granting of a deferral 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) 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 application submitted by Janssen-Cilag International NV on 7 September 2015 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 24 June 2016, in accordance with Article 18 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a 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

A 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, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral 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, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to Janssen-Cilag International NV, Turnhoutseweg 30, 2340 - Beerse, Belgium.

EMA/PDCO/259592/2016
London, 24 June 2016

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral

EMEA-001838-PIP01-15

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 16(1) of Regulation (EC) No 1901/2006 as amended, Janssen-Cilag International NV submitted for agreement to the European Medicines Agency on 7 September 2015 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 13 October 2015.

Supplementary information was provided by the applicant on 4 April 2016. The applicant proposed modifications to the paediatric investigation plan.

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Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 18 of said Regulation;
   - to grant a deferral in accordance with Article 21 of said Regulation.

   The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed 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 (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, 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 April 2025
Deferral for one or more measures contained in the paediatric investigation plan:	Yes