MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-101112-PIP01-23

Scope of the Application

Active Substance(s)

Interleukin-23 receptor antagonist peptide (JNJ-77242113)

Condition(s)

Treatment of psoriasis

Pharmaceutical Form(s)

Film-coated tablet Age-appropriate formulation

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Janssen-Cilag Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Janssen-Cilag Limited submitted to the licensing authority on 16/08/2023 10:22 BST an application for a Paediatric Investigation Plan

The procedure started on 04/12/2023 08:13 GMT

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to agree a paediatric investigation plan and grant a deferral and grant a waiver

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-101112-PIP01-23

Of 15/04/2024 11:22 BST

On the adopted decision for Interleukin-23 receptor antagonist peptide (JNJ-77242113) (MHRA-101112-PIP01-23) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on a paediatric investigation plan

This decision applies to a Paediatric Investigation Plan for Interleukin-23 receptor antagonist peptide (JNJ-77242113), Film-coated tablet Age-appropriate formulation , ORAL USE .

This decision is addressed to Janssen-Cilag Limited, 50-100 Holmers Way, Buckinghamshire , High Wycombe, UNITED KINGDOM, HP12 4EG

ANNEX I

1. Waiver

1.1 Condition:

Treatment of psoriasis The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 years of age Pharmaceutical form(s): Film-coated tablet Age-appropriate formulation Route(s) of administration: ORAL USE Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of psoriasis

2.2 Indication(s) targeted by the PIP:

Treatment of moderate to severe plaque psoriasis in paediatric patients from 6 years to less than 18 years of age who are candidates for systemic therapy

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from 6 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Film-coated tablet Age-appropriate formulation

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	2	Study 1 Development of an age-appropriate oral formulation for paediatric use. Study 2 Stability studies to support the dispersion of the tablet formulation.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	2	Study 3 (77242113PSO3001) Double-blind, randomised, placebo-controlled trial to evaluate pharmacokinetics, safety, efficacy of JNJ-77242113 in children from 12 years to less than 18 years of age (and adults) with moderate to severe plaque psoriasis. Study 4 Clinical trial to evaluate pharmacokinetics, safety, efficacy of JNJ-77242113 in children from 6 years to less than 12 years of age with moderate to severe plaque psoriasis.
Extrapolation, Modeling & Simulation Studies	2	Study 5 Modelling and simulation dose finding study. Extrapolation Plan Study 3 and Study 4 are part of the extrapolation plan to extrapolate efficacy data from adult and adolescents to the paediatric population from 6 years to less than 12 years of age and adolescent patients with psoriasis with a body weight cut-off to be determined.
Other Studies	0	Not applicable.
Other Measures	0	Not applicable.

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	30/04/2030
Deferral of one or more studies contained in the paediatric investigation plan:	Yes