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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan (MHRA-101388-PIP01-24-M01) and to the deferral

MHRA-101388-PIP01-24-M02

Scope of the Application

Active Substance(s)

DARIDOREXANT HYDROCHLORIDE

Condition(s)

Treatment of insomnia

Pharmaceutical Form(s)

Film-coated tablet; Age-appropriate oral solid dosage form

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Idorsia Pharmaceuticals Deutschland GmbH

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Idorsia Pharmaceuticals Deutschland GmbH submitted to the licensing authority on 04/09/2024 13:09 BST an application for a Modification

The procedure started on 11/10/2024 12:57 BST

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 accept change(s) to the agreed paediatric investigation plan and to the deferral.

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.

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

gov.uk/mhra

Final Decision Letter

MHRA-101388-PIP01-24-M02

Of 14/10/2024 12:36 BST

On the adopted decision for DARIDOREXANT HYDROCHLORIDE (MHRA-101388-PIP01-24-M02) 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 modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for DARIDOREXANT HYDROCHLORIDE, Film-coated tablet; Age-appropriate oral solid dosage form , ORAL USE .

This decision is addressed to Idorsia Pharmaceuticals Deutschland GmbH, Marie-Curie-Strasse 8 , Lörrach, GERMANY, D-79539

ANNEX I

1. Waiver

1.1 Condition:

Treatment of insomnia. The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age. Pharmaceutical form(s): Film-coated tablet Age-appropriate oral solid dosage form 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 insomnia.

2.2 Indication(s) targeted by the PIP:

Treatment of insomnia in children with co-morbid neurodevelopmental and psychiatric disorders.

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

The paediatric population from 2 years of age to less than 18 years of age.

2.4 Pharmaceutical Form(s):

Film-coated tablet Age-appropriate oral solid dosage form

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age-appropriate oral solid pharmaceutical form (mini-tablets).
Non-Clinical Studies	1	Study 2 Definitive juvenile toxicity study in rats.
Clinical Studies	4	Study 3 (ID-078A205) Multi-centre, double-blind, randomised, placebo-controlled, parallel-group polysomnography dose-finding study assessing the efficacy, safety, and pharmacokinetics of a multiple-dose oral administration of daridorexant in paediatric subjects aged from 10 years to less than 18 years of age with insomnia. Study 4 Multi-centre, 3-period study assessing the efficacy, safety and tolerability of oral treatment with daridorexant in paediatric subjects from 2 to less than 18 years of age with insomnia disorder with comorbid neurodevelopmental and psychiatric disorders (NDPDs). Study 5 Multi-centre, open-label extension study assessing the long-term safety and tolerability of daridorexant in paediatric subjects from 2 to less than 18 years of age with insomnia disorder with comorbid neurodevelopmental and psychiatric disorders (NDPDs).

		Study 6 Multi-centre, double-blind, randomised, placebo-controlled, crossover, polysomnography study assessing the efficacy, safety, and pharmacokinetics of a single-dose oral administration of daridorexant in paediatric subjects aged 2 years to < 10 years with insomnia disorder associated with neurodevelopmental disorders (attention deficit hyperactivity disorder or autism spectrum disorder). Added in procedure MHRA-101388-PIP01-24-M01.
Extrapolation, Modeling & Simulation Studies	0	Not applicable.
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:	31/05/2031
Deferral of one or more studies contained in the paediatric investigation plan:	Yes