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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

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

MHRA-100514-PIP01-22

Scope of the Application

Active Substance(s)

Gliadin Protease

Condition(s)

Treatment of coeliac disease

Pharmaceutical Form(s)

Tablet; Age -appropriate oral dosage form

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Takeda UK Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Takeda UK Limited submitted to the licensing authority on 20/05/2022 15:57 BST an application for a Paediatric Investigation Plan

The procedure started on 12/12/2022 11:51 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-100514-PIP01-22

Of 23/12/2022 14:28 GMT

On the adopted decision for Gliadin Protease (MHRA-100514-PIP01-22) 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 Gliadin Protease, Tablet; Age -appropriate oral dosage form , ORAL USE .

This decision is addressed to Takeda UK Limited , 1 Kingdom Street, London, UNITED KINGDOM, W2 6BD

ANNEX I

1. Waiver

1.1 Condition:

Treatment of coeliac disease The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 years of age Pharmaceutical form(s): Tablet. Age-appropriate oral dosage form Route(s) of administration: ORAL USE Reason for granting waiver: on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of coeliac disease

2.2 Indication(s) targeted by the PIP:

As an adjunct to a gluten free diet for the treatment of symptomatic coeliac disease

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):

Tablet. Age-appropriate oral dosage form

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of age-appropriate oral dosage form.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	3	Study 2 (TAK-062-2001) Double-blind, randomised, placebo-controlled study to evaluate the safety and efficacy of gliadin protease in adolescents from 12 years to less than 18 years of age (and adults) with coeliac disease. Study 3 Double-blind, randomised, placebo-controlled study to evaluate the safety and efficacy of gliadin protease in adolescents from 12 years to less than 18 years of age (and adults) with coeliac disease. Study 4 Open-label study to evaluate pharmacokinetics, pharmacodynamics, safety and immunogenicity of gliadin protease in children from 6 years to less than 12 years of age with coeliac disease.
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:	31/01/2032
Deferral of one or more studies contained in the paediatric investigation plan:	Yes