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 (and to grant a full product specific waiver)

MHRA-100154-PIP01-21-M01

Scope of the Application

Active Substance(s)

Cotadutide

Condition(s)

Treatment of Type 2 Diabetes Mellitus

Pharmaceutical Form(s)

Solution for injection in pre-filled pen

Route(s) of Administration

Subcutaneous use

Name / Corporate name of the PIP applicant

AstraZeneca UK Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, AstraZeneca UK Limited submitted to the licensing authority on 12/07/2021 16:57 BST an application for a

The procedure started on 16/11/2021 09:09 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:

accept change(s) to the agreed paediatric investigation plan (and to grant a full product specific 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.

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

gov.uk/mhra

Final Decision Letter

MHRA-100154-PIP01-21-M01

Of 24/11/2021 10:55 GMT

On the adopted decision for Cotadutide (MHRA-100154-PIP01-21-M01) 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 and deferral included in that paediatric investigation plan)

This decision applies to a for Cotadutide , Solution for injection in pre-filled pen , Subcutaneous use .

This decision is addressed to AstraZeneca UK Limited, 600 Capability Green, Luton, United Kingdom, LU1 3LU

ANNEX I

1. Waiver

1.1 Condition:

Treatment of Type 2 Diabetes Mellitus The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 10 years of age; The paediatric population from 10 years to less than 18 years of age Pharmaceutical form(s): Solution for injection in pre-filled pen Route(s) of administration: Subcutaneous use Reason for granting waiver: from birth to less than 10 years of age : on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s). from 10 years to less than 18 years of age: 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 Type 2 Diabetes Mellitus

2.2 Indication(s) targeted by the PIP:

Deleted in modification MHRA-100154-PIP01-21-M01

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

Not applicable – all subsets of the paediatric populations now subject to a full product specific waiver

2.4 Pharmaceutical Form(s):

Deleted in modification MHRA-100154-PIP01-21-M01

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable
Non-Clinical Studies	0	Study 1 (Deleted in modification MHRA-100154-PIP01-21-M01)
Clinical Studies	0	Study 2 (Deleted in modification MHRA-100154-PIP01-21-M01) Study 3 (Deleted in modification MHRA-100154-PIP01-21-M01)
Extrapolation, Modeling & Simulation Studies	0	Study 4 (Deleted in modification MHRA-100154-PIP01-21-M01) Study 5 (Deleted in modification MHRA-100154-PIP01-21-M01) Study 6 (Deleted in modification MHRA-100154-PIP01-21-M01)
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:	Not applicable
Date of completion of the paediatric investigation plan:	
Deferral of one or more studies contained in the paediatric investigation plan:	Not applicable