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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

confirm the applicability of the Class Waiver

MHRA-101500-PIP01-24

Scope of the Application

Active Substance(s)

zanidatamab

Condition(s)

Treatment of gastroesophageal adenocarcinoma (GEA).

Pharmaceutical Form(s)

Powder for concentrate for solution for infusion

Route(s) of Administration

INTRAVENOUS USE

Name / Corporate name of the PIP applicant

Jazz Pharmaceuticals UK Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Jazz Pharmaceuticals UK Limited submitted to the licensing authority on 31/05/2024 15:48 BST an application for a Waiver

The procedure started on 02/07/2024 13:25 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 confirm the applicability of the Class 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-101500-PIP01-24

Of 08/10/2024 07:36 BST

On the adopted decision for zanidatamab (MHRA-101500-PIP01-24) in accordance with the Human Medicines Regulations 2012.

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

Confirmation of the applicability of the Class Waiver for the listed condition(s)

This decision applies to a Waiver for zanidatamab, Powder for concentrate for solution for infusion , INTRAVENOUS USE .

This decision is addressed to Jazz Pharmaceuticals UK Limited , Wing B, Building 5700, Spires House, John Smith Drive, Oxford Business Park South,, Oxford, UNITED KINGDOM, OX4 2RW

ANNEX I

1. Waiver

1.1 Condition:

Treatment of gastroesophageal adenocarcinoma (GEA). The waiver applies / applied to: Paediatric Subset(s): All subsets of the paediatric population from birth to less than 18 years of age Pharmaceutical form(s): Powder for concentrate for solution for infusion Route(s) of administration: INTRAVENOUS USE Reason for granting waiver: the product belongs to 'the class of Her- / Epidermal growth factor-receptor antibody medicinal products for treatment of breast malignant neoplasms, intestinal malignant neoplasms and head and neck epithelial malignant neoplasms' as stated in Annex II of the adopted Class Waiver Decision CW/0001/2015

2. Paediatric Investigation Plan:

2.1 Condition(s):

Not Applicable

2.2 Indication(s) targeted by the PIP:

Not Applicable

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

Not Applicable

2.4 Pharmaceutical Form(s):

Not Applicable

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures		
Non-Clinical Studies		
Clinical Studies		
Extrapolation, Modeling & Simulation Studies		
Other Studies		
Other Measures		

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

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	
Date of completion of the paediatric investigation plan:	
Deferral of one or more studies contained in the paediatric investigation plan:	