

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

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Decision Cover Letter

Decision of the licensing authority to:

grant a product specific waiver.

MHRA-101395-PIP01-24

Scope of the Application

Active Substance(s)

Zanidatamab

Condition(s)

Treatment of biliary tract cancer (BTC).

Pharmaceutical Form(s)

All pharmaceutical forms

Route(s) of Administration

All routes of administration

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 20/03/2024 21:47 GMT an application for a Waiver

The procedure started on 29/08/2024 12:55 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 grant a 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.

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Final Decision Letter

MHRA-101395-PIP01-24

Of 20/09/2024 14:52 BST

On the adopted decision for Zanidatamab (MHRA-101395-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:

Granting a waiver in all age groups for the listed condition(s).

This decision applies to a Waiver for Zanidatamab, All pharmaceutical forms , All routes of administration .

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 biliary tract cancer (BTC) The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 18 years of age. Pharmaceutical form(s): All pharmaceutical forms Route(s) of administration: All routes of administration Reason for granting waiver: On the grounds the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

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:	