MHRA
10 South Colonnade
Canary Wharf
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United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral

MHRA-100054-PIP01-21

Scope of the Application

Active Substance(s)

RO7496998 (AT-527)

Condition(s)

Treatment of Coronavirus disease 2019 (COVID-19)

Pharmaceutical Form(s)

Tablet

Route(s) of Administration

Oral use

Name / Corporate name of the PIP applicant

Atea Pharmaceuticals, Inc.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Atea Pharmaceuticals, Inc. submitted to the licensing authority on 08/03/2021 11:42 GMT an application for a Paediatric Investigation Plan

The procedure started on 07/04/2021 14:23 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:

The agreement of a paediatric investigation plan and on the granting of a 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.

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Final Decision Letter

MHRA-100054-PIP01-21

Of 22/11/2021 13:06 GMT

On the adopted decision for RO7496998 (AT-527) (MHRA-100054-PIP01-21) 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 RO7496998 (AT-527), Tablet , Oral use .

This decision is addressed to Atea Pharmaceuticals, Inc., 6 Falcon Way, Shire Park, Welwyn Garden City,, United Kingdom, 02110

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of Coronavirus disease 2019 (COVID-19)

2.2 Indication(s) targeted by the PIP:

Treatment of Coronavirus disease 2019 (COVID-19) in paediatric patients from birth to less than 18 years of age.

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

The paediatric population from birth 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 an age-appropriate formulation of RO7496998 for use in paediatric COVID-19 patients from birth to less than 12 years of age
Non-Clinical Studies	0	Not applicable
Clinical Studies	2	Study 2: A randomized, double-blind, placebo controlled, outpatient study to evaluate the efficacy, safety, and antiviral activity of RO7496998 (AT-527) in paediatric (and adult) patients with mild or moderate COVID-19; Study 3: A single arm study to assess the PK, antiviral activity, safety, and exploratory efficacy of RO7496998 treatment of paediatric patients from birth to less than 12 years of age with mild to moderate COVID-19.
Extrapolation, Modeling & Simulation Studies	3	Study 4: Population pharmacokinetic (PK) model describing jointly the PK of AT-511 (free base form of RO7496998) and AT-273 (the surrogate for the intracellular concentration of the active triphosphate metabolite AT-9010) in adolescent (and adult) patients with mild or moderate COVID-19; Study 5: Bayesian feedback analysis of the PK data collected in paediatric patients (birth to less than 12 years) with COVID-19 using the integrated population PK model (Study 3) to establish that the PK of AT-511 and AT-273 is similar between paediatric and adult patients with COVID-19; Study 6: Extrapolation study of efficacy and safety of AT-527 from adults to paediatric patients from

		birth to less than 18 years of age with confirmed COVID-19.
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:	31/01/2024
Deferral of one or more studies contained in the paediatric investigation plan:	Yes