MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
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-100305-PIP01-21

Scope of the Application

Active Substance(s)

Single chain urokinase plasminogen activator (scuPA)

Condition(s)

Treatment of pleural effusion

Pharmaceutical Form(s)

Powder for solution for injection

Route(s) of Administration

Intrapleural use

Name / Corporate name of the PIP applicant

Lung Therapeutics, Inc

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Lung Therapeutics, Inc submitted to the licensing authority on 20/10/2021 13:30 BST an application for a Paediatric Investigation Plan

The procedure started on 31/03/2022 08:47 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 agree a paediatric investigation plan and grant 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-100305-PIP01-21

Of 08/04/2022 11:04 BST

On the adopted decision for Single chain urokinase plasminogen activator (scuPA) (MHRA-100305-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 Single chain urokinase plasminogen activator (scuPA), Powder for solution for injection , Intrapleural use .

This decision is addressed to Lung Therapeutics, Inc, 3801 S. Capital of Texas Hwy, Suite 330, Austin, United States, 78704

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of pleural effusion

2.2 Indication(s) targeted by the PIP:

Treatment of infected, non-draining pleural effusions (including complicated parapneumonic pleural effusion [CPE], empyema and other forms of pleural space infection).

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):

Powder for solution for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable
Non-Clinical Studies	1	Not applicable
Clinical Studies	0	Study 1 (LTI-001-PED1) Open-label, single-arm, sequential-dose cohort study to assess the safety, pleural pharmacokinetics, tolerability, and efficacy of single chain urokinase plasminogen activator (scuPA) in paediatric patients from birth to less than 18 years of age for the treatment of loculated, non-draining pleural effusions.
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:	29/02/2028
Deferral of one or more studies contained in the paediatric investigation plan:	Yes