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

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Decision Cover Letter

Decision of the licensing authority to:

confirm the applicability of the Class Waiver

MHRA-102313-PIP01-26

Scope of the Application

Active Substance(s)

Lorecivivint

Condition(s)

Treatment of osteoarthritis of the knee and hip

Pharmaceutical Form(s)

Suspension for injection

Route(s) of Administration

INTRA-ARTICULAR USE

Name / Corporate name of the PIP applicant

Biosplice Therapeutics, Inc

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Biosplice Therapeutics, Inc submitted to the licensing authority on 14/01/2026 17:03 GMT an application for a Waiver

The procedure started on 23/01/2026 15:22 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:

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.

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Final Decision Letter

MHRA-102313-PIP01-26

Of 24/03/2026 15:03 GMT

On the adopted decision for Lorecivivint (MHRA-102313-PIP01-26) 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 Lorecivivint, Suspension for injection , INTRA-ARTICULAR USE .

This decision is addressed to Biosplice Therapeutics, Inc, 6555 Nancy Ridge Drive, Suite 300, San Diego, UNITED STATES OF AMERICA, CA 92121

ANNEX I

1. Waiver

1.1 Condition:

Treatment of osteoarthritis of the knee and hip 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): Suspension for injection Route(s) of administration: Intra-articular use Reason for granting waiver: For the paediatric population from birth to less than 18 years of age: - the product belongs to the class of ‘Primary and secondary osteoarthrosis’ as stated in Annex II of the adopted Class Waiver Decision CW/0001/2025.

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:	