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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

grant a product specific waiver.

MHRA-101288-PIP01-23

Scope of the Application

Active Substance(s)

Interleukin-2 ; Interleukin-1 beta, human ; Granulocyte colony-stimulating factor ; Tumor necrosis factor-alpha ; Interferon gamma

Condition(s)

Treatment of squamous cell carcinoma of the head and neck (SCCHN)

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

Peritumoural use; Perilymphatic use

Name / Corporate name of the PIP applicant

Cel-Sci Corporation

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Cel-Sci Corporation submitted to the licensing authority on 21/12/2023 13:39 GMT an application for a Paediatric Investigation Plan

The procedure started on 13/08/2024 13:09 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.

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

gov.uk/mhra

Final Decision Letter

MHRA-101288-PIP01-23

Of 28/08/2024 11:58 BST

On the adopted decision for Interleukin-2 ; Interleukin-1 beta, human ; Granulocyte colony-stimulating factor ; Tumor necrosis factor-alpha ; Interferon gamma (MHRA-101288-PIP01-23) 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 Paediatric Investigation Plan for Interleukin-2 ; Interleukin-1 beta, human ; Granulocyte colony-stimulating factor ; Tumor necrosis factor-alpha ; Interferon gamma , Solution for injection , Peritumoural use; Perilymphatic use .

This decision is addressed to Cel-Sci Corporation, 8229 Boone Boulevard, Suite 802, Vienna, UNITED STATES OF AMERICA, VA 22182

ANNEX I

1. Waiver

1.1 Condition:

Treatment of squamous cell carcinoma of the head and neck. The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 18 years of age. Pharmaceutical form(s): Solution for injection Route(s) of administration: PERITUMOURAL USE; PERILYMPHATIC USE Reason for granting waiver: On the grounds the specific medicinal product does not represent a significant therapeutic benefit as clinical studies are not feasible

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	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	0	Not applicable.
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:	Not applicable.
Date of completion of the paediatric investigation plan:	
Deferral of one or more studies contained in the paediatric investigation plan:	Not applicable.