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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-100048-PIP01-21

Scope of the Application

Active Substance(s)

Afamitresgene autoleucel

Condition(s)

Treatment of soft tissue sarcoma

Pharmaceutical Form(s)

Dispersion for infusion

Route(s) of Administration

Intravenous use

Name / Corporate name of the PIP applicant

Adaptimmune LLC

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Adaptimmune LLC submitted to the licensing authority on 19/04/2021 18:07 BST an application for a Paediatric Investigation Plan

The procedure started on 13/12/2021 16:26 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 agree a paediatric investigation plan and grant a deferral and grant a 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-100048-PIP01-21

Of 16/12/2021 16:27 GMT

On the adopted decision for Afamitresgene autoleucel (MHRA-100048-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 Afamitresgene autoleucel, Dispersion for infusion , Intravenous use .

This decision is addressed to Adaptimmune LLC, 351 Rouse Boulevard, Philadelphia, United States, 19112

ANNEX I

1. Waiver

1.1 Condition:

Treatment of soft tissue sarcoma The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 10 years of age Pharmaceutical form(s): Dispersion for infusion Route(s) of administration: Intravenous use Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of soft tissue sarcoma

2.2 Indication(s) targeted by the PIP:

Treatment of advanced/ metastatic synovial sarcoma

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

The paediatric population from 10 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Dispersion for infusion

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable
Non-Clinical Studies	0	Not applicable
Clinical Studies	1	Study 1 Single arm, open label, non-comparative study to evaluate the activity, safety and tolerability of afamitresgene autoleucel in huma leucocyte antigen serotype HLA-A*02 children from 10 years to less than 18 years of age (and adults) with MAGE-A4 expressing metastatic or inoperable (advanced) synovial sarcoma or myxoid/ round cell liposarcoma (MRCLS).
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:	Yes
Date of completion of the paediatric investigation plan:	30/11/2022
Deferral of one or more studies contained in the paediatric investigation plan:	Yes