MHRA
10 South Colonnade
Canary Wharf
London
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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 and grant a waiver

MHRA-102207-PIP01-25

Scope of the Application

Active Substance(s)

Dazukibart

Condition(s)

Treatment of idiopathic inflammatory myopathy

Pharmaceutical Form(s)

Concentrate for solution for infusion

Route(s) of Administration

Intravenous use

Name / Corporate name of the PIP applicant

Pfizer Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Pfizer Limited submitted to the licensing authority on 04/11/2025 11:24 GMT an application for a Paediatric Investigation Plan

The procedure started on 02/12/2025 13:11 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.

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Final Decision Letter

MHRA-102207-PIP01-25

Of 22/07/2026 16:25 BST

On the adopted decision for Dazukibart (MHRA-102207-PIP01-25) 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 Dazukibart, Concentrate for solution for infusion , Intravenous use .

This decision is addressed to Pfizer Limited, Ramsgate Road , Sandwich, UNITED KINGDOM, CT139NJ

ANNEX I

1. Waiver

1.1 Condition:

Treatment of idiopathic inflammatory myopathy The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age Pharmaceutical form(s): Concentrate for solution for infusion Route(s) of administration: Intravenous use Reason for granting waiver: on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of idiopathic inflammatory myopathy

2.2 Indication(s) targeted by the PIP:

Treatment of idiopathic inflammatory myopathy (IIM)

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

The paediatric population from 2 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Concentrate for solution for infusion

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of a pharmaceutical form of appropriate strength that is suitable for administration in paediatric patients from 2 years of age.
Non-Clinical Studies	2	Study 2 (20LJ053) 6-month chronic toxicity study of dazukibart in cynomolgus monkeys. Study 3 (21GR024) Enhanced pre- and postnatal development toxicity study to evaluate the potential effects of dazukibart in cynomolgus monkeys on pregnancy and parturition, embryo-foetal development, and the survival, growth, and postnatal development of offspring.
Clinical Studies	2	Study 4 (C0251009) Double-blind, randomised, placebo controlled trial to evaluate pharmacokinetics, safety, and efficacy of dazukibart as add-on to standard of care in adolescents from 12 years to less than 18 years of age with active juvenile idiopathic inflammatory myopathy (JIIM). Study 5 (C0251016) Single-arm, open-label trial to evaluate dazukibart pharmacokinetics, pharmacodynamics, safety, and activity as add-on to standard of care in children from 2 years to less than 12 years of age with active juvenile idiopathic inflammatory myopathy.

Extrapolation, Modeling & Simulation Studies	5	Study 6 Population Pharmacokinetic and Pharmacodynamic model in adult dermatomyositis and polymyositis (DM and PM), and juvenile dermatomyositis and polymyositis (JDM and JPM) to confirm dosing for adolescent subjects (from 12 years to less than 18 years of age) and to provide initial dosing recommendation to be used in PIP Study 5 (C0251016) (from 2 years to less than 12 years of age) population. Study 7 Exposure-response Model in adult DM and PM, and adolescent JDM and JPM patients (from 12 years to less than 18 years of age) to be used as a basis for extrapolation of efficacy from adolescent JDM population to the adolescent JPM population. Study 8 Population Pharmacokinetic and Pharmacodynamic model in children from 2 years to less than 12 years of age to characterise the PK in paediatric participants and to simulate exposure and biomarker levels to be used as a basis for extrapolation for the children JDM and JPM population. Study 9 Exposure-response model in children from 2 years to less than 12 years of age to be used as a basis for extrapolation of efficacy from adolescents with JDM and JPM to children with JDM and children with JPM. Extrapolation Plan Studies 4, 5, 6, 7, 8 and 9 are part of the extrapolation plan of efficacy data from adult, adolescent (from 12 years to less than 18 years) and children (from 2 to less than 12 years) patients with the condition of IIM.
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:	31/05/2035
Deferral of one or more studies contained in the paediatric investigation plan:	Yes