

**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 and grant a waiver

MHRA-102046-PIP01-25

### **Scope of the Application**

#### **Active Substance(s)**

Pegozafermin

#### **Condition(s)**

Treatment of metabolic dysfunction-associated steatohepatitis (MASH).

#### **Pharmaceutical Form(s)**

Solution for injection

#### **Route(s) of Administration**

SUBCUTANEOUS USE

#### **Name / Corporate name of the PIP applicant**

89bio Inc.

#### **Basis for the Decision**

Pursuant to the Human Medicines Regulations 2012, 89bio Inc. submitted to the licensing authority on 22/08/2025 13:57 BST an application for a Paediatric Investigation Plan

The procedure started on 02/09/2025 19:58 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 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-102046-PIP01-25

Of 12/01/2026 08:21 GMT

On the adopted decision for Pegzofermin (MHRA-102046-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 Pegzofermin, Solution for injection ,  
SUBCUTANEOUS USE .

This decision is addressed to 89bio Inc. , 655 Montgomery Street Floor 15th, San Francisco, UNITED STATES OF AMERICA, 94111-2635

## ANNEX I

### 1. Waiver

#### 1.1 Condition:

Treatment of metabolic dysfunction-associated steatohepatitis (MASH). The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 years of age  
Pharmaceutical form(s): Solution for injection  
Route(s) of administration: SUBCUTANEOUS  
USE  
Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments

### 2. Paediatric Investigation Plan:

#### 2.1 Condition(s):

Treatment of metabolic dysfunction-associated steatohepatitis (MASH).

## 2.2 Indication(s) targeted by the PIP:

Treatment of metabolic dysfunction-associated steatohepatitis (MASH) with liver fibrosis in patients aged 6 years to less than 18 years.

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

The paediatric population from 6 years to less than 18 years of age

## 2.4 Pharmaceutical Form(s):

Solution for injection

## 2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	2	Study 1 Randomised, double-blind, placebo-controlled, efficacy and safety study, preceded by an open label, single ascending and multiple ascending dose, pharmacokinetic, pharmacodynamic, safety and tolerability, dose finding lead in phase, of pegozafermin in paediatric MASH patients aged 12 years to less than 18 years. Study 2 Randomised, double-blind, placebo-controlled, efficacy and safety study, preceded by an open label, single ascending and multiple ascending dose, pharmacokinetic, pharmacodynamic, safety and tolerability, dose finding lead in phase, of pegozafermin in paediatric MASH patients aged 6 years to less than 12 years.
Extrapolation, Modeling & Simulation Studies	1	Study 3 Population pharmacokinetic (PK)/pharmacodynamic (PD) model to predict initial paediatric doses to be used in PIP studies 1 and 2.
Other Studies	0	Not applicable.
Other Measures	0	Not applicable.

## 3. Follow-up, completion and deferral of a PIP:

<b>Concerns on potential long term safety and efficacy issues in relation to paediatric use:</b>	Yes
<b>Date of completion of the paediatric investigation plan:</b>	30/09/2043
<b>Deferral of one or more studies contained in the paediatric investigation plan:</b>	Yes