EMADOC-1700519818-2117850

# European Medicines Agency decision

EMA/PE/0000232782

of 15 May 2025

on the agreement of a paediatric investigation plan and on the granting of a deferral for (1R,2S)-1-(6-Bromo-2-methoxyquinolin-3-yl)-2-(2,6-dimethoxypyridin-4-yl)-4-(dimethylamino)-1-(2,3,6-trimethoxypyridin-4-yl)butan-2-ol tartrate in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

**Disclaimer**

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

**Only the English text is authentic.**

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The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the application submitted by The Global Alliance For TB Drug Development Inc. on 29/04/2024 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation,,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 28 March 2025, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the agreement of a paediatric investigation plan and on the granting of a deferral.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a deferral.

[1] OJ L 378, 27.12.2006, p.1, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

***Article 1***

A paediatric investigation plan for (1R,2S)-1-(6-Bromo-2-methoxyquinolin-3-yl)-2-(2,6-dimethoxypyridin-4-yl)-4-(dimethylamino)-1-(2,3,6-trimethoxypyridin-4-yl)butan-2-ol tartrate, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

***Article 2***

A deferral for (1R,2S)-1-(6-Bromo-2-methoxyquinolin-3-yl)-2-(2,6-dimethoxypyridin-4-yl)-4-(dimethylamino)-1-(2,3,6-trimethoxypyridin-4-yl)butan-2-ol tartrate, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

***Article 3***

This decision is addressed to The Global Alliance For TB Drug Development Inc., 80 Pine Street, New York, NY 10005-1702, United States.

EMADOC-1700519818-1860829
Amsterdam, 28 March 2025

# Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral

EMA/PE/0000232782

## Scope of the application

**Active substance(s):**

(1R,2S)-1-(6-Bromo-2-methoxyquinolin-3-yl)-2-(2,6-dimethoxypyridin-4-yl)-4-(dimethylamino)-1-(2,3,6-trimethoxypyridin-4-yl)butan-2-ol tartrate (TBAJ-876)

**Invented name and authorisation status:**

See Annex II

**Condition(s):**

Treatment of tuberculosis

**Pharmaceutical form(s):**

Tablet

Age-appropriate formulation

**Route(s) of administration:**

Oral use

**Name/corporate name of the PIP applicant:**

The Global Alliance For TB Drug Development Inc.

## Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, The Global Alliance For TB Drug Development Inc. submitted for agreement to the European Medicines Agency on 29 April 2024 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 27 January 2025.

Supplementary information was provided by the applicant on 19 December 2024. The applicant proposed modifications to the paediatric investigation plan.

## Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 17(1) of said Regulation;
   - to grant a deferral in accordance with Article 21 of said Regulation.

   The Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee

2. The measures and timelines of the agreed paediatric investigation plan are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

# Annex I

# The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

# 1. Waiver

Not applicable

# 2. Paediatric investigation plan

## *2.1. Condition:*

Treatment of tuberculosis

### 2.1.1. Indication(s) targeted by the PIP

Treatment of pulmonary tuberculosis.

### 2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From birth to less than 18 years of age

### 2.1.3. Pharmaceutical form(s)

Tablet

Age-appropriate formulation

### 2.1.4. Measures

| Area | Description |
|---|---|
| Quality-related studies | Study 1<br><br>Development of an age-appropriate formulation of TBAJ-876 (scored dispersible tablets for oral use in one or two strengths) for children and adolescents who cannot swallow tablets or need a lower dose based on body weight. |
| Non-clinical studies | Study 2<br><br>Dose-range finding juvenile animal study to evaluate the toxicity and toxicokinetics of TBAJ-876 in juvenile rats.<br><br>Study 3<br><br>Definitive juvenile animal study to evaluate the toxicity and toxicokinetics of TBAJ-876 in juvenile rats. |
| Clinical studies | Study 4<br><br>Open-label, single-arm study to evaluate pharmacokinetics, safety and tolerability, and antimycobacterial activity of TBAJ-876 in participants from birth to less than 18 years of age with pulmonary tuberculosis, with and without human immunodeficiency virus co-infection. |

| | |
|---|---|
| Modelling and simulation analyses | Study 5<br><br>Population-PK model for participants from birth to less than 18 years of age with pulmonary tuberculosis |
| Other studies | Not applicable |
| Extrapolation plan | PIP study 4 and 5 are part of an extrapolation plan from adults to children as agreed by the PDCO |

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

| | |
|---|---|
| Concerns on potential long term safety/efficacy issues in relation to paediatric use: | No |
| Date of completion of the paediatric investigation plan: | By December 2038 |
| Deferral for one or more measures contained in the paediatric investigation plan: | Yes |

# Annex II

# Information about the authorised medicinal product

***Information provided by the applicant:***

**The product is not authorised anywhere in the European Community.**