EMA/114596/2024

# European Medicines Agency decision

P/0120/2024

of 12 April 2024

on the agreement of a paediatric investigation plan and on the granting of a deferral for trimodulin (human IgM, IgA, IgG solution), (EMEA-002883-PIP03-23) 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 Biotest AG on 16 March 2023 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 23 February 2024, 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 trimodulin (human IgM, IgA, IgG solution), solution for infusion, intravenous use, 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 trimodulin (human IgM, IgA, IgG solution), solution for infusion, intravenous use, 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 Biotest AG, Landsteinerstrasse 5, 63303 – Dreieich, Germany.

EMA/PDCO/536041/2023
Amsterdam, 23 February 2024

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

EMEA-002883-PIP03-23

## Scope of the application

**Active substance(s):**

Trimodulin (human IgM, IgA, IgG solution)

**Invented name and authorisation status:**

See Annex II

**Condition(s):**

Treatment of lower respiratory tract and lung infections

**Pharmaceutical form(s):**

Solution for infusion

**Route(s) of administration:**

Intravenous use

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

Biotest AG

## Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Biotest AG submitted for agreement to the European Medicines Agency on 16 March 2023 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 24 April 2023.

Supplementary information was provided by the applicant on 19 October 2023.

## 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 lower respiratory tract and lung infections

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

Treatment of lower respiratory tract and lung infections

### 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)

Solution for infusion

### 2.1.4. Measures

| **Area** | **Description** |
|---|---|
| Quality-related studies | Not applicable. |
| Non-clinical studies | Not applicable. |
| Clinical studies | ***Study 1 (03-CAP-Children)***<br><br>Double-blind, randomised, multiple dose, placebo controlled trial to evaluate efficacy, safety and pharmacokinetics of trimodulin as add-on to best standard of care in children and adolescents from 45 weeks post-menstrual age (PMA) to less than 18 years of age with severe community-acquired pneumonia.<br>***Study 2 (03-CAP-Neonates)***<br><br>Double-blind, randomised, multiple dose, placebo controlled trial to evaluate efficacy, safety and pharmacokinetics of trimodulin as add-on to best standard of care in neonates less than 45 weeks post-menstrual age (PMA) with neonatal pneumonia. |
| Modelling and simulation analyses | ***Study 3 (01-CAP)***<br><br>PBPK model to predict initial paediatric doses to be used in further clinical studies, and to analyse PK data collected in paediatric studies to inform dosing recommendation in |

| | |
|---|---|
| | paediatric subjects from 2 years of age to less than 18 years of age.<br><br>***Study 4 (02-CAP)***<br><br>PopPK(/PD) to predict paediatric doses to be used in further clinical studies, and to confirm or modify the paediatric posology compared to the regimen used in clinical trials for children from 2 years of age to less than 18 years of age.<br><br>***Study 5 (04-CAP)***<br><br>PBPK to analyse (sparse) PK data collected in paediatric studies to inform dosing recommendation in paediatric subjects from birth to less than 2 years of age.<br><br>***Study 6 (05-CAP)***<br><br>PopPK(/PD) to predict initial dosing recommendations and to confirm or modify the paediatric posology compared to the regimen used in clinical trials for children from birth to less than 2 years of age. |
| Other studies | Not applicable. |
| Extrapolation plan | Not applicable. |

# 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 July 2032 |
| 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.**