EMA/182112/2024

# European Medicines Agency decision

P/0171/2024

of 3 May 2024

on the acceptance of a modification of an agreed paediatric investigation plan for atrasentan (hydrochloride), (EMEA-001666-PIP02-21-M01) 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 European Medicines Agency's decision P/0187/2023 issued on 15 May 2023.

Having regard to the application submitted by Chinook Therapeutics, Inc. on 18 December 2023 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 22 March 2024, in accordance with Article 22 of Regulation (EC) No 1901/2006,

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 acceptance of changes to the agreed paediatric investigation plan and to the deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the 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***

Changes to the agreed paediatric investigation plan for atrasentan (hydrochloride), age-appropriate oral liquid formulation, tablet, oral use, gastric use, including changes to the deferral, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

***Article 2***

This decision is addressed to Chinook Therapeutics, Inc., 400 Fairview Ave. North, Suite 900, 98109 – Seattle, USA.

EMA/PDCO/13771/2024
Amsterdam, 22 March 2024

# Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-001666-PIP02-21-M01

## Scope of the application

**Active substance(s):**

Atrasentan (hydrochloride)

**Invented name and authorisation status:**

See Annex II

**Condition(s):**

Treatment of IgA nephropathy

**Pharmaceutical form(s):**

Age-appropriate oral liquid formulation

Tablet

**Route(s) of administration:**

Oral use

Gastric use

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

Chinook Therapeutics, Inc.

## Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Chinook Therapeutics, Inc. submitted to the European Medicines Agency on 18 December 2023 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0187/2023 issued on 15 May 2023.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral.

The procedure started on 22 January 2024.

## Scope of the modification

Some timelines of the Paediatric Investigation Plan have been modified.

## Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan and to the deferral in the scope set out in the Annex I of this opinion.

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

2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver 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

## *1.1. Condition:*

Treatment of IgA nephropathy

The waiver applies to:

- the paediatric population from birth to less than 2 years of age;
- film-coated tablet, age-appropriate oral formulation, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies are not feasible.

# 2. Paediatric investigation plan

## *2.1. Condition:*

Treatment of IgA nephropathy

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

Treatment of children with IgA nephropathy at high risk for progression of kidney function decline, who are on a stable dose of, or are refractory or intolerant to renin-angiotensin system (RAS) inhibitors

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

From 2 years to less than 18 years of age

### 2.1.3. Pharmaceutical form(s)

Film-coated tablet, age-appropriate oral formulation

### 2.1.4. Measures

| Area | Description |
|---|---|
| Quality-related studies | **Study 1**<br>Development of an age-appropriate oral formulation |
| Non-clinical studies | Not applicable |
| Clinical studies | **Study 2**<br>Open-label, non-comparative trial to evaluate pharmacokinetics, safety and efficacy of atrasentan in subjects from 2 years to less than 18 years of age with IgA nephropathy |

| | |
|---|---|
| Modelling and simulation studies | **Study 3**<br>Modelling and simulation study to evaluate the use of atrasentan in children and adolescents from 2 years to less than 18 years of age with IgA nephropathy |
| Other studies | Not applicable |
| Extrapolation plan | Studies 2 and 3 are part of an extrapolation plan covering the paediatric population from 2 years to less than 18 years of age, 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 March 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.**