EMA/385668/2016

# European Medicines Agency decision

P/0162/2016

of 15 June 2016

on the acceptance of a modification of an agreed paediatric investigation plan for retosiban (EMEA-001359-PIP01-12-M03) 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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0201/2013 issued on 2 September 2013, the decision P/0073/2015 issued on 1 April 2015, and the decision P/0194/2015 issued on 4 September 2015,

Having regard to the application submitted by GlaxoSmithKline Trading Services Limited on 2 February 2016 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 29 April 2016, 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.

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

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

Has adopted this decision:

***Article 1***

Changes to the agreed paediatric investigation plan for retosiban, solution for infusion, intravenous use, 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 GlaxoSmithKline Trading Services Limited, GlaxoSmithKline Trading Services Limited, Currabinny, N/A - Carrigaline, County Cork, Ireland.

Done at London, 15 June 2016

For the European Medicines Agency
Zaïde Frias
Head of Division
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/130932/2016
London, 29 April 2016

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

EMEA-001359-PIP01-12-M03

## Scope of the application

**Active substance(s):**

Retosiban

**Condition(s):**

Treatment of spontaneous preterm labour

**Pharmaceutical form(s):**

Solution for infusion

**Route(s) of administration:**

Intravenous use

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

GlaxoSmithKline Trading Services Limited

## Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, GlaxoSmithKline Trading Services Limited submitted to the European Medicines Agency on 2 February 2016 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/0201/2013 issued on 2 September 2013, the decision P/0073/2015 issued on 1 April 2015, and the decision P/0194/2015 issued on 4 September 2015.

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

The procedure started on 1 March 2016.

## Scope of the modification

Some measures and 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 in the scope set out in the Annex I of this opinion.

   The Norwegian Paediatric Committee member 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 annex 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 spontaneous preterm labour

The waiver applies to:

- all boys from birth to less than 18 years of age and prepubertal girls;
- for solution for injection, intravenous use;
- 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*

Treatment of spontaneous preterm labour

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

Treatment of spontaneous preterm labour to improve neonatal outcomes by prolonging pregnancy in women with an uncomplicated singleton pregnancy between 24 and less than 34 weeks gestation

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

Adolescent girls from puberty to less than 18 years of age

### 2.1.3. Pharmaceutical form(s)

Solution for injection

### 2.1.4. Measures

| Area | Number of studies | Description |
|---|---|---|
| Quality-related studies | 0 | Not applicable. |
| Non-clinical studies | 0 | Not applicable. |
| Clinical studies | 2 | Study 1 has been deleted.<br>**Study 2**<br>Double-blind, randomised, parallel-group study to compare the efficacy of retosiban as compared to atosiban in adult and adolescent pregnant women with preterm labour between 24 to less than 34 weeks' gestation (study 200721). |

| | | |
|---|---|---|
| | | **Study 3**<br><br>Randomised, double-blind, parallel-group study to compare the efficacy and safety of retosiban versus placebo in adult and adolescent pregnant women diagnosed with spontaneous preterm labour (study 200719). |
| Extrapolation, modelling and simulation studies | 0 | Not applicable. |
| Other studies | 0 | Not applicable. |
| Other measures | 0 | Not applicable. |

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

| | |
|---|---|
| Concerns on potential long term follow-up safety/efficacy issues in relation to paediatric use: | Yes |
| Date of completion of the paediatric investigation plan: | By March 2019 |
| Deferral for one or more studies contained in the paediatric investigation plan: | No |