EMA/528354/2023

# European Medicines Agency decision

P/0502/2023

of 1 December 2023

on the refusal of a modification of an agreed paediatric investigation plan and on the granting of a waiver for mirabegron (Betmiga), (EMEA-000597-PIP02-10-M10) 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.**

# European Medicines Agency decision

P/0502/2023

of 1 December 2023

on the refusal of a modification of an agreed paediatric investigation plan and on the granting of a waiver for mirabegron (Betmiga), (EMEA-000597-PIP02-10-M10) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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/172/2010 issued on 10 September 2010, the decision P/0191/2013 issued on 9 August 2013, the decision P/0011/2014 issued on 22 January 2014, the decision P/0014/2015 issued on 30 January 2015, the decision P/0116/2015 issued on 5 June 2015, the decision P/0287/2016 issued on 4 November 2016, the decision P/0350/2017 issued on 1 December 2017, the decision P/0350/2019 issued on 30 September 2019, and the decision P/0550/2022 issued on 4 January 2022,

Having regard to the application submitted by Astellas Pharma Europe B.V. on 4 August 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 10 November 2023, in accordance with Article 22 of Regulation (EC) No 1901/2006 and of its own motion in accordance with Article 12 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 refusal of changes to the agreed paediatric investigation plan and to the deferral and on the granting of a waiver.

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

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

[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 mirabegron (Betmiga), prolonged-release granules for oral suspension, prolonged-release tablet, oral use, including changes to the deferral, 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, are hereby refused.

***Article 2***

A waiver for mirabegron (Betmiga), prolonged-release granules for oral suspension, prolonged-release tablet, oral use, the details of which are set out in the opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

***Article 3***

This decision is addressed to Astellas Pharma Europe B.V., Sylviusweg 62, 2333 BE – Leiden, The Netherlands.

EMA/PDCO/362188/2023
Amsterdam, 10 November 2023

# Opinion of the Paediatric Committee on the refusal of a modification of an agreed Paediatric Investigation Plan and on the granting of a product-specific waiver

EMEA-000597-PIP02-10-M10

## Scope of the application

**Active substance(s):**

Mirabegron

**Invented name and authorisation status:**

See Annex II

**Condition(s):**

Treatment of idiopathic overactive bladder

**Authorised indication(s):**

See Annex II

**Pharmaceutical form(s):**

Prolonged-release granules for oral suspension

Prolonged-release tablet

**Route(s) of administration:**

Oral use

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

Astellas Pharma Europe B.V.

## Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Astellas Pharma Europe B.V. submitted to the European Medicines Agency on 4 August 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/172/2010 issued on 10 September 2010, the decision P/0191/2013 issued on

9 August 2013, the decision P/0011/2014 issued on 22 January 2014, the decision P/0014/2015 issued on 30 January 2015, the decision P/0116/2015 issued on 5 June 2015, the decision P/0287/2016 issued on 4 November 2016, the decision P/0350/2017 issued on 1 December 2017, the decision P/0350/2019 issued on 30 September 2019, and the decision P/0550/2022 issued on 4 January 2022.

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

The procedure started on 11 September 2022.

## Opinion

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 refuse the changes proposed by the applicant regarding the paediatric investigation plan and the deferral,
- and in accordance with Article 12 of Regulation (EC) No 1901/2006 as amended, recommends to grant a product-specific waiver of its own motion for all subsets of the paediatric population concluded in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

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

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

# Annex I

# Grounds for the granting of the waiver

# 1. Waiver

## *1.1. Condition:*

Treatment of idiopathic overactive bladder

The waiver applies to:

- the paediatric population from birth to less than 18 years of age;
- prolonged-release granules for oral suspension, prolonged-release tablet, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies are not feasible.

# Annex II

# Information about the authorised medicinal product

## Condition(s) and authorised indication(s)

1. Treatment of overactive bladder

Authorised indication(s):

Symptomatic treatment of urgency, increased micturition frequency and/or urgency incontinence as may occur in adult patients with overactive bladder (OAB) syndrome.

- Invented name(s): Betmiga
- Authorised pharmaceutical form(s): Prolonged-release tablet.
- Authorised route(s) of administration: Oral use
- Authorised via centralised procedure.