

EMA/629508/2022

European Medicines Agency decision P/0288/2022

of 11 August 2022

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for vibegron (EMEA-001415-PIP02-21) 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 726/2004¹,

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 Agency²,

Having regard to the application submitted by Urovant Sciences GmbH on 6 September 2021 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 24 June 2022, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation and Article 13 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 and on the granting of a waiver.
- (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.
- (4) 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

A paediatric investigation plan for vibegron, film-coated tablet, granules, oral 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 vibegron, film-coated tablet, granules, oral 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

A waiver for vibegron, film-coated tablet, granules, oral 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 4

This decision is addressed to Urovant Sciences GmbH, Grosspeter Tower, 29 Grosspeteranlage, Suites 2006-2010, 4052 – Basel, Switzerland.

EMA/PDCO/203727/2022
Amsterdam, 24 June 2022

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

EMA-001415-PIP02-21

Scope of the application

Active substance(s):

Vibegron

Condition(s):

Treatment of myoneurogenic bladder disorders

Pharmaceutical form(s):

Film-coated tablet

Granules

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Urovant Sciences GmbH

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Urovant Sciences GmbH submitted for agreement to the European Medicines Agency on 6 September 2021 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 19 October 2021.

Supplementary information was provided by the applicant on 17 March 2022. 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;
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and 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.

2. The measures and timelines of the agreed 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 myoneurogenic bladder disorders

The waiver applies to:

- the paediatric population from birth to less than 6 months of age;
- for film-coated tablet, granules, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric investigation plan

2.1. Condition:

Treatment of myoneurogenic bladder disorders

2.1.1. Indication(s) targeted by the PIP

Treatment of detrusor overactivity in children with neurogenic bladder dysfunction

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

From 6 months to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Film-coated tablet

Granules

2.1.4. Measures

Area	Description
Quality-related studies	Study 1 Development of an immediate release granules formulation for use in the paediatric population. Study 2 Development of an immediate release 50 mg film-coated tablet for use in the paediatric population.
Non-clinical studies	Not applicable

Clinical studies	Study 3 Open-label, baseline-controlled, multicentre, long-term study to evaluate the safety, efficacy, and pharmacokinetics of vibegron in paediatric patients 2 years to less than 18 years of age with neurogenic detrusor overactivity on clean intermittent catheterisation (URO-901-3007). Study 4 Double-blind, active-controlled, study to evaluate the safety and efficacy of vibegron compared to oxybutynin in paediatric patients 5 years to less than 18 years of age with neurogenic detrusor overactivity on clean intermittent catheterisation (URO-901-3009). Study 5 Open-label, baseline-controlled, long-term study to evaluate the safety, activity, and pharmacokinetics of vibegron in paediatric patients from 6 months to less than 2 years of age with neurogenic detrusor overactivity on clean intermittent catheterisation (URO-901-3008).
Extrapolation, modelling and simulation studies	Study 6 Population PK (PPK) study to describe the PK of vibegron in paediatric patients and to establish dose based on target adult exposure in patients from 12 years to less than 18 years of age and in patients 2 to less than 12 years of age.
Other studies	None
Other measures	None

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 November 2031
Deferral for one or more measures contained in the paediatric investigation plan:	Yes