EMA/102423/2018

European Medicines Agency decision

P/0052/2018

of 22 February 2018

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for brivaracetam (Briviact), (EMEA-000332-PIP02-17) 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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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 application submitted by UCB Pharma S.A. on 23 November 2017 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 26 January 2018, 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.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

A paediatric investigation plan for brivaracetam (Briviact), film-coated tablet, oral solution, 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 brivaracetam (Briviact), film-coated tablet, oral solution, 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 brivaracetam (Briviact), film-coated tablet, oral solution, 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 UCB Pharma S.A., Allee de la Recherche, 60, 1070 – Brussels, Belgium.

EMA/PDCO/17049/2018
London, 26 January 2018

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

EMEA-000332-PIP02-17

Scope of the application

Active substance(s):

Brivaracetam

Invented name:

Briviact

Condition(s):

Treatment of paediatric epilepsy syndromes

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Film-coated tablet

Oral solution

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

UCB Pharma S.A.

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, UCB Pharma S.A. submitted for agreement to the European Medicines Agency on 23 November 2017 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 3 January 2018.

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)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population.

   The Norwegian Paediatric Committee member 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 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 paediatric epilepsy syndromes

The waiver applies to:

- preterm newborn infants, term newborn infants (from birth to less than 28 days);
- film-coated tablet and oral solution, oral 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 Paediatric Epilepsy Syndromes

2.1.1. Indication(s) targeted by the PIP

Treatment of refractory paediatric epilepsy syndromes with adjunctive administration of brivaracetam

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

From 28 days to less than 18 years

2.1.3. Pharmaceutical form(s)

Film-coated tablet (10 mg, 25 mg and 50 mg)

Oral solution (1 mg/ml, 10 mg/ml)

2.1.4. Measures

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	3	**Study 1** 9-week oral toxicity study followed by a 30-day recovery period in juvenile rats. (NCD1671, same study as in EMEA-000332-PIP01-08-M13) **Study 2** Study to evaluate brain weight in juvenile and adult rats. (NCD1883, same study as in EMEA-000332-PIP01-08-M13) **Study 3**

		9-month oral toxicity study in juvenile dogs with a 2-months recovery period. (NCD1863, same study as in EMEA-000332-PIP01-08-M13)
Clinical	4	**Study 4** In silico study for prediction of brivaracetam disposition in children. (N01313, same study as in EMEA-000332-PIP01-08-M13) **Study 5** Open-label, single-arm, multi-centre, pharmacokinetic, safety and efficacy study of adjunctive administration of brivaracetam in children aged 1 month to less than 16 years with refractory paediatric epilepsy syndromes or epilepsy. (N01263, same study as in EMEA-000332-PIP01-08-M13) **Study 6** Randomized, double-blind, placebo-controlled, parallel-group, multicentre study to evaluate the efficacy, safety, and tolerability of brivaracetam as adjunctive therapy in patients aged 1 month to 16 years with a paediatric epileptic syndrome based on the results of measure 4. (N01269) **Study 7** Open-label, single-arm, long-term follow-up study of brivaracetam in children with epilepsy. (N01266, same study as in EMEA-000332-PIP01-08-M13)

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By June 2019
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of partial-onset seizures

Authorised indication(s):

- Briviact is indicated as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adult and adolescent patients from 16 years of age with epilepsy

Authorised pharmaceutical form(s):

Film-coated tablets

Oral solution

Solution for injection/infusion

Authorised route(s) of administration:

Oral use

Intravenous use