EMA/622893/2020

European Medicines Agency decision

P/0465/2020

of 4 December 2020

on the acceptance of a modification of an agreed paediatric investigation plan for veliparib (EMEA-000499-PIP02-10-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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on the acceptance of a modification of an agreed paediatric investigation plan for veliparib (EMEA-000499-PIP02-10-M01) 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 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/212/2011 issued on 2 September 2011,

Having regard to the application submitted by AbbVie Ltd on 10 July 2020 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 16 October 2020, 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.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for veliparib, capsule, oral liquid, oral 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 AbbVie Ltd, AbbVie House, Vanwall Business Park, Vanwall Road, SL6 4UB - Maidenhead, United Kingdom.

EMA/PDCO/415227/2020
Amsterdam, 16 October 2020

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

EMEA-000499-PIP02-10-M01

Scope of the application

Active substance(s):

Veliparib

Condition(s):

Treatment of high-grade glioma

Pharmaceutical form(s):

Capsule

Oral liquid

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

AbbVie Ltd

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Abbott Ltd submitted to the European Medicines Agency on 10 July 2020 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/212/2011 issued on 2 September 2011.

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

The procedure started on 18 August 2020.

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 and to the deferral 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 high-grade glioma

The waiver applies to:

- the paediatric population from birth to less than 3 years of age;
- for capsule and oral liquid, oral use;
- on the grounds that the specific medicinal product is likely to be ineffective.

The waiver applies to:

- the paediatric population from 3 years to less than 18 years of age for whom radiation therapy is not part of the treatment;
- for capsule and oral liquid, oral use;
- on the grounds that the specific medicinal product is likely to be ineffective.

2. Paediatric Investigation Plan

2.1. Condition:

Treatment of high-grade glioma

2.1.1. Indication(s) targeted by the PIP

Treatment of newly diagnosed supratentorial high-grade glioma

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

From 3 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

- capsule, oral use;
- oral liquid, oral use.

2.1.4. Studies

Area	Number of studies	Description
Quality	1	Study 1: Development of an age-appropriate oral liquid formulation
Non-clinical	1	Study 2: Juvenile toxicology and toxicokinetic study
Clinical	2	Study 3: Open-label, non-controlled, multiple-dose, dose-escalating, single-agent trial to evaluate pharmacokinetics, safety and activity of veliparib in

		combination with temozolomide in children from birth to less than 18 years of age (and young adults) with recurrent or refractory malignant central nervous system tumours Study 4: Double-blind, randomised, placebo-controlled, multi-centre trial to evaluate safety and efficacy of veliparib in combination with radiation therapy and temozolomide in children from 3 years to less than 18 years (and young adults) with high-grade glioma

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 November 2027
Deferral for one or more studies contained in the paediatric investigation plan:	Yes