EMA/654593/2011

European Medicines Agency decision

P/212/2011

of 2 September 2011

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for veliparib (EMEA-000499-PIP02-10) 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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An agency of the European Union

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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 application submitted by Abbott Laboratories Ltd on 6 August 2010 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 15 July 2011, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulationand 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 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 veliparib, capsule, oral liquid, 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 veliparib, capsule, oral liquid, 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 veliparib, capsule, oral liquid, 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 Abbott Laboratories Ltd, Abbott House, Vanwall Business Park, Vanwall Road, SL6 4XE, Maidenhead, Berks, United Kingdom.

Done at London, 2 September 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director
(Signature on file)

EMA/PDCO/487195/2011

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

EMEA-000499-PIP02-10

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:

Abbott Laboratories Ltd

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Abbott Laboratories Ltd submitted for agreement to the European Medicines Agency on 6 August 2010 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 18 November 2010.

Supplementary information was provided by the applicant on 29 April 2011. The applicant proposed modifications to the paediatric investigation plan.

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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 18 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 on its own motion in accordance with Article 12 of said Regulation and concluded in accordance with Article 11(1)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all 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 annex and appendix.

London, 15 July 2011

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

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

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

Area	Number of studies	Description
		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 December 2020
Deferral for one or more studies contained in the paediatric investigation plan:	Yes