EMA/982073/2011

European Medicines Agency decision

P/312/2011

of 22 December 2011

on the acceptance of a modification of an agreed paediatric investigation plan for eltrombopag (Revolade), (EMEA-000170-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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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/234/2011 issued on 30 September 2011,

Having regard to the application submitted by GlaxoSmithKline Trading Services Limited on 16 November 2011 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 9 December 2011, 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.

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

[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 eltrombopag (Revolade), film-coated tablet, powder for oral suspension, oral use, 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 agreed PIP covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in PIP EMEA-000170-PIP01-07 (decision P/83/2008) including subsequent modifications thereof.

Article 3

This decision is addressed to GlaxoSmithKline Trading Services Limited, 6900 Cork Airport Business Park, Kinsdale Road, Cork, Ireland.

Done at London, 22 December 2011

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/982073/2011

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

EMEA-000170-PIP02-10-M01

Scope of the application

Active substance(s):

Eltrombopag

Invented name:

Revolade

Condition(s):

Treatment of Secondary Thrombocytopenia

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Film-coated tablet

Powder for oral suspension

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

GlaxoSmithKline Trading Services Limited

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, GlaxoSmithKline Trading Services Limited submitted to the European Medicines Agency on 24 October 2011 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/234/2011 issued on 30 September 2011.

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

The procedure started on 16 November 2011.

Scope of the modification

Some measures of the original 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 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(es) and appendix.

London, 9 December 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

Not applicable.

2. Paediatric Investigation Plan

2.1. Condition: Treatment of Secondary Thrombocytopenia

2.1.1. 2.1.1. Indication(s) targeted by the PIP

Treatment of thrombocytopenia secondary to treatment of myeloid or lymphoid malignancies or of solid tumours.

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

From birth to less than 18 years of age.

2.1.3. 2.1.3 Pharmaceutical form(s)

Film-coated tablet

Powder for oral suspension

2.1.4. 2.1.4. Studies

Area	Number of studies	Description
Quality	1	**Study 1**: Development of a powder for oral suspension in fixed single dose sachets.
Non-clinical	0	Not applicable.
Clinical	1	**Study 2**: Double-blind, placebo-controlled, randomised, multicentre trial to evaluate safety and efficacy of eltrombopag in addition to best standard of care in children with malignant diseases and secondary thrombocytopenia, from birth to less than 18 years of age.

3. Follow-up, completion and deferral of PIP

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

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of idiopathic thrombocytopenic purpura (ITP)

   Authorised indications:

   Revolade is indicated for adult chronic immune (idiopathic) thrombocytopenic purpura (ITP) splenectomised patients who are refractory to other treatments (e.g. corticosteroids, immunoglobulins). Revolade may be considered as second line treatment for adult non-splenectomised patients where surgery is contraindicated.

EU Number	**Invented name**	**Strength**	**Pharmaceutical Form**	**Route of Administration**	**Packaging**	**Package size**
EU/1/10/612/001	Revolade	25 mg	Film-coated tablet	Oral use	Blister (PA/Alu/PVC/Alu)	14 tablets
EU/1/10/612/002	Revolade	25 mg	Film-coated tablet	Oral use	Blister (PA/Alu/PVC/Alu)	28 tablets
EU/1/10/612/003	Revolade	25 mg	Film-coated tablet	Oral use	Blister (PA/Alu/PVC/Alu)	84 (3 x 28) tablets
EU/1/10/612/004	Revolade	50 mg	Film-coated tablet	Oral use	Blister (PA/Alu/PVC/Alu)	14 tablets
EU/1/10/612/005	Revolade	50 mg	Film-coated tablet	Oral use	Blister (PA/Alu/PVC/Alu)	28 tablets
EU/1/10/612/006	Revolade	50 mg	Film-coated tablet	Oral use	Blister (PA/Alu/PVC/Alu)	84 (3 x 28) tablets