

EMA/508736/2014

European Medicines Agency decision

P/0262/2014

of 3 October 2014

on the agreement of a paediatric investigation plan and on the granting of a deferral for eltrombopag (olamine) (Revolade), (EMA-000170-PIP03-13) 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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency²,

Having regard to the application submitted by GlaxoSmithKline Trading Services Limited on 8 November 2013 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 15 August 2014, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 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.
- (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.

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 eltrombopag (olamine) (Revolade), film-coated tablet, powder for oral suspension, 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 eltrombopag (olamine) (Revolade), film-coated tablet, powder for oral suspension, 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

This agreed PIP covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/83/2008 issued on 14 October 2008, including subsequent modifications thereof, and in the decision P/234/2011 issued on 30 September 2011.

Article 4

This decision is addressed to GlaxoSmithKline Trading Services Limited, 6900 Cork airport Business Park, Kinsale Road, N/A - Cork, Ireland.

Done at London, 3 October 2014

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



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/338266/2014 **corr**

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

EMA-000170-PIP03-13

Scope of the application

Active substance(s):

Eltrombopag (olamine)

Invented name:

Revolade

Condition(s):

Treatment of aplastic anaemia

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



Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, GlaxoSmithKline Trading Services Limited submitted for agreement to the European Medicines Agency on 8 November 2013 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 18 December 2013.

Supplementary information was provided by the applicant on 21 May 2014. The applicant proposed modifications to the paediatric investigation plan and withdrew its request for a waiver.

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.

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 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.

London, 15 August 2014

On behalf of the Paediatric Committee
Dr Dirk Mentzer, 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 (PIP)

1. Waiver

Not applicable.

2. Paediatric investigation plan

2.1. Condition:

Treatment of aplastic anaemia

2.1.1. Indication(s) targeted by the PIP

Treatment of cytopenias in paediatric patients with severe aplastic anaemia who are not receiving haematopoietic stem cell transplant

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. Pharmaceutical form(s)

Film-coated tablet for oral use

Powder for oral suspension for oral use

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	Study 1 Development of a powder for oral suspension in fixed single dose sachets.
Non-clinical studies	0	Not applicable.
Clinical studies	2	Study 2 Open-label, non-controlled, multiple dose trial to evaluate pharmacokinetics, safety, activity and acceptability/palatability of eltrombopag in children from birth to less than 18 years of age with severe aplastic anaemia that is refractory to, or has relapsed after immunosuppressive therapy or with newly-diagnosed severe aplastic anaemia in combination with immunosuppressive therapy. Study 3 Open-label, non-controlled, multiple dose trial to evaluate pharmacokinetics, safety and activity of eltrombopag in combination with immunosuppressive therapy in adults (and children from 2 years to less than 18 years of age) with newly-diagnosed severe aplastic anaemia.

Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By December 2020
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 immune (idiopathic) thrombocytopenic purpura

Authorised indication(s):

- 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.

2. Treatment of secondary thrombocytopenia

Authorised indication(s):

- Revolade is indicated in adult patients with chronic hepatitis C virus (HCV) infection for the treatment of thrombocytopenia, where the degree of thrombocytopenia is the main factor preventing the initiation or limiting the ability to maintain optimal interferon-based therapy (see sections 4.4 and 5.1).

Authorised pharmaceutical form(s):

Film-coated tablet

Authorised route(s) of administration:

Oral use