EMA/193031/2016

European Medicines Agency decision

P/0167/2016

of 15 June 2016

on the acceptance of a modification of an agreed paediatric investigation plan for eltrombopag (Revolade) (EMEA-000170-PIP01-07-M04) 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/83/2008 issued on 14 October 2008, the decision P/207/2009 issued on 30 October 2009 and the decision P/0307/2012 issued on 21 December 2012,

Having regard to the application submitted by Novartis Europharm Limited on 7 March 2016 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 29 April 2016, 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), powder for oral suspension film-coated tablet, 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 decision is addressed to Novartis Europharm Limited, Frimley Business Park, GU16 7SR – Camberley, United Kingdom.

Done at London, 15 June 2016

For the European Medicines Agency
Zaïde Frias
Head of Division
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/192686/2016 corr
London, 29 April 2016

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

EMEA-000170-PIP01-07-M04

Scope of the application

Active substance(s):

Eltrombopag

Invented name:

Revolade

Condition(s):

Treatment of Idiopathic Thrombocytopenia Purpura (ITP)

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder for oral suspension

Film-coated tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Novartis Europharm 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, Novartis Europharm Limited submitted to the European Medicines Agency on 7 March 2016 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/83/2008 issued on 14 October 2008, the decision P/207/2009 issued on 30 October 2009 and the decision P/0307/2012 issued on 21 December 2012.

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

The procedure started on 29 March 2016.

Scope of the modification

Amendment of the scope of the Paediatric Investigation Plan.

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.

   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 Idiopathic Thrombocytopenia Purpura (ITP)

The waiver applies to:

- all subsets of the paediatric population from birth to less than 1 years of age;
- for powder for oral suspension and film-coated tablet, 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 Idiopathic Thrombocytopenia Purpura (ITP)

2.1.1. Indication(s) targeted by the PIP

Treatment of Chronic Idiopathic thrombocytopenic purpura (ITP)

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

From 1 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Powder for oral suspension and Film-coated tablet, oral use

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		Not applicable.
Clinical	1	Study 2: Multicenter, placebo-controlled study to investigate the safety, tolerability and efficacy of eltrombopag in paediatric patients diagnosed with chronic Idiopathic Thrombocytopenic Purpura (ITP), from 1 year to less than 18 years old.

The date of completion of the paediatric investigation plan corresponds to the timeline for completion of the latest measure(s) reported below.

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 2014
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 idiopathic thrombocytopenic purpura (ITP)

Authorised indication(s):

Revolade is indicated for chronic immune (idiopathic) thrombocytopenic purpura (ITP) patients aged 1 year and above who are refractory to other treatments (e.g. corticosteroids, immunoglobulins)

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

3. Treatment of aplastic anaemia

Authorised indication(s):

Revolade is indicated in adult patients with acquired severe aplastic anaemia (SAA) who were either refractory to prior immunosuppressive therapy or heavily pretreated and are unsuitable for haematopoietic stem cell transplantation

Authorised pharmaceutical formulation(s):

Film-coated tablet

Powder for oral suspension

Authorised route(s) of administration:

Oral use