European Medicines Agency

Doc. Ref. EMEA/614741/2009
P/207/2009

EUROPEAN MEDICINES AGENCY DECISION

of 30 October 2009

on the acceptance of a modification of an agreed Paediatric Investigation Plan for eltrombopag (EMEA-000170-PIP01-07-M02) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006, as amended.

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THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

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 as amended 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 decision P/83/2008 of the European Medicines Agency on 14 October 2008,

Having regard to the application submitted by GlaxoSmithKline Trading Services Limited on 10 July 2009 under Article 22 of Regulation (EC) No 1901/2006 as amended proposing changes to the agreed Paediatric Investigation Plan,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 18 September 2009, in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended,

Having regard to Article 25 of Regulation (EC) No 1901/2006 as amended,

WHEREAS:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to an agreed Paediatric Investigation Plan,

(2) It is therefore appropriate to adopt a Decision on the acceptance of changes to an 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, film-coated tablets / powder or granules for dispersion, 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, are hereby accepted.

Article 2

This decision, that supersedes previous decision of the European Medicines Agency P/83/2008, as far as the agreed changes to the Paediatric Investigation Plan for eltrombopag, film-coated tablets / powder or granules for dispersion, oral use, are concerned, is addressed to GlaxoSmithKline Trading Services Limited, 6900 Cork Airport Business Park, Kinsale Road, Cork, Ireland.

Done at London, 30 October 2009

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

Doc. Ref. EMEA/PDCO/558020/2009
EMEA-000170-PIP01-07-M02

OPINION OF THE PAEDIATRIC COMMITTEE ON THE ACCEPTANCE OF A MODIFICATION OF AN AGREED PAEDIATRIC INVESTIGATION PLAN

Scope of the application

Active substance(s):
Eltrombopag

Condition(s):
Idiopathic Thrombocytopenia Purpura (ITP)

Pharmaceutical form(s):
Film-coated Tablets
Powder or Granules for dispersion

Route(s) of administration:
Oral use

Name/corporate name of the PIP applicant:
GlaxoSmithKline Trading Services Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, GlaxoSmithKline Trading Services Limited submitted to the EMEA on 10 July 2009 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the EMEA decision P/83/2008 of 14 October 2008. The application for modification proposed changes.

The procedure started on 23 July 2009.

Scope of the modification

The applicant modifications concerned clarifications and revision of some of the agreed measures and timelines.

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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 the changes proposed by the applicant regarding the measures and the timelines of the paediatric investigation plan

The Icelandic and the Norwegian Paediatric Committee members agree 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 Agency, together with its annex and appendix.

London, 18 September 2009

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

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

A. CONDITION(S)

Idiopathic thrombocytopenic purpura (ITP)

B. WAIVER

- **Condition**

  Idiopathic thrombocytopenic purpura (ITP)

  The waiver applies to:

  – Newborns and infants from birth to less than 1 year for film-coated tablets and powder/granules for dispersion, 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).

  – for Film-coated tablets and Powder/granules for dispersion, 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).

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

  Idiopathic thrombocytopenic purpura (ITP)

- **Proposed PIP indication**

  Treatment of Chronic Idiopathic thrombocytopenic purpura (ITP)

- **Subset(s) of the paediatric population concerned by the paediatric development**

  From 1 year to less than 18 years.

- **Formulation(s)**

  Film-coated tablets and Powder/granules for dispersion, oral use

- **Studies**

Area	Number of studies	Description
Quality	1	Development of a powder for oral suspension in fixed single-dose sachets.
Clinical	1	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.

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	**Yes**
Date of completion of the paediatric investigation plan:	**by December 2014**
A deferral has been granted for initiation of some or all studies contained in the paediatric investigation plan:	**Yes**
A deferral has been granted for completion of some or all studies contained in the paediatric investigation plan:	**Yes**