



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/878740/2011

European Medicines Agency decision P/309/2011

of 20 December 2011

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for (1-(3-chloro-5-([4-(4-chloro-2-thienyl)-5-(4-cyclohexylpiperazin-1-yl)-1,3-thiazol-2-yl]carbamoyl)-2-pyridyl)piperidine-4-carboxylic acid monomaleate) (E5501) (EMEA-001136-PIP01-11) 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 Eisai Limited on 11 March 2011 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 11 November 2011, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation and Article 13 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 (1-(3-chloro-5-{[4-(4-chloro-2-thienyl)-5-(4-cyclohexylpiperazin-1-yl)-1,3-thiazol-2-yl]carbamoyl}-2-pyridyl)piperidine-4-carboxylic acid monomaleate) (E5501), film-coated tablet, 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 (1-(3-chloro-5-{[4-(4-chloro-2-thienyl)-5-(4-cyclohexylpiperazin-1-yl)-1,3-thiazol-2-yl]carbamoyl}-2-pyridyl)piperidine-4-carboxylic acid monomaleate) (E5501), film-coated tablet, 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

A waiver for (1-(3-chloro-5-{[4-(4-chloro-2-thienyl)-5-(4-cyclohexylpiperazin-1-yl)-1,3-thiazol-2-yl]carbamoyl}-2-pyridyl)piperidine-4-carboxylic acid monomaleate) (E5501), film-coated tablet, 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 4

This decision is addressed to Eisai Limited, European Knowledge Centre, Mosquito Way, AL10 9SN - Hatfield, Hertfordshire, United Kingdom.

Done at London, 20 December 2011

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



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/719757/2011

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

EMA-001136-PIP01-11

Scope of the application

Active substance(s):

(1-(3-chloro-5-{[4-(4-chloro-2-thienyl)-5-(4-cyclohexylpiperazin-1-yl)-1,3-thiazol-2-yl]carbamoyl}-2-pyridyl)piperidine-4-carboxylic acid monomaleate) (E5501)

Condition(s):

Treatment of Idiopathic Thrombocytopenic Purpura

Treatment of Thrombocytopenic Purpura Secondary to Liver Disease

Pharmaceutical form(s):

Film-coated tablet

Oral suspension

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Eisai Limited

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Eisai Limited submitted for agreement to the European Medicines Agency on 11 March 2011 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 20 April 2011.

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An agency of the European Union



Supplementary information was provided by the applicant on 24 August 2011.

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 in accordance with Article 13 of said Regulation and concluded in accordance with Articles 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population and Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

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 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(es) and appendix.

London, 11 November 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 Idiopathic Thrombocytopenic Purpura

The waiver applies to:

- Infants from birth to less than 1 years of age
- for film-coated tablet and oral suspension, 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).

1.2. Condition: Treatment of Thrombocytopenic Purpura Secondary to Liver Disease

The waiver applies to:

- All paediatric subsets from birth to less than 18 years of age
- for film-coated tablet and oral suspension, oral use
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

2. Paediatric Investigation Plan

2.1. Condition: Treatment of Idiopathic Thrombocytopenic Purpura

2.1.1. Indication(s) targeted by the PIP

Treatment of thrombocytopenia in patients aged 1 year to less than 18 years with chronic immune (idiopathic) thrombocytopenic purpura (ITP), who have had insufficient response to at least one prior ITP treatment.

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

From 1 year to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Film coated tablet

Oral suspension, oral use

2.1.4. Studies

Area	Number of studies	Description
Quality	2	Study 1: Development of ready-to-use oral suspension Study 2: Bioavailability study in healthy adults.

Area	Number of studies	Description
Non-clinical	2	Study 3: 4-week dose range finding oral toxicity study in juvenile rats. Study 4: 10-week oral toxicity study in juvenile rats followed by a 4-week recovery period.
Clinical	1	Study 5: Randomized, double-blind, placebo-controlled, parallel group trial to assess efficacy, PK/PD, and safety of E5501 in children with chronic idiopathic thrombocytopenic purpura.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No.
Date of completion of the paediatric investigation plan:	By Dec 2019.
Deferral for one or more studies contained in the paediatric investigation plan:	Yes.