European Medicines Agency

Doc. Ref. EMA/359732010
P/9/2010

EUROPEAN MEDICINES AGENCY DECISION

of 29 January 2010

on the agreement of a Paediatric Investigation Plan and on the granting of a deferral and on the granting of a waiver for Givinostat (EMEA-000551-PIP01-09) 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 application submitted by Italfarmaco SpA on 26 March 2009 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting 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 December 2009, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 of said Regulation and of its own motion in accordance with Article 21 of said Regulation**,**

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 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 Givinostat, 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 Givinostat, 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 Givinostat, 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 Italfarmaco SpA, Via dei Lavoratori, 54, 20092 Cinisello Balsamo (MI), Italy.

Done at London, 29 January 2010

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. EMA/PDCO/794941/2009
EMEA-000551-PIP01-09

OPINION OF THE PAEDIATRIC COMMITTEE ON THE AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN AND A DEFERRAL AND A WAIVER

Scope of the application

Active substance(s):
Givinostat

Condition(s):
Juvenile idiopathic arthritis

Pharmaceutical form(s):
Oral suspension

Route(s) of administration:
Oral use

Name/corporate name of the PIP applicant:
Italfarmaco SpA

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Italfarmaco SpA submitted for agreement to the EMEA on 26 March 2009 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 30 April 2009.

Supplementary information was provided by the applicant on 1 October 2009.

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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 on its own motion 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 Article 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.

The Norwegian Paediatric Committee member does 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 Agency, together with its annex(es) and appendix.

London, 11 December 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)

Juvenile idiopathic arthritis

B. WAIVER

- **Condition**

  Juvenile idiopathic arthritis

  The waiver applies:

  - to children from birth to less than 2 years;
  - for Givinostat, oral suspension;
  - 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**

  Juvenile idiopathic arthritis

- **Proposed PIP indication**

  Treatment of patients with polyarticular course of juvenile idiopathic arthritis

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

  From 2 to less than 18 years.

- **Formulation(s)**

  Oral suspension

- **Studies**

Area	Number of studies	Description
Quality	1	1. Development of age-appropriate oral suspension
Non-clinical	4	2. Toxicity study in juvenile rats 3. Pre- and postnatal development toxicity study in rats 4. Carcinogenicity study in rats. 5. Carcinogenicity study in mice.
Clinical	2	6. Multicentre, open-label, dose finding, preliminary safety and efficacy study in patients with polyarticular course of JIA not adequately responding to the standard treatment. 7. Multicentre, randomised, withdrawal placebo-controlled efficacy and safety study in patients with Polyarticular course JIA not adequately responding to standard treatment.

Measures to address long term follow-up of potential safety issues and efficacy in relation to paediatric use:	**Yes**
Date of completion of the paediatric investigation plan:	**By April 2014**
Deferral for some or all studies contained in the paediatric investigation plan:	**Yes**