EMA/37454/2013

# European Medicines Agency decision

P/0015/2013

of 25 January 2013

on the acceptance of a modification of an agreed paediatric investigation plan for laquinimod (sodium) (EMEA-000972-PIP01-10-M02) 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.**

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
**Telephone** +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
**E-mail** info@ema.europa.eu **Website** www.ema.europa.eu

An agency of the European Union

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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/58/2011 issued on 4 March 2011, the decision P/0027/2012 issued on 27 January 2012,

Having regard to the application submitted by Teva Pharma GmbH on 14 September 2012 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 7 December 2012, 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 laquinimod (sodium), capsule, 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 Teva Pharma GmbH, Graf-Arco-Straße 3, D-89079 Ulm, Germany.

Done at London, 25 January 2013

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

EMA/PDCO/634685/2012 Corr

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

EMEA-000972-PIP01-10-M02

## Scope of the application

**Active substance(s):**

Laquinimod (sodium)

**Condition(s):**

Treatment of multiple sclerosis

**Pharmaceutical form(s):**

Capsule

**Route(s) of administration:**

Oral use

**Name/corporate name of the PIP applicant:**

Teva Pharma GmbH

## Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Teva Pharma GmbH submitted to the European Medicines Agency on 14 September 2012 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/58/2011 issued on 4 March 2011 and the decision P/0027/2012 issued on 27 January 2012.

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

The procedure started on 10 October 2012.

## Scope of the modification

Timeline of measures of the Paediatric Investigation Plan have been modified.

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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 changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion.

   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 European Medicines Agency, together with its annex and appendix.

London, 7 December 2012

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 Multiple Sclerosis*

The waiver applies to:

- All subsets of the paediatric population from birth to less than 10 years of age;
- for capsule, 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 Multiple Sclerosis*

### 2.1.1. Indication(s) targeted by the PIP

Treatment of remitting-relapsing forms of multiple sclerosis (RRMS).

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

From 10 years to less than 18 years of age.

### 2.1.3. Pharmaceutical form(s)

Capsule.

### 2.1.4. Studies

| Area | Number of studies | Description |
|---|---|---|
| Quality | 0 | Not applicable. |
| Non-clinical | 2 | Study 1<br>39 week repeat dose toxicity study in juvenile dogs.<br>Study 2<br>4 week toxicity study in juvenile rats. |
| Clinical | 2 | Study 3<br>Open-label, single-arm study to evaluate the pharmacokinetics, safety and tolerability of a single oral dose of laquinimod in children from 10 years to less than 18 years with remitting-relapsing multiple sclerosis.<br>Study 4<br>Randomised, multicentre, parallel group, active controlled trial to evaluate safety, tolerability and effect of oral laquinimod , compared to disease modifying treatment in children from 10 years to less than 18 years with |

| Area | Number of studies | Description |
|---|---|---|
| | | relapsing remitting multiple sclerosis (RRMS) using blinded MRI assessment. |

## 3. Follow-up, completion and deferral of PIP

| | |
|---|---|
| Concerns on potential long term safety and efficacy issues in relation to paediatric use: | Yes |
| Date of completion of the paediatric investigation plan: | By June 2018 |
| Deferral for one or more measures contained in the paediatric investigation plan: | Yes |