European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 23 December 2008

on the application for agreement of a Paediatric Investigation Plan for telaprevir (EMEA-000196-PIP01-08) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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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 Tibotec BVBA on 7 March 2008 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting a waiver under Article 13 of said Regulation and a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 14 November 2008, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 of said Regulation and 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 a positive opinion,

(2) It is therefore appropriate to adopt a Decision following the Paediatric Committee's opinion on the Paediatric Investigation Plan,

(3) It is therefore appropriate to adopt a Decision granting a waiver,

(4) It is therefore appropriate to adopt a Decision granting a deferral.

[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 telaprevir, film-coated tablet and chewable tablet, 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 waiver for telaprevir, film-coated tablet and chewable tablet, 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 deferral for telaprevir, film-coated tablet and chewable tablet, oral use, the details of which are set out in the Opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 4

This decision is addressed to Tibotec BVBA, Generaal De Wittelaan L11 B3, 2800 – Mechelen, Belgium.

Done at London, 23 December 2008

For the European Medicines Agency
Thomas Lönngren
Executive Director
(Signature on file)

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

EMEA/PDCO582730/2008
EMEA-000196-PIP-01-08

POSITIVE OPINION OF THE PAEDIATRIC COMMITTEE ON A REQUEST FOR AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN FOR

Scope of the application

Active substance:
Telaprevir

Condition(s):
Chronic viral hepatitis C

Pharmaceutical form(s):
Film-coated tablet
Chewable tablet

Route(s) of administration:
Oral use

Name/corporate name of the PIP applicant:
Tibotec BVBA

Basis for opinion

Pursuant to Article 16.1 of Regulation (EC) No 1901/2006 as amended, Tibotec BVBA submitted for agreement to the EMEA on 7 March 2008 a paediatric investigation plan for the above mentioned medicinal product.

The procedure started on 8 May 2008.

Supplementary information was provided by the applicant on 5 September 2008.

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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 Regulation (EC) No 1901/2006 as amended,
- to grant a deferral in accordance with Article 21 of Regulation (EC) No 1901/2006 as amended,
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended and concluded in accordance with Article 11(1)(c) of Regulation (EC) No 1901/2006 as amended, 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 Agency, together with its annex(es) and appendix(ces).

London, 14 November 2008

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)

Chronic Hepatitis C

B. WAIVER

- **Condition**

Chronic Hepatitis C

The waiver applies to:

- Children less than 3 years old, for film-coated tablets and chewable tablets;
- on the grounds that the medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Chronic Hepatitis C

- **Proposed PIP indication**

Telaprevir in combination with peginterferon alfa and ribavirin is indicated for the treatment of children and adolescents with genotype 1 chronic hepatitis C virus infection.

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

Children and adolescents from 3 to less than 18 years

- **Formulation(s)**

chewable tablets, oral use
film-coated tablets, oral use

- **Studies**

Area	Number of studies	Description
Quality	1	Development of chewable tablet formulation, in 100 and 250 mg strength.
Non-clinical	0	Not applicable.
Clinical	2	1) Single-dose, randomized, two-way crossover study in adults to evaluate the relative bioavailability of the chewable tablet formulation to the adult tablet formulation. 2) Two-phase, safety and pharmacokinetics, placebo-controlled study of telaprevir in association with peginterferon and ribavirin in children and adolescents.

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 June 2014**
Deferral for initiation of some or all studies contained in the paediatric investigation plan:	**Yes**
Deferral for completion of some or all studies contained in the paediatric investigation plan:	**Yes**