

EMA/476808/2012

European Medicines Agency decision P/0165/2012

of 26 July 2012

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for asunaprevir (EMA-001190-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 Bristol-Myers Squibb International Corporation on 6 October 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 6 July 2012, 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 asunaprevir, capsule, soft, 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 deferral for asunaprevir, capsule, soft, 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 waiver for asunaprevir, capsule, soft, 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 4

This decision is addressed to Bristol-Myers Squibb International Corporation, Parc de l'Alliance, Avenue de Finlande 8, 1420 Braine-l'Alleud, Belgium.

Done at London, 26 July 2012

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

EMA/PDCO/396467/2012

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

EMA-001190-PIP01-11

Scope of the application

Active substance(s):

Asunaprevir

Condition(s):

Treatment of chronic hepatitis C

Pharmaceutical form(s):

Capsule, soft

Chewable tablet

Route(s) of administration:

Oral use

Name / corporate name of the PIP applicant:

Bristol-Myers Squibb International Corporation

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Bristol-Myers Squibb International Corporation submitted for agreement to the European Medicines Agency on 6 October 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 16 November 2011.

Supplementary information was provided by the applicant on 19 April 2012. The applicant proposed modifications to the paediatric investigation plan.

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 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 Norwegian Paediatric Committee member agrees 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.

Langen, Germany, 6 July 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 chronic hepatitis C

The waiver applies to:

- Infants and children less than 3 years of age;
- for capsule soft, chewable tablet, oral use;
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

2. Paediatric Investigation Plan

2.1. Condition: Treatment of chronic hepatitis C

2.1.1. Indication(s) targeted by the PIP

Asunaprevir, in combination with daclatasvir, is indicated for the treatment of children and adolescents from 3 years to less than 18 years of age with genotype (GT) 1b chronic hepatitis C (CHC).

Asunaprevir in combination with daclatasvir and peginterferon alfa/ribavirin (RBV) is indicated for the treatment of children and adolescents from 3 years to less than 18 years of age with GT-1 or -4 chronic hepatitis C, who are interferon/RBV non-responders.

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

From 3 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Capsule soft, oral use

Chewable tablet, oral use

2.1.4. Studies

Area	Number of studies	Description
Quality	1	Study 1: Development of an age-appropriate chewable tablet.
Non-clinical	2	Study 2: Pre- and postnatal development study. Study 3: Ten-week oral toxicity study in juvenile rats.

Area	Number of studies	Description
Clinical	3	Study 4: Open-label, PK, safety, tolerability, and efficacy of asunaprevir (ASV) plus peginterferon alpha (Alfa)/ribavirin (RBV) in treatment-naïve paediatric patients with genotypes (GT)-1 or -4 chronic hepatitis C (CHC). Study 5: Open-label, single-arm, safety and efficacy study of daclatasvir (DCV) in combination with ASV in paediatric patients with GT-1b CHC. Study 6: Open-label, single-arm, safety and efficacy of peginterferon alfa/ribavirin in combination with DCV and ASV in non-responder paediatric patients with GT-1 or GT-4 CHC.

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 July 2020.
Deferral for one or more studies contained in the paediatric investigation plan:	Yes.