EMA/721473/2016

# European Medicines Agency decision

P/0311/2016

of 7 November 2016

on the acceptance of a modification of an agreed paediatric investigation plan for daclatasvir (Daklinza), (EMEA-001191-PIP01-11-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.**

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
**Telephone** +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
**Contact EMA** www.ema.europa.eu/contact

# European Medicines Agency decision

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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/0166/2012 issued on 26 July 2012, and the decision P/0180/2014 issued on 17 July 2014,

Having regard to the application submitted by Bristol-Myers Squibb Pharma EEIG on 25 July 2016 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 14 October 2016, 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 and to the deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the 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***

Changes to the agreed paediatric investigation plan for daclatasvir (Daklinza), chewable tablet, film-coated tablet, oral use, including changes to the deferral, 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 Bristol-Myers Squibb Pharma EEIG, Uxbridge Business Park, Sanderson Road UB8 1DH - Uxbridge, United Kingdom.

EMA/PDCO/518242/2016
London, 14 October 2016

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

EMEA-001191-PIP01-11-M02

## Scope of the application

**Active substance(s):**

Daclatasvir

**Invented name:**

Daklinza

**Condition(s):**

Treatment of chronic hepatitis C

**Authorised indication(s):**

See Annex II

**Pharmaceutical form(s):**

Chewable tablet

Film-coated tablet

**Route(s) of administration:**

Oral use

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

Bristol-Myers Squibb Pharma EEIG

**Information about the authorised medicinal product:**

See Annex II

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
**Telephone** +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5510
**Send a question via our website** www.ema.europa.eu/contact

## Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Bristol-Myers Squibb Pharma EEIG submitted to the European Medicines Agency on 25/07/2016 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/0166/2012 issued on 26 July 2012, and the decision P/0180/2014 issued on 17 July 2014.

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

The procedure started on 16 August 2016.

## Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

## 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 and to the deferral in the scope set out in the Annex I of this opinion.

   The Norwegian Paediatric Committee member agrees 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 annexes and appendix.

# 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 (PIP)

# 1. Waiver

## *1.1. Condition*

Treatment of chronic hepatitis C

The waiver applies to:

- the paediatric population from birth to less than 3 years of age;
- for film-coated tablet, chewable tablet, oral use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset.

# 2. Paediatric Investigation Plan

## *2.1. Condition*

Treatment of chronic hepatitis C

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

Daclatasvir (DCV) in combination with sofosbuvir (SOF) is indicated for the treatment of children and adolescents from 3 years to less than 18 years of age with genotype (GT)-1 to -6 chronic hepatitis C, who are treatment-naïve or treatment-experienced

### 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)

Film-coated tablet

Chewable tablet

### 2.1.4. Studies

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

| | | |
|---|---|---|
| Clinical studies | 1 | **Study 4**<br>Deleted in EMEA-001191-PIP01-11-M02.<br>**Study 5**<br>Open-label, single-arm trial to evaluate pharmacokinetics, safety and efficacy of DCV in combination with sofosbuvir in children from 3 to less than 18 years of age with GT-1 to -6 chronic hepatitis C (CHC). |
| Extrapolation, modelling and simulation studies | 0 | Not applicable. |
| Other studies | 0 | Not applicable. |
| Other measures | 0 | Not applicable. |

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

| | |
|---|---|
| Concerns on potential long term safety/efficacy issues in relation to paediatric use: | Yes. |
| Date of completion of the paediatric investigation plan: | By October 2021. |
| Deferral for one or more studies contained in the paediatric investigation plan: | Yes. |

# Annex II

# Information about the authorised medicinal product

## Condition(s) and authorised indication(s)

1. Treatment of chronic hepatitis C

Authorised indication(s):

- Daklinza is indicated in combination with other medicinal products for the treatment of chronic hepatitis C virus (HCV) infection in adults (see sections 4.2, 4.4 and 5.1).

  For HCV genotype specific activity, see sections 4.4 and 5.1.

## Authorised pharmaceutical form(s)

Film-coated tablet

## Authorised route(s) of administration

Oral use