EMA/75416/2018

European Medicines Agency decision

P/0042/2018

of 16 February 2018

on the acceptance of a modification of an agreed paediatric investigation plan for dasatinib (Sprycel), (EMEA-000567-PIP01-09-M05) 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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on the acceptance of a modification of an agreed paediatric investigation plan for dasatinib (Sprycel), (EMEA-000567-PIP01-09-M05) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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/225/2009 issued on 3 November 2009, the decision P/31/2010 issued on 5 March 2010, and the decision P/200/2011 issued on 5 August 2011, the decision P/0204/2012 issued on 3 September 2012 and the decision P/0118/2013 issued on 2 May 2013,

Having regard to the application submitted by Bristol-Myers Squibb Pharma EEIG on 5 January 2018 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 26 January 2018, 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 dasatinib (Sprycel), film-coated tablet, powder for oral suspension, 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 Bristol-Myers Squibb Pharma EEIG, Uxbridge Business Park, Sanderson Road, UB8 1DH - Uxbridge, United Kingdom.

EMA/PDCO/20824/2018
London, 26 January 2018

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

EMEA-000567-PIP01-09-M05

Scope of the application

Active substance(s):

Dasatinib

Invented name:

Sprycel

Condition(s):

Treatment of Philadelphia chromosome (BCR-ABL translocation)-positive chronic myeloid leukaemia

Treatment of Philadelphia chromosome (BCR-ABL translocation)-positive acute lymphoblastic leukaemia

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Film-coated tablet

Powder for oral suspension

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

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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 5 January 2018 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/225/2009 issued on 3 November 2009, the decision P/31/2010 issued on 5 March 2010, and the decision P/200/2011 issued on 5 August 2011, the decision P/0204/2012 issued on 3 September 2012 and the decision P/0118/2013 issued on 2 May 2013.

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

The procedure started on 23 January 2018.

Scope of the modification

Some measures 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 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 Philadelphia chromosome (BCR-ABL translocation)-positive chronic myeloid leukaemia

The waiver applies to:

- the paediatric population from birth to less than 1 year of age;
- film-coated tablet, powder for oral suspension, oral use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset.

1.2. Condition

Treatment of Philadelphia chromosome (BCR-ABL translocation)-positive acute lymphoblastic leukaemia

The waiver applies to:

- the paediatric population from birth to less than 1 year of age;
- film-coated tablet, powder for oral suspension, oral use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset.

2. Paediatric Investigation Plan

2.1. Condition

Treatment of Philadelphia chromosome (BCR-ABL translocation)-positive chronic myeloid leukaemia

2.1.1. Indication(s) targeted by the PIP

Treatment of Philadelphia chromosome (BCR-ABL translocation)-positive (Ph+) chronic myeloid leukaemia

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

From 1 year to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Film-coated tablet, oral use

Powder for oral suspension, oral use

2.1.4. Studies

Area	Number of studies	Description
Quality	1	**Study 1** Development of powder for oral suspension
Non-clinical	0	Not applicable
Clinical	3	**Study 2** Open-label, multi-centre, dose-escalation trial to evaluate pharmacokinetics and safety of dasatinib in children from 2 years to less than 18 years of age (and in adults) with recurrent or refractory solid tumour or imatinib-resistant Ph+ leukaemia **Study 3** Open-label, multi-centre, dose-escalation trial to evaluate pharmacokinetics and safety of dasatinib in children from 1 year to less than 18 years of age with Ph+ chronic myeloid leukaemia or acute leukaemia **Study 4** Open-label, multi-centre trial to evaluate pharmacokinetics, safety and efficacy of dasatinib in children from 1 years to less than 18 years of age with Ph+ chronic myeloid leukaemia of all phases (including treatment-naïve patients in chronic phase) or relapsed / refractory Ph+ acute lymphoblastic leukaemia

2.2. Condition

Treatment of Philadelphia chromosome (BCR-ABL translocation)-positive acute lymphoblastic leukaemia

2.2.1. Indication(s) targeted by the PIP

Treatment of Philadelphia chromosome (BCR-ABL translocation)-positive (Ph+) acute lymphoblastic leukaemia

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

From 1 year to less than 18 years of age

2.2.3. Pharmaceutical form(s)

Film-coated tablet, oral use

Powder for oral suspension, oral use

2.2.4. Studies

Area	Number of studies	Description
Quality	1	**Study 1** As for condition treatment of Philadelphia chromosome (BCR-ABL translocation)-positive chronic myeloid leukaemia
Non-clinical	0	Not applicable.
Clinical	5	**Study 2** As for condition treatment of Philadelphia chromosome (BCR-ABL translocation)-positive chronic myeloid leukaemia **Study 3** As for condition treatment of Philadelphia chromosome (BCR-ABL translocation)-positive chronic myeloid leukaemia **Study 4** As for condition treatment of Philadelphia chromosome (BCR-ABL translocation)-positive chronic myeloid leukaemia **Study 5** Open-label, multi-centre trial evaluating safety and tolerability of dasatinib in combination with multi-agent chemotherapy in children from 1 year to less than 18 years of age (and adults) with newly-diagnosed Ph+ acute lymphoblastic leukaemia **Study 6** Open-label, multi-centre, historically-controlled trial to evaluate safety and efficacy of dasatinib plus chemotherapy compared to chemotherapy alone and compared to imatinib plus chemotherapy in children from 1 year to less than 18 years of age with newly diagnosed Ph+ acute lymphoblastic leukaemia

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

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of Philadelphia chromosome (BCR-ABL translocation)-positive chronic myeloid leukaemia

Authorised indications:

Sprycel is indicated for the treatment of adult patients with:

- newly diagnosed Philadelphia chromosome positive (Ph+) chronic myelogenous leukaemia (CML) in the chronic phase.
- chronic, accelerated or blast phase CML with resistance or intolerance to prior therapy including imatinib mesilate.

2. Treatment of Philadelphia chromosome (BCR-ABL translocation)-positive acute lymphoblastic leukaemia

Authorised indications:

Sprycel is indicated for the treatment of adult patients with:

- Ph+ acute lymphoblastic leukaemia (ALL) and lymphoid blast CML with resistance or intolerance to prior therapy.

Authorised pharmaceutical form(s):

Film-coated tablet

Authorised route(s) of administration:

Oral use