European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 5 March 2010

on the acceptance of a modification of an agreed Paediatric Investigation Plan for dasatinib (Sprycel) (EMEA-000567-PIP01-09-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006, as amended.

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on the acceptance of a modification of an agreed Paediatric Investigation Plan for dasatinib (Sprycel) (EMEA-000567-PIP01-09-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

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 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 decision P/225/2009 of the European Medicines Agency on 3 November 2009,

Having regard to the application submitted by Bristol-Myers Squibb Pharma EEIG on 4 December 2009 under Article 22 of Regulation (EC) No 1901/2006 as amended proposing changes to the agreed Paediatric Investigation Plan,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 19 February 2010, in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended,

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 an opinion on the acceptance of changes to an agreed Paediatric Investigation Plan.

(2) It is therefore appropriate to adopt a Decision on the acceptance of changes to an 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 and age-appropriate oral formulation, 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, are hereby accepted.

Article 2

This decision is addressed to Bristol-Myers Squibb Pharma EEIG, Uxbridge Business Park, Sanderson Road, UB8 1DH Uxbridge, United Kingdom.

Done at London, 5 March 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

19 February 2010
EMA/PDCO/74448/2010

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

EMEA-000567-PIP01-09-M01

Scope of the application

Active substance(s):

Dasatinib

Invented name:

Sprycel

Condition(s):

- Philadelphia chromosome (BCR-ABL translocation)-positive chronic myeloid leukaemia
- Philadelphia chromosome (BCR-ABL translocation)-positive acute lymphoblastic leukaemia

Pharmaceutical form(s):

- Film-coated tablet
- Age-appropriate oral formulation

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Bristol-Myers Squibb Pharma EEIG

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Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
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Information about the authorised medicinal product:

See Annex II

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 4 December 2009 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 of 3 November 2009. The application for modification proposed changes.

The procedure started on 23 December 2009.

Scope of the modification

Some measures and timelines of the original Opinion 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 the changes proposed by the applicant regarding the measures and the timelines of the paediatric investigation plan and of the deferral,

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(es) and appendix.

London, 19 February 2010

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

1. CONDITION(S)

- Philadelphia chromosome (BCR-ABL translocation)-positive chronic myeloid leukaemia
- Philadelphia chromosome (BCR-ABL translocation)-positive acute lymphoblastic leukaemia

2. WAIVER

Condition

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

The waiver applies to:

- children from birth to less than 1 year of age
- for film-coated tablet and age-appropriate formulation
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset.

Condition

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

The waiver applies to:

- children from birth to less than 1 year of age
- for film-coated tablet and age-appropriate formulation
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset.

3. PAEDIATRIC INVESTIGATION PLAN

Condition to be investigated

- Philadelphia chromosome (BCR-ABL translocation)-positive chronic myeloid leukaemia
- Philadelphia chromosome (BCR-ABL translocation)-positive acute lymphoblastic leukaemia

Indication targeted by the pip

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

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

From 1 year to less than 18 years

Pharmaceutical form(s)

- Film-coated tablet, oral use
- Age-appropriate formulation, oral use

Studies

Area	Number of studies	Description
Quality	1	Age-appropriate formulation for oral use (such as liquid or multi-particulate formulation).
Non-clinical	0	Not applicable.
Clinical	5	Study 1: 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 2: Open-label, multi-centre, dose-escalation trial to evaluate pharmacokinetics and safety of dasatinib in children from 1 years to less than 18 years of age with Ph+ chronic myeloid leukaemia or acute leukaemia. Study 3: 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. Study 4: Open-label, multi-centre trial evaluating safety and tolerability of dasatinib in combination with multi-agent chemotherapy in children from 1 years to less than 18 years of age (and adults) with newly-diagnosed Ph+ acute lymphoblastic leukaemia. Study 5: Open-label, randomised, parallel-group, multi-centre trial to evaluate safety and efficacy of dasatinib compared to imatinib in children aged from 1 year to less than 18 years with newly diagnosed Ph+ acute lymphoblastic leukaemia.

4. FOLLOW-UP, COMPLETION AND DEFERRAL OF PIP

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 May 2015
Deferral for some or all studies contained in the paediatric investigation plan	Yes

ANNEX II

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

EU Number	Invented name	Strength	Pharmaceutical Form	Route of Administration	Packaging	Content (concentration)	Package size
EU/1/06/363/001	Sprycel	20 mg	Film-coated tablet	Oral use	bottle (HDPE)		60 tablets
EU/1/06/363/002	Sprycel	50 mg	Film-coated tablet	Oral use	bottle (HDPE)		60 tablets
EU/1/06/363/003	Sprycel	70 mg	Film-coated tablet	Oral use	bottle (HDPE)		60 tablets
EU/1/06/363/004	Sprycel	20 mg	Film-coated tablet	Oral use	blister (alu/alu)		56 tablets
EU/1/06/363/005	Sprycel	50 mg	Film-coated tablet	Oral use	blister (alu/alu)		56 tablets
EU/1/06/363/006	Sprycel	70 mg	Film-coated tablet	Oral use	blister (alu/alu)		56 tablets
EU/1/06/363/007	Sprycel	20 mg	Film-coated tablet	Oral use	blister (alu/alu)		60 x 1 tablets (unit dose)
EU/1/06/363/008	Sprycel	50 mg	Film-coated tablet	Oral use	blister (alu/alu)		60 x 1 tablets (unit dose)
EU/1/06/363/009	Sprycel	70 mg	Film-coated tablet	Oral use	blister (alu/alu)		60 x 1 tablets (unit dose)
EU/1/06/363/010	Sprycel	100 mg	Film-coated tablet	Oral use	bottle (HDPE)		30 tablets
EU/1/06/363/011	Sprycel	100 mg	Film-coated tablet	Oral use	blister (alu/alu)		30 x 1 tablets (unit dose)