EMA/792883/2015

European Medicines Agency decision

P/0297/2015

of 21 December 2015

on the acceptance of a modification of an agreed paediatric investigation plan for nilotinib (Tasigna) (EMEA-000290-PIP01-08-M04) 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 726/2004[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/60/2009 issued on 27 March 2009, the decision P/0274/2012 issued on 21 November 2012, and the decision P/0088/2013 issued on 29 April 2013,

Having regard to the application submitted by Novartis Europharm Ltd. on 20 August 2015 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 13 November 2013, 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 and to the waiver.

(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 andthe 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

Changes to the agreed paediatric investigation plan for nilotinib (Tasigna), capsule, hard, oral use, including changes to the deferral and the waiver, 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 Novartis Europharm Ltd., Frimley Business Park, GU16 7SR – Camberley, United Kingdom.

Done at London, 21 December 2015

For the European Medicines Agency
Zaïde Frias
Head of Division
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/587249/2015
London, 13 November 2015

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

EMEA-000290-PIP01-08-M04

Scope of the application

Active substance(s):

Nilotinib

Invented name:

Tasigna

Condition(s):

Treatment of chronic myeloid leukaemia

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Capsule, hard

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Novartis Europharm Ltd

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Novartis Europharm Ltd. submitted to the European Medicines Agency on 20 August 2015 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/60/2009 issued on 27 March 2009, the decision P/0274/2012 issued on 21 November 2012, and the decision P/0088/2013 issued on 29 April 2013.

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

The procedure started on 15 September 2015.

Scope of the modification

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

The scope of the Paediatric Investigation Plan was amended to exclude a condition.

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 and to the waiver 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 myeloid leukaemia

The waiver applies to:

- the paediatric population from birth to less than 1 years of age;
- for capsule, hard for 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(s).

2. Paediatric Investigation Plan

2.1. Condition:

Treatment of chronic myeloid leukaemia

2.1.1. Indication(s) targeted by the PIP

Treatment of Philadelphia chromosome-positive 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

2.1.3. Pharmaceutical form(s)

Capsule, 200 mg, 150 mg and 50 mg, un-manipulated or contents dispersed with apple sauce, oral use

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies		Not applicable.
Non-clinical studies	1	Study 1: Oral (gavage) juvenile development study in rats
Clinical studies	3	Study 2: Study to compare the bioavailability of nilotinib when administered as intact capsule or the capsule content mixed with yogurt or apple sauce in adult volunteers Study 3: Multiple-dose, open-label, single-agent, non-controlled trial to evaluate pharmacokinetics, pharmacodynamics, safety and activity in paediatric patients from 1 year to less than 18 years with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic or accelerated phase who are imatinib- and/or

		dasatinib-intolerant or in whom the disease is imatinib- and / or dasatinib-resistant, or with refractory or relapsed Philadelphia chromosome-positive acute lymphoblastic leukaemia Study 4: Multiple-dose, open-label, single-agent, non-controlled, multi-centre trial to evaluate pharmacokinetics, safety and activity in paediatric patients from 1 year to less than 18 years with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic or accelerated phase who are imatinib- or dasatinib-intolerant or in whom the disease is imatinib- or dasatinib-resistant or with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase

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 2016
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 chronic myeloid leukaemia

Authorised indications:

Tasigna is indicated for the treatment of adult patients with newly diagnosed Philadelphia chromosome positive chronic myelogenous leukaemia (CML) in the chronic phase.

Tasigna is indicated for the treatment of adult patients with:

- Newly diagnosed Philadelphia chromosome positive chronic myelogenous leukaemia (CML) in the chronic phase;
- Chronic phase and accelerated phase Philadelphia chromosome positive CML with resistance or intolerance to prior therapy including imatinib. Efficacy data in patients with CML in blast crisis are not available.

Authorised pharmaceutical formulation(s):

Capsule, hard

Authorised route(s) of administration:

Oral use