EMA/776034/2013

European Medicines Agency decision

P/0325/2013

of 19 December 2013

on the acceptance of a modification of an agreed paediatric investigation plan for anagrelide (Xagrid) (EMEA-000720-PIP01-09-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.

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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/99/2010 issued on 4 June 2010 and the decision P/179/2011 issued on 1 August 2011,

Having regard to the application submitted by Shire Pharmaceutical Contracts Limited on 25 October 2013 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 6 December 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.

(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 anagrelide (Xagrid), hard capsule, 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 Shire Pharmaceutical Contracts Limited, Hampshire International Business Park, Chineham, RG24 8EP – Basingstoke, United Kingdom.

Done at London, 19 December 2013

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

EMA/PDCO/700116/2013

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

EMEA-000720-PIP01-09-M02

Scope of the application

Active substance(s):

Anagrelide

Invented name:

Xagrid

Condition(s):

Treatment of essential thrombocythaemia

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Hard capsule

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Shire Pharmaceutical Contracts Limited

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, Shire Pharmaceutical Contracts Limited submitted to the European Medicines Agency on 25 October 2013 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/99/2010 issued on 4 June 2010, and the decision P/179/2011 issued on 1 August 2011.

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

The procedure started on 19 November 2013.

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 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 of the paediatric population and condition 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.

London, 6 December 2013

On behalf of the Paediatric Committee
Dr Dirk Mentzer, 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 Essential Thrombocythaemia

The waiver applies to:

- The paediatric population from birth to less than 6 years of age;
- for hard capsule, 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(s).

2. Paediatric Investigation Plan

2.1. Condition: treatment of Essential Thrombocythaemia

2.1.1. Indication(s) targeted by the PIP

Treatment of essential thrombocythaemia (ET) in paediatric patients aged 6 to less than 18 years who are intolerant to their current therapy or whose elevated platelet counts are not reduced to an acceptable level by their current therapy.

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

From 6 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Hard capsule, oral use

2.1.4. Measures

Area	Number of measures	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	3	• Retrospective analysis of pooled data from studies SPD422-202 and SPD422-203 to compare PK/PD parameters across the age groups 6-11 years, 12-17 years, 18-64 years and ≥65 years. • A retrospective analysis of pooled safety data from patients aged <18 years of age from studies available in the Shire anagrelide clinical database. • Multicentre paediatric observational study in Essential Thrombocythaemia (ET), evaluating drug utilisation and effects of cytoreductive agents treatment in children 6 to less than 18 years of age

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By March 2013
Deferral for one or more studies contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of essential thrombocythaemia

Authorised indication(s):

- Xagrid is indicated for the reduction of elevated platelet counts in at risk essential Thrombocythaemia (ET) patients who are intolerant to their current therapy or whose elevated platelet counts are not reduced to an acceptable level by their current therapy.

Authorised pharmaceutical form(s):

Hard capsule

Authorised route(s) of administration:

Oral use