EMA/282473/2010

European Medicines Agency decision

P/99/2010

of 4 June 2010

on the agreement of a paediatric investigation plan and on the granting of a waiver for anagrelide hydrochloride monohydrate, Xagrid (EMEA-000720-PIP01-09) 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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8670
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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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 application submitted by Shire Pharmaceutical Contracts Ltd on 12 August 2009 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 16 April 2010, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 13 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a 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

A paediatric investigation plan for anagrelide hydrochloride monohydrate, Xagrid, hard capsule, 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, is hereby agreed.

Article 2

A waiver for anagrelide hydrochloride monohydrate, Xagrid, hard capsule, 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, is hereby granted.

Article 3

This decision is addressed to Shire Pharmaceutical Contracts Ltd, Hampshire International Business Park, Chineham, Basingstoke, RG24 8EP, United-Kingdom.

Done at London, 4 June 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/225362/2010

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a waiver

EMEA-000720-PIP01-09

Scope of the application

Active substance(s):

Anagrelide hydrochloride monohydrate

Invented name:

Xagrid

Condition(s):

Essential thrombocythaemia

Pharmaceutical form(s):

Hard capsule

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Shire Pharmaceutical Contracts Ltd

Information about the authorised medicinal product: see Annex II

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Shire Pharmaceutical Contracts Ltd submitted for agreement to the European Medicines Agency on 12 August 2009 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 17 September 2009.

Supplementary information was provided by the applicant on 4 February 2010.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
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E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 18 of said Regulation,
   - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Articles 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population.

   The Icelandic and the Norwegian Paediatric Committee member(s) agree with the above-mentioned recommendation of the Paediatric Committee.

2. 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 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, 16 April 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)

Essential thrombocythaemia

2. Waiver

2.1. Condition

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).

3. Paediatric Investigation Plan

3.1. Condition to be investigated

Essential thrombocythaemia

3.1.1. Indication 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.

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

From 6 to less than 18 years of age.

3.1.3. Pharmaceutical form(s)

Hard capsule, oral use

3.1.4. Studies

Area	Number of studies	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.

Area	Number of studies	Description
		• 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

4. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues, 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

EU Number	Invented name Name	Strength	Pharmaceutical form	Route of administration	Packaging	Content	Package size
EU/1/04/295/001	Xagrid	0.5 mg	Hard capsule	Oral use	HDPE bottle with child-resistant closure and desiccant	100 capsules	60 ml bottle