EMA/470735/2012

# European Medicines Agency decision

P/0149/2012

of 24 July 2012

on the refusal of a product specific waiver for tivantinib (EMEA-001284-PIP01-12) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

**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 application submitted by Daiichi Sankyo Development Limited on 12 March 2012 under Article 13 of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 8 June 2012 in accordance with Article 13 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee has given an opinion on the refusal of a product specific waiver.

(2) It is therefore appropriate to adopt a decision refusing 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 waiver for tivantinib, tablet, 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 refused.

***Article 2***

This decision is addressed to Daiichi Sankyo Development Limited, Chiltern Place, Chalfont Park, SL9 0BG - Gerrards Cross, United Kingdom.

Done at London, 24 July 2012

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

EMA/PDCO/226809/2012

# Opinion of the Paediatric Committee on the refusal of a product-specific waiver

EMEA-001284-PIP01-12

## Scope of the application

**Active substance(s):**

Tivantinib

**Condition(s):**

Treatment of hepatoblastoma

**Pharmaceutical form(s):**

Tablet

**Route(s) of administration:**

Oral use

**Name/corporate name of the PIP applicant:**

Daiichi Sankyo Development Limited

## Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Daiichi Sankyo Development Limited submitted to the European Medicines Agency on 12 March 2012 an application for a product-specific waiver on the grounds set out in Article 11 of said Regulation for the above mentioned medicinal product.

The procedure started on 16 April 2012.

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## Opinion

1. The Paediatric Committee, having assessed the waiver application in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to refuse the granting of a product-specific waiver for all subsets of the paediatric population and the above mentioned condition(s) as it does not meet the grounds detailed in Article 11(1) of said Regulation.

  The Icelandic and the Norwegian Paediatric Committee members agree with the above-mentioned recommendation of the Paediatric Committee.

2. The scientific conclusions and the grounds for refusal are set out in the summary report appended to this opinion.

3. The grounds for refusal are summarised in Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its appendix.

London, 8 June 2012

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

# Annex I

# Grounds for the refusal of the waiver

# 1. Waiver

The waiver is refused for the following:

## *1.1. Condition: treatment of hepatoblastoma*

The request for the waiver applied to:

- all subsets of the paediatric population from birth to less than 18 years of age,
- for tablet, oral use.

The waiver request does not provide evidence to support the following grounds set out in Article 11(1) of Regulation (EC) No 1901/2006 that:

a) the specific medicinal product is likely to be ineffective or unsafe in the paediatric population;

b) the disease or condition for which the specific medicinal product is intended occurs only in adult populations;

c) the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients;

because:

- the disease or condition for which the specific medicinal product is intended, does occur in the paediatric population(s);
- the specific medicinal product may represent a significant therapeutic benefit as the needs are not met.

The waiver request is therefore refused by the PDCO.