EMA/910938/2019

European Medicines Agency decision

P/0044/2019

of 29 January 2019

on the granting of a product specific waiver for pexidartinib (EMEA-001939-PIP03-16) 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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on the granting of a product specific waiver for pexidartinib (EMEA-001939-PIP03-16) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 Inc on 16 January 2017 under Article 16(1) of Regulation (EC) No 1901/2006, also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 14 December 2018 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 granting of a product specific waiver.

(2) It is therefore appropriate to adopt a decision granting a waiver.

Has adopted this decision:

Article 1

A waiver for pexidartinib, capsule, hard, 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 2

This decision is addressed to Daiichi Sankyo Inc, 399 Thornall Street, 08837 - Edison NJ, USA.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

EMA/PDCO/656608/2018
London, 14 December 2018

Opinion of the Paediatric Committee on the granting of a product-specific waiver

EMEA-001939-PIP03-16

Scope of the application

Active substance(s):

Pexidartinib

Condition(s):

Treatment of benign soft tissue neoplasms

Pharmaceutical form(s):

Capsule, hard

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Daiichi Sankyo Inc

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Daiichi Sankyo Inc submitted for agreement to the European Medicines Agency on 16 January 2017 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 21 February 2017.

Supplementary information was provided by the applicant on 10 September 2018.

The applicant withdrew its proposed paediatric investigation plan and withdrew its request for a deferral and proposed to extend the scope of the waiver to cover all subsets of the paediatric population.

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Opinion

1. The Paediatric Committee, having assessed the waiver application in accordance with Article 17 and Article 13 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to grant a product-specific waiver for all subsets of the paediatric population and the above mentioned condition(s) in accordance with Article 11(1)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population.

   The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The grounds for the granting of the waiver are set out in Annex I.

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

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition:

Treatment of benign soft tissue neoplasms

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- capsule, hard, oral use;
- on the grounds that the specific medicinal product is likely to be unsafe.