EMA/557943/2016

European Medicines Agency decision

P/0253/2016

of 26 September 2016

on the refusal of a paediatric investigation plan and on the refusal of a deferral for angiotensin II (LJPC-501) (EMEA-001912-PIP01-15) 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 La Jolla Pharmaceutical Company, Inc. on 21 December 2015 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 16 September 2016, in accordance with Article 18 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation,

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

Whereas:

(1) The Paediatric Committee of the European Medicines Agency, following a re-examination procedure of the Paediatric Committee's opinion according to Article 25(3) of Regulation (EC) No 1901/2006, has given an opinion on the refusal of a paediatric investigation plan and on the refusal of a deferral.

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

(3) It is therefore appropriate to adopt a decision refusing a deferral.

[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 angiotensin II (LJPC-501), solution for infusion, intravenous 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

A deferral for angiotensin II (LJPC-501), solution for infusion, intravenous 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 3

This decision is addressed to La Jolla Pharmaceutical Company, Inc., 10182 Telesis Court Suite 600, CA 92121 - San Diego, USA.

EMA/PDCO/588803/2016
London, 16 September 2016

Final opinion of the Paediatric Committee on the refusal of a Paediatric Investigation Plan and a deferral

EMEA-001912-PIP01-15

Scope of the application

Active substance(s):

Angiotensin II (LJPC-501)

Condition(s):

Treatment of catecholamine-resistant hypotension associated with distributive shock

Pharmaceutical form(s):

Solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

La Jolla Pharmaceutical Company, Inc.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, La Jolla Pharmaceutical Company, Inc. submitted for agreement to the European Medicines Agency on 21 December 2015 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

An Opinion was adopted by the Paediatric Committee on 22 July 2016 for the above mentioned product. La Jolla Pharmaceutical Company, Inc. received the Paediatric Committee Opinion on 1 August 2016.

On 30 August 2016 La Jolla Pharmaceutical Company, Inc. submitted to the European Medicines Agency a written request including detailed grounds for a re-examination of the Opinion.

The re-examination procedure started on 31 August 2016.

Final Opinion

1. The Paediatric Committee, having assessed the detailed grounds for re-examination, in accordance with Article 25(3) of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report :

   1.1. to maintain its opinion and:

   - to refuse the paediatric investigation plan in accordance with Article 18 of said Regulation, as the measures and the timelines are not appropriate to ensure the generation of the necessary data determining the conditions in which the medicinal product may be used to treat the paediatric population or some subsets, nor to adapt a paediatric formulation, or do not bring expected significant therapeutic benefit;
   - to refuse a deferral in accordance with Article 21 of said Regulation.

The Norwegian Paediatric Committee member agrees 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.

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