EMA/380136/2019

European Medicines Agency decision

P/0227/2019

of 8 July 2019

on the refusal of a paediatric investigation plan for genetically modified replication-incompetent herpes simplex virus-1 expressing collagen VII (EMEA-002472-PIP02-19) 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 Krystal Biotech, Inc. on 18 January 2019 under Article 16(1) of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 28 June 2019, in accordance with Article 17 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, 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.

(2) It is therefore appropriate to adopt a decision refusing a 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

A paediatric investigation plan for genetically modified replication-incompetent herpes simplex virus-1 expressing collagen VII, gel, topical 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 Krystal Biotech, Inc., 2100 Wharton Street, Suite 701, 15203 - Pittsburgh, United States.

EMA/PDCO/319787/2019
Amsterdam, 28 June 2019

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

EMEA-002472-PIP02-19

Scope of the application

Active substance(s):

Genetically modified replication-incompetent herpes simplex virus-1 expressing collagen VII

Condition(s):

Treatment of dystrophic epidermolysis bullosa

Pharmaceutical form(s):

Gel

Route(s) of administration:

Topical use

Name/corporate name of the PIP applicant:

Krystal Biotech, Inc.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Krystal Biotech, Inc. submitted for agreement to the European Medicines Agency on 18 January 2019 an application for a paediatric investigation plan for the above mentioned medicinal product.

An Opinion was adopted by the Paediatric Committee on 26 April 2019 for the above mentioned product. Krystal Biotech, Inc. received the Paediatric Committee Opinion on 16 May 2019.

On 3 June 2019 Krystal Biotech, 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 4 June 2019.

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 17(1) 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.

   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.

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