



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/338388/2019

## European Medicines Agency decision

P/0222/2019

of 21 June 2019

on the granting of a product specific waiver for 5'-hydroxy-2'-deoxy-P-thiothymidylyl-(3'→5')-2'-deoxy-P-thiocytidylyl-(3'→5')-2'-deoxy-P-thio-7-deaza-guanylyl-(3'→5')-2'-deoxy-P-thioadenylyl-(3'→5')-2'-deoxy-P-thioadenylyl-(3'→5')-2'-deoxy-P-thiocytidylyl-(3'→5')-2'-deoxy-P-thio-7-deaza-guanylyl-(3'→5')-2'-deoxy-P-thiothymidylyl-(3'→5')-2'-deoxy-P-thiothymidylyl-(3'→5')-2'-deoxy-P-thiocytidylyl-(3'→5')-2'-deoxy-P-thio-7-deaza-guanylyl-1-glycerol-3-thiophosphoryl-2'-deoxy-P-thio-7-deaza-guanylyl-(5'→3')-2'-deoxy-P-thiocytidylyl-(5'→3')-2'-deoxy-P-thiothymidylyl-(5'→3')-2'-deoxy-P-thiothymidylyl-(5'→3')-2'-deoxy-P-thio-7-deaza-guanylyl-(5'→3')-2'-deoxy-P-thiocytidylyl-(5'→3')-2'-deoxy-P-thioadenylyl-(5'→3')-2'-deoxy-P-thioadenylyl-(5'→3')-2'-deoxy-P-thio-7-deaza-guanylyl-(5'→3')-2'-deoxy-P-thiocytidylyl-(5'→3')-5'-hydroxy-2'-deoxythymidine docosodium salt (tilsotolimod or IMO-2125) (EMEA-002318-PIP03-19) 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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# European Medicines Agency decision

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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<sup>1</sup>,

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<sup>2</sup>,

Having regard to the application submitted by Idera Pharmaceuticals Inc. on 25 February 2019 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 29 May 2019 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.

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<sup>1</sup> OJ L 378, 27.12.2006, p.1.

<sup>2</sup> OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

**Article 1**

A waiver for 5'-hydroxy-2'-deoxy-P-thiothymidylyl-(3'→5')-2'-deoxy-P-thiocytidylyl-(3'→5')-2'-deoxy-P-thio-7-deaza-guanylyl-(3'→5')-2'-deoxy-P-thioadenylyl-(3'→5')-2'-deoxy-P-thiocytidylyl-(3'→5')-2'-deoxy-P-thio-7-deaza-guanylyl-(3'→5')-2'-deoxy-P-thiothymidylyl-(3'→5')-2'-deoxy-P-thiocytidylyl-(3'→5')-2'-deoxy-P-thio-7-deaza-guanylyl-1-glycerol-3-thiophosphoryl-2'-deoxy-P-thio-7-deaza-guanylyl-(5'→3')-2'-deoxy-P-thiocytidylyl-(5'→3')-2'-deoxy-P-thiothymidylyl-(5'→3')-2'-deoxy-P-thiothymidylyl-(5'→3')-2'-deoxy-P-thio-7-deaza-guanylyl-(5'→3')-2'-deoxy-P-thiocytidylyl-(5'→3')-2'-deoxy-P-thioadenylyl-(5'→3')-2'-deoxy-P-thioadenylyl-(5'→3')-2'-deoxy-P-thio-7-deaza-guanylyl-(5'→3')-2'-deoxy-P-thiocytidylyl-(5'→3')-5'-hydroxy-2'-deoxythymidine docosasodium salt (tilsotolimod or IMO-2125), solution for injection, intratumoral 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 Select outcome.

**Article 2**

This decision is addressed to Idera Pharmaceuticals Inc., 505 Eagleview Blvd. Suite 212, 19341 – Exton, United States.



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/PDCO/170918/2019  
Amsterdam, 29 May 2019

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

EMA-002318-PIP03-19

### Scope of the application

#### Active substance(s):

5'-hydroxy-2'-deoxy-P-thiothymidylyl-(3'→5')-2'-deoxy-P-thiocytidylyl-(3'→5')-2'-deoxy-P-thio-7-deaza-guanylyl-(3'→5')-2'-deoxy-P-thioadenylyl-(3'→5')-2'-deoxy-P-thioadenylyl-(3'→5')-2'-deoxy-P-thiocytidylyl-(3'→5')-2'-deoxy-P-thio-7-deaza-guanylyl-(3'→5')-2'-deoxy-P-thiothymidylyl-(3'→5')-2'-deoxy-P-thiothymidylyl-(3'→5')-2'-deoxy-P-thiocytidylyl-(3'→5')-2'-deoxy-P-thio-7-deaza-guanylyl-1-glycerol-3-thiophosphoryl-2'-deoxy-P-thio-7-deaza-guanylyl-(5'→3')-2'-deoxy-P-thiocytidylyl-(5'→3')-2'-deoxy-P-thiothymidylyl-(5'→3')-2'-deoxy-P-thiothymidylyl-(5'→3')-2'-deoxy-P-thio-7-deaza-guanylyl-(5'→3')-2'-deoxy-P-thiocytidylyl-(5'→3')-2'-deoxy-P-thioadenylyl-(5'→3')-2'-deoxy-P-thioadenylyl-(5'→3')-2'-deoxy-P-thio-7-deaza-guanylyl-(5'→3')-2'-deoxy-P-thiocytidylyl-(5'→3')-5'-hydroxy-2'-deoxythymidine docosasodium salt (tilsotolimod or IMO-2125)

#### Condition(s):

Treatment of malignant melanoma

#### Pharmaceutical form(s):

Solution for injection

#### Route(s) of administration:

Intratumoral use

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

Idera Pharmaceuticals Inc.

### Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Idera Pharmaceuticals Inc. submitted to the European Medicines Agency on 25 February 2019 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 1 April 2019.

## **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 grant a product-specific waiver for all subsets of the paediatric population and the above mentioned condition(s) in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies are not feasible.

The Norwegian Paediatric Committee member does agree 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 malignant melanoma

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- solution for injection, intratumoral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies are not feasible.