EMA/111582/2014

European Medicines Agency decision

P/0057/2014

of 6 March 2014

on the agreement of a paediatric investigation plan and on the granting of a deferral for herpes simplex 1 virus thymidine kinase and truncated low affinity nerve growth factor receptor transfected donor lymphocytes (EMEA-001370-PIP02-13) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This Decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

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 MolMed S.p.A. on 5 August 2013 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 14 February 2014, 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 has given an opinion on the agreement of a paediatric investigation plan and on the granting of a deferral.

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

(3) It is therefore appropriate to adopt a decision granting 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 herpes simplex 1 virus thymidine kinase and truncated low affinity nerve growth factor receptor transfected donor lymphocytes, cell suspension 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 agreed.

Article 2

A deferral for herpes simplex 1 virus thymidine kinase and truncated low affinity nerve growth factor receptor transfected donor lymphocytes, cell suspension 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 granted.

Article 3

This decision is addressed to MolMed S.p.A., Via Olgettina 58, 20132 – Milano, Italy.

Done at London, 6 March 2014

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

EMA/PDCO/735468/2013

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral

EMEA-001370-PIP02-13

Scope of the application

Active substance(s):

Herpes simplex 1 virus thymidine kinase and truncated low affinity nerve growth factor receptor transfected donor lymphocytes

Condition(s):

Adjunctive treatment in haematopoietic cell transplantation

Pharmaceutical form(s):

Cell suspension for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

MolMed S.p.A.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, MolMed S.p.A. submitted for agreement to the European Medicines Agency on 5 August 2013 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 12 Spetember 2013.

Supplementary information was provided by the applicant on 22 November 2013. The applicant proposed modifications to the paediatric investigation plan.

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Opinion

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

   - to agree to the paediatric investigation plan in accordance with Article 18 of said Regulation;
   - to grant 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 measures and timelines of the agreed paediatric investigation plan are set out in the Annex I.

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

London, 14 February 2014

On behalf of the Paediatric Committee
Dr Dirk Mentzer, Chairman
(Signature on file)

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed Paediatric Investigation Plan

1. Waiver

Not applicable

2. Paediatric Investigation Plan

2.1. Condition: adjunctive treatment in haematopoietic cell transplantation

2.1.1. Indication(s) targeted by the PIP

Adjunctive treatment in haematopoietic cell transplantation

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From birth to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Cell suspension for infusion for intravenous use

2.1.4. Measures

Area	Number of studies	Description
Quality related studies		Not applicable.
Non-clinical studies		Not applicable.
Clinical studies	2	**Study 1)** TK009 IPR/27.A Open-label, non-randomized trial to evaluate the maximum tolerated dose and the activity of MM-TK cells administered in paediatric patients from birth to less than 18 years of age who are candidates for haploidentical haemopoietic stem cell transplantation. **Study 2)** TK010 IPR/28.A Randomized, active-controlled, open-label, multicentre study to evaluate activity of MM-TK donor lymphocytes compared to standard strategy in high risk acute leukaemia paediatric patients undergoing haploidentical (HSCT).

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety or efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By December 2022
Deferral for one or more measures contained in the paediatric investigation plan:	Yes