EMA/543162/2018

European Medicines Agency decision

P/0282/2018

of 12 September 2018

on the agreement of a paediatric investigation plan and on the granting of a waiver for autologous cartilage derived cultured chondrocytes (EMEA-002217-PIP01-17) 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 TETEC AG on 7 July 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 27 July 2018, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 13 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 waiver.

(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 waiver.

[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 autologous cartilage derived cultured chondrocytes, implant, implantation, 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 waiver for autologous cartilage derived cultured chondrocytes, implant, implantation, 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 TETEC AG, Aspenhaustr. 18, 72770 – Reutlingen, Germany.

EMA/PDCO/302106/2018
London, 27 July 2018

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

EMEA-002217-PIP01-17

Scope of the application

Active substance(s):

Autologous cartilage derived cultured chondrocytes

Condition(s):

Treatment of cartilage disorders

Pharmaceutical form(s):

Implant

Route(s) of administration:

Implantation

Name/corporate name of the PIP applicant:

TETEC AG

Basis for Opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, TETEC AG submitted for agreement to the European Medicines Agency on 7 July 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 15 August 2017.

Supplementary information was provided by the applicant on 25 April 2018. The applicant proposed modifications to the paediatric investigation plan and withdrew its request for a deferral.

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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 the paediatric investigation plan in accordance with Article 17(1) of said Regulation;
   - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded 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 over existing treatments for paediatric patients.

   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 and the subset(s) of the paediatric population and condition(s) covered by the waiver 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.

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 (PIP)

1. Waiver

1.1. Condition

Treatment of cartilage disorders

The waiver applies to:

- the paediatric population from birth to closure of the epiphyses as determined radiologically;
- implant, implantation;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric investigation plan

2.1. Condition

Treatment of cartilage disorders

2.1.1. Indication(s) targeted by the PIP

Treatment of cartilage disorders

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

From closure of the epiphyses as determined radiologically to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Implant

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	0	Not applicable.
Clinical studies	2	**Study 1** (2016-002817-22) Open-label, uncontrolled, single-arm trial to evaluate the activity and safety of autologous cartilage derived cultured chondrocytes in children with closed epiphyses from 14 years to less than 18 years of age (and adults) with focal cartilage defects of the knee.

		Study 2 (NIS 330) Open label, uncontrolled, retrospective, single arm, non-interventional study to collect and evaluate clinical data on safety and activity of NOVOCART Inject (product including autologous cartilage derived cultured chondrocytes, similar but not identical to the subject of this Paediatric Investigation Plan) in children with closed epiphyses below 18 years of age (and adults) with cartilage defects in the knee.
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By May 2021
Deferral for one or more measures contained in the paediatric investigation plan:	No