EMA/112125/2019

European Medicines Agency decision

P/0074/2019

of 22 March 2019

on the acceptance of a modification of an agreed paediatric investigation plan for autologous cartilage derived cultured chondrocytes (EMEA-001823-PIP01-15-M01) 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 European Medicines Agency's decision P/0242/2016 issued on 9 September 2016,

Having regard to the application submitted by TETEC AG on 26 October 2018 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 1 February 2019, in accordance with Article 22 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 has given an opinion on the acceptance of changes to the agreed paediatric investigation plan and to the deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the 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

Changes to the agreed paediatric investigation plan for autologous cartilage derived cultured chondrocytes, implant, implantation, including changes to the deferral, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to TETEC AG , Aspenhaustr. 18, 72770 – Reutlingen, Germany.

EMA/PDCO/782028/2018
London, 1 February 2019

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-001823-PIP01-15-M01

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 22 of Regulation (EC) No 1901/2006 as amended, TETEC AG submitted to the European Medicines Agency on 26 October 2018 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0242/2016 issued on 9 September 2016.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral.

The procedure started on 4 December 2018.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan and to the deferral in the scope set out in the Annex I of this opinion.

   The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the 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** Open label, randomised, active-controlled trial to evaluate efficacy and safety of autologous cartilage derived cultured chondrocytes compared to microfracture in children from closure of the epiphyses to less than 18 years of age with focal articular cartilage defects of the knee. (2011-005798-22)

		Study 2 Single-arm, prospective study to evaluate safety and efficacy of autologous cartilage derived cultured chondrocytes in children from closure of the epiphyses to less than 18 years of age with full-thickness articular cartilage defect of the knee. (N3D Paediatric Study)
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	1	**Study 3** Retrospective analysis of case notes from adolescent patients treated with autologous cartilage derived cultured chondrocytes outside the studies compared with results generated in patients included in studies 1 and 2
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 April 2023
Deferral for one or more measures contained in the paediatric investigation plan:	Yes