EMA/428127/2021

European Medicines Agency decision

P/0315/2021

of 12 August 2021

on the refusal of a modification of an agreed paediatric investigation plan and on the refusal of a deferral and on the granting of a product-specific waiver for *in vitro* expanded autologous human articular chondrocytes (EMEA-002217-PIP01-17-M02) 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 European Medicines Agency's decision P/0282/2018 issued on 12 September 2018,

Having regard to the application submitted by TETEC Tissue Engineering Technologies AG on 5 March 2021 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver and proposing a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 25 June 2021, in accordance with Article 22 of Regulation (EC) No 1901/2006 and of its own motion in accordance with Article 12 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 refusal of changes to the agreed paediatric investigation plan and on the refusal of a deferral and on the granting of a product-specific waiver.

(2) It is therefore appropriate to adopt a decision on the refusal of changes to the agreed paediatric investigation plan and on the refusal of a deferral.

(3) It is therefore appropriate to adopt a decision on the granting of a product-specific 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

Changes to the agreed paediatric investigation plan for *in vitro* expanded autologous human articular chondrocytes, implant, intraarticular 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, are hereby refused.

Article 2

A deferral for *in vitro* expanded autologous human articular chondrocytes, implant, intraarticular use, the details of which are set out in the opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby refused.

Article 3

A product-specific waiver for *in vitro* expanded autologous human articular chondrocytes, implant, intraarticular 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 4

This decision is addressed to TETEC Tissue Engineering Technologies AG, Aspenhaustr. 18, 72770 - Reutlingen, Germany.

EMA/PDCO/188690/2021 Corr
Amsterdam, 25 June 2021

Opinion of the Paediatric Committee on the refusal of a modification of an agreed Paediatric Investigation Plan and on the refusal of a deferral and on the granting of a product specific waiver

EMEA-002217-PIP01-17-M02

Scope of the application

Active substance(s):

In vitro expanded autologous human articular chondrocytes

Condition(s):

Treatment of cartilage disorders

Pharmaceutical form(s):

Implant

Route(s) of administration:

Intraarticular use

Name/corporate name of the PIP applicant:

TETEC Tissue Engineering Technologies AG

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, TETEC Tissue Engineering Technologies AG submitted to the European Medicines Agency on 5 March 2021 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/0282/2018 issued on 12 September 2018.

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

The procedure started on 27 April 2021.

Scope of the modification

The waiver has been extended to cover all subsets of the paediatric population.

Opinion

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 refuse the changes proposed by the applicant regarding the paediatric investigation plan;
- to refuse a deferral;
- and in accordance with Article 12 of Regulation (EC) No 1901/2006 as amended, recommends to grant a product-specific waiver on its own motion for all subsets of the paediatric population 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.

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 cartilage disorders

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- implant, intraarticular use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.