

EMA/380491/2023

European Medicines Agency decision P/0355/2023

of 8 September 2023

on the granting of a product specific waiver for acellular tubular graft composed of human collagen types I and III and other extracellular matrix proteins, including fibronectin and vitronectin (EMA-003345-PIP01-22) 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 726/2004¹,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency²,

Having regard to the application submitted by Humacyte Global, Inc. on 17 October 2022 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 21 July 2023 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.

¹ OJ L 378, 27.12.2006, p.1, as amended.

² OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

A waiver for acellular tubular graft composed of human collagen types I and III and other extracellular matrix proteins, including fibronectin and vitronectin, implant, implant 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 2

This decision is addressed to Humacyte Global, Inc., 2525 E. NC Highway 54, 27709 – Durham, United States.

EMA/PDCO/261647/2023
Amsterdam, 21 July 2023

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

EMA-003345-PIP01-22

Scope of the application

Active substance(s):

Acellular tubular graft composed of human collagen types I and III and other extracellular matrix proteins, including fibronectin and vitronectin

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of vascular injuries

Pharmaceutical form(s):

Implant

Route(s) of administration:

Implant use

Name/corporate name of the PIP applicant:

Humacyte Global, Inc.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Humacyte Global, Inc. submitted for agreement to the European Medicines Agency on 17 October 2022 an application for a paediatric investigation plan for the above-mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 21 November 2022.

Supplementary information was provided by the applicant on 24 April 2023.

The applicant withdrew its proposed paediatric investigation plan and proposed to extend the scope of the waiver to cover all subsets of the paediatric population.

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 over existing treatments for paediatric patients.

The Paediatric Committee member of Norway agrees 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 annexes and appendix.

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition:

Treatment of vascular injuries

The waiver applies to:

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

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.