EMA/458006/2020

European Medicines Agency decision

P/0364/2020

of 9 September 2020

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for bilayer, engineered, collagen hydrogel-based skin graft composed of autologous keratinocytes and fibroblasts (EMEA-002699-PIP01-19) 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 CUTISS AG on 28 October 2019 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 24 July 2020, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation 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 agreement of a paediatric investigation plan and on the granting of a deferral 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 deferral.

(4) 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 bilayer, engineered, collagen hydrogel-based skin graft composed of autologous keratinocytes and fibroblasts, living tissue equivalent, 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 agreed.

Article 2

A deferral for bilayer, engineered, collagen hydrogel-based skin graft composed of autologous keratinocytes and fibroblasts, living tissue equivalent, 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 3

A product-specific waiver for bilayer, engineered, collagen hydrogel-based skin graft composed of autologous keratinocytes and fibroblasts, living tissue equivalent, 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 4

This decision is addressed to CUTISS AG, Weinbergstrasse 35, 8092 – Zürich, Switzerland.

EMA/PDCO/269551/2020
Amsterdam, 24 July 2020

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

EMEA-002699-PIP01-19

Scope of the application

Active substance(s):

Bilayer, engineered, collagen hydrogel-based skin graft composed of autologous keratinocytes and fibroblasts

Condition(s):

Treatment of burns

Pharmaceutical form(s):

Living tissue equivalent

Route(s) of administration:

Implant use

Name/corporate name of the PIP applicant:

CUTISS AG

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, CUTISS AG submitted for agreement to the European Medicines Agency on 28 October 2019 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 3 December 2019.

Supplementary information was provided by the applicant on 20 April 2020. The applicant proposed modifications to the paediatric investigation plan and withdrew the request for a waiver.

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 deferral in accordance with Article 21 of said Regulation;
   - to grant a waiver for one or more subsets of the paediatric population of its own motion in accordance with Article 12 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 burns

The waiver applies to:

- newborn infants of less than 37 weeks postmenstrual age;
- living tissue equivalent; implant use;
- 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 burns

2.1.1. Indication(s) targeted by the PIP

Treatment of partial deep dermal and full thickness burns

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

From birth (from 37 weeks postmenstrual age) to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Living tissue equivalent

2.1.4. Measures

Area	**Number of measures**	**Description**
Quality-related studies	0	Not applicable.
Non-clinical studies	0	Not applicable.
Clinical studies	3	**Study 1 (ESG-01-2011)** Open-label trial to evaluate the safety of autologous tissue-engineered skin substitute (PrimeSkin/denovoSkin) for the treatment of large deep partial and full thickness skin defects in children from 1 year to less than 18 years of age (and adults).

		Study 2 (TBRU-dS-BC-PIIb) Open-label, intra-patient randomised, controlled trial to evaluate the safety and efficacy of an autologous bio-engineered dermo-epidermal skin substitute (PrimeSkin/denovoSkin) for the treatment of partial deep dermal and full-thickness burns in comparison to autologous split-thickness skin grafts (STSG) in children from birth to less than 12 years of age. **Study 3 (TBRU-dS-BA-PIIb)** Open-label, intra-patient randomised, controlled trial to evaluate the safety and efficacy of an autologous bio-engineered dermo-epidermal skin substitute (PrimeSkin/denovoSkin) for the treatment of partial deep dermal and full-thickness burns in comparison to autologous split-thickness skin grafts (STSG) in adolescents from 12 years to less than 18 years of age (and adults).
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:	No
Date of completion of the paediatric investigation plan:	By July 2024
Deferral for one or more measures contained in the paediatric investigation plan:	Yes