EMA/350898/2023

European Medicines Agency decision

P/0331/2023

of 10 August 2023

on the acceptance of a modification of an agreed paediatric investigation plan for bilayer, engineered, collagen hydrogel-based skin graft composed of autologous keratinocytes and fibroblasts (EMEA-002699-PIP01-19-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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0364/2020 issued on 9 September 2020,

Having regard to the application submitted by CUTISS AG on 24 April 2023 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 21 July 2023, 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, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for bilayer, engineered, collagen hydrogel-based skin graft composed of autologous keratinocytes and fibroblasts, living tissue equivalent, implant use, 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 CUTISS AG, 12 Wagistrasse, 8952 – Schlieren, Switzerland.

EMA/PDCO/203495/2023
Amsterdam, 21 July 2023

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

EMEA-002699-PIP01-19-M01

Scope of the application

Active substance(s):

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

Invented name and authorisation status:

See Annex II

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 22 of Regulation (EC) No 1901/2006 as amended, CUTISS AG submitted to the European Medicines Agency on 24 April 2023 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/0364/2020 issued on 9 September 2020.

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

The procedure started on 22 May 2023.

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 Paediatric Committee member of Norway 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 annexes 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	**Description**
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	**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	Not applicable
Other studies	Not applicable
Other measures	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 2027
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community