EMA/810422/2012

European Medicines Agency decision

P/0310/2012

of 21 December 2012

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for human dermal fibroblasts cultured on bioresorbable polyglactin mesh (ABH001) (EMEA-001326-PIP01-12) 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 TMC Pharma on 5 June 2012 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 7 December 2012, in accordance with Article 18 of Regulation (EC) No 1901/2006, and of its own motion in accordance with Article 21 of said Regulation and Article 13 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 human dermal fibroblasts cultured on bioresorbable polyglactin mesh (ABH001), living tissue equivalent, dermis, topical 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 human dermal fibroblasts cultured on bioresorbable polyglactin mesh (ABH001), living tissue equivalent, dermis, topical 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 waiver for human dermal fibroblasts cultured on bioresorbable polyglactin mesh (ABH001), living tissue equivalent, dermis, topical 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 TMC Pharma, Lodge Farm Barn, Elvetham Park Estate, Fleet road, Hartley Wintney, RG27 8AS Hampshire, United Kingdom.

Done at London, 21 December 2012

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/506376/2012

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

EMEA-001326-PIP01-12

Scope of the application

Active substance(s):

Human dermal fibroblasts cultured on bioresorbable polyglactin mesh (ABH001)

Condition(s):

Treatment of epidermolysis bullosa

Pharmaceutical form(s):

Living tissue equivalent, dermis

Route(s) of administration:

Topical use

Name/corporate name of the PIP applicant:

TMC Pharma

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, TMC Pharma submitted for agreement to the European Medicines Agency on 5 June 2012 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 11 July 2012.

Supplementary information was provided by the applicant on 17 September 2012. The applicant proposed modifications to the paediatric investigation.

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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 18 of said Regulation,
   - to grant a deferral on its own motion in accordance with Article 21 of said Regulation,
   - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 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 Icelandic and the Norwegian Paediatric Committee members agree 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.

London, 7 December 2012

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

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

1. Waiver

1.1. Condition: Treatment of epidermolysis bullosa

The waiver applies to:

- Newborns less than 1 month of age;
- for living tissue equivalent, dermis, topical 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 epidermolysis bullosa

2.1.1. Indication(s) targeted by the PIP

Treatment of chronic wounds in patients with epidermolysis bullosa.

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

From 1 month to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Living tissue equivalent, dermis.

2.1.4. Measures

Area	Number of measures	Description
Quality	0	Not applicable.
Non-clinical	1	Wound healing in athymic rats with dermal wounds.
Clinical	1	Prospective, randomized, open-label, intra-patient controlled efficacy and safety study to evaluate the efficacy of ABH001 in initiating healing of selected cutaneous, clinically non-infected stalled chronic wounds in adult and paediatric patients at least 1 month of age with epidermolysis bullosa.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes.
Date of completion of the paediatric investigation plan:	By October 2014.
Deferral for one or more measures contained in the paediatric investigation plan:	Yes.