EMA/248970/2013

European Medicines Agency decision

P/0122/2013

of 28 May 2013

on the acceptance of a modification of an agreed paediatric investigation plan for concentrate of proteolytic enzymes in bromelain (NexoBrid), (EMEA-000142-PIP02-09-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 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/227/2010 issued on 28 October 2010,

Having regard to the application submitted by Teva Pharma GmbH on 17 January 2013 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 12 April 2013, 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.

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

[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 concentrate of proteolytic enzymes in bromelain (NexoBrid), powder and gel for gel, cutaneous use, 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 Teva Pharma GmbH, Graf-Arco-Str. 3, 89079 – Ulm, Germany.

Done at London, 28 May 2013

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

EMA/PDCO/62868/2013

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

EMEA-000142-PIP02-09-M01

Scope of the application

Active substance(s):

Concentrate of proteolytic enzymes in bromelain

Invented name:

NexoBrid

Condition(s):

Treatment of burns

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder and gel for gel.

Route(s) of administration:

Cutaneous use

Name/corporate name of the PIP applicant:

Teva Pharma GmbH

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Teva Pharma GmbH submitted to the European Medicines Agency on 17 January 2013 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/227/2010 issued on 28 October 2010.

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

The procedure started on 13 February 2013.

Scope of the modification

A timeline and details of the wording of the pharmaceutical form and the active substance 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 in the scope set out in the Annex I of this opinion.

   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 paediatric investigation plan 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.

London, 12 April 2013

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

Not applicable.

2. Paediatric Investigation Plan

2.1. Condition: treatment of burns

2.1.1. Indication(s) targeted by the PIP

Removal of eschar in deep partial and/or full thickness burns.

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

From birth to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Powder and gel for gel.

2.1.4. Measures

Area	Number of measures	Description
Quality	0	Not applicable.
Non-clinical	2	**Measure 1** SA single dose toxicity study of concentrate of proteolytic enzymes in bromelain powder administered intravenously to minipigs with a 14-day observation period. **Measure 2** 14-Day repeated intravenous dose study in juvenile pigs with collection of toxicokinetic data.
Clinical	3	**Measure 3** Multicentre trial to assess long-term scar formation and quality of life in adults and children aged from 4 to less than 18 years comparing debridement of burn wounds with concentrate of proteolytic enzymes in bromelain to standard of care. **Measure 4** Open-label, randomised, multicentre trial to evaluate pharmacokinetics, safety, efficacy and immunogenicity of concentrate of proteolytic enzymes in bromelain for debridement of partial thickness and full thickness thermal burns compared to standard of care in children aged from birth to less than 18 years.

Area	Number of measures	Description
		Measure 5 Multicentre trial to assess long-term scar formation and quality of life children after participating in study 4 comparing debridement with concentrate of proteolytic enzymes in bromelain to standard of care in children aged from birth to less than 18 years.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By March 2019
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of burns

Authorised indication(s):

- NexoBrid is indicated for removal of eschar in adults with deep partial- and full-thickness thermal burns.

Authorised pharmaceutical form(s):

Powder and gel for gel

Authorised route(s) of administration:

Cutaneous use