EMA/953999/2011

European Medicines Agency decision

P/304/2011

of 20 December 2011

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the refusal of a waiver for recombinant human granulocyte colony stimulating factor coupled with recombinant human albumin fusion protein (EMEA-001042-PIP02-11) 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 Teva GmbH on 10 February 2011 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 11 November 2011, in accordance with Article 18 of Regulation (EC) No 1901/2006, and 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 refusal 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 refusing 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 recombinant human granulocyte colony stimulating factor coupled with recombinant human albumin fusion protein, powder for solution for injection, subcutaneous 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 recombinant human granulocyte colony stimulating factor coupled with recombinant human albumin fusion protein, powder for solution for injection, subcutaneous 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 recombinant human granulocyte colony stimulating factor coupled with recombinant human albumin fusion protein, powder for solution for injection, subcutaneous 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 refused.

Article 4

This decision is addressed to Teva GmbH, Wasastrasse 50, 01445 – Radebeul, Germany.

Done at London, 20 December 2011

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

EMA/PDCO/705162/2011

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

EMEA-001042-PIP02-11

Scope of the application

Active substance(s):

Recombinant human granulocyte colony stimulating factor coupled with recombinant human albumin fusion protein

Condition(s):

Prevention of chemotherapy-induced febrile neutropenia

Treatment of chemotherapy-induced neutropenia

Pharmaceutical form(s):

Powder for solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Teva GmbH

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Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Teva GmbH submitted for agreement to the European Medicines Agency on 10 February 2011 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 23 March 2011.

Supplementary information was provided by the applicant on 22 August 2011. The applicant proposed modifications to the paediatric investigation.

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 in accordance with Article 21 of said Regulation,
   - to refuse the granting of a waiver in accordance with Article 13 of said Regulation, for some of the subsets of the paediatric population and the above mentioned conditions as it does not meet the grounds detailed in Article 11(1) of said Regulation.

     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 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(es) and appendix.

London, 11 November 2011

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

The waiver is refused for the following:

1.1. Conditions: Prevention of chemotherapy-induced febrile neutropenia Treatment of chemotherapy-induced neutropenia

The waiver applied by the applicant concerns:

- the paediatric population from birth to less than 2 years of age;
- for powder for solution for injection, subcutaneous use.

on the grounds set out in Article 11(1)(c) of Regulation (EC) No 1901/2006 that:

the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

The waiver request does not provide evidence to support these grounds. The PDCO is of the view that the specific medicinal product may represent a significant therapeutic benefit as the needs are not met.

The waiver request is therefore refused by the PDCO.

2. Paediatric Investigation Plan

2.1. Condition: Prevention of chemotherapy-induced febrile neutropenia

2.2. Condition: Treatment of chemotherapy-induced neutropenia

2.2.1. Indication(s) targeted by the PIP

Treatment of neutropenia and reduction in incidence of febrile neutropenia in paediatric patients treated with cytotoxic chemotherapy for a malignant disease (excluding chronic myeloid leukaemia and myelodysplastic syndromes).

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

From birth to less than 18 years of age.

2.2.3. Pharmaceutical form(s)

Powder for solution for injection.

2.2.4. Studies

Area	Number of studies	Description
Quality	1	**Study 1** Development of powder for solution for subcutaneous injection including strength of 25 mg.
Non-clinical	0	Not applicable.
Clinical	2	**Study 2** Open-label, active-controlled, randomised, dose-finding trial to evaluate pharmacokinetics, pharmacodynamic, safety and tolerability of the Recombinant human granulocyte colony stimulating factor coupled with recombinant human albumin fusion protein compared to filgrastim in children from 2 to less than 18 years of age with solid tumours or lymphoma receiving chemotherapy. **Study 3** Measure to extrapolate efficacy to the paediatric population less than 2 years of age.

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 December 2014
Deferral for one or more studies contained in the paediatric investigation plan:	Yes