EMA/538451/2020

European Medicines Agency decision

P/0414/2020

of 23 October 2020

on the agreement of a paediatric investigation plan and on the granting of a deferral for recombinant human granulocyte colony-stimulating factor – human immunoglobulin Fc fusion protein (rhG-CSF-Fc) (EMEA-002507-PIP02-19) 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 Generon (Shanghai) Corporation on 28 November 2019 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 4 September 2020, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 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.

(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.

[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 – human immunoglobulin Fc fusion protein (rhG-CSF-Fc), 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 – human immunoglobulin Fc fusion protein (rhG-CSF-Fc), 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

This decision is addressed to Generon (Shanghai) Corporation, Suite 111, Building 9, 787 Kang Qiao Road, 201315 – Shanghai, China.

EMA/PDCO/333486/2020
Amsterdam, 4 September 2020

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

EMEA-002507-PIP02-19

Scope of the application

Active substance(s):

Recombinant human granulocyte colony-stimulating factor – human immunoglobulin Fc fusion protein (rhG-CSF-Fc)

Condition(s):

Treatment of chemotherapy-induced neutropenia

Prevention of chemotherapy-induced febrile neutropenia

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Generon (Shanghai) Corporation

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Generon (Shanghai) Corporation submitted for agreement to the European Medicines Agency on 28 November 2019 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 6 January 2020.

Supplementary information was provided by the applicant on 21 April 2020. The applicant proposed modifications to the paediatric investigation plan.

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.

   The Paediatric Committee member agrees 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 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

Not applicable

2. Paediatric investigation plan

2.1. Condition:

Treatment of chemotherapy-induced neutropenia

2.1.1. Indication(s) targeted by the PIP

Reduction in the duration of neutropenia in patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes)

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)

Solution for injection

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of vials to allow appropriate dosing of recombinant human granulocyte colony-stimulating factor – human immunoglobulin Fc fusion protein to the paediatric population (GC-627-06-CMC001)
Non-clinical studies	0	Not applicable
Clinical studies	2	**Study 2** Open-label, single-dose, dose escalation study to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of recombinant human granulocyte colony-stimulating factor – human immunoglobulin Fc fusion protein in paediatric subjects from birth to less than 18 years of age (and adults) with soft tissue sarcoma receiving myelotoxic chemotherapy (GC-627-06) **Study 3** Randomised, open-label, active-controlled study to assess the efficacy and safety of recombinant human granulocyte colony-stimulating factor – human immunoglobulin Fc

		fusion protein in paediatric subjects from birth to less than 18 years of age (and adults) with soft tissue sarcoma receiving myelotoxic chemotherapy (GC-627-07)
Extrapolation, modelling and simulation studies	1	**Study 4** Modelling and simulation study to investigate the dose and to evaluate the use of recombinant human granulocyte colony-stimulating factor – human immunoglobulin Fc fusion protein for the treatment of chemotherapy-induced neutropenia and prevention of chemotherapy-induced febrile neutropenia in paediatric patients from birth to less than 18 years of age (GC-627-Modelling)
Other studies	0	Not applicable
Other measures	0	Not applicable

2.2. Condition:

Prevention of chemotherapy-induced febrile neutropenia

2.2.1. Indication(s) targeted by the PIP

Reduction in the incidence of febrile neutropenia in patients treated with cytotoxic chemotherapy for malignancy (with the exception of 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)

Solution for injection

2.2.4. Measures

Area	**Number of measures**	**Description**
Quality-related studies	1	**Study 1** Same as study 1 for the condition treatment of chemotherapy-induced neutropenia
Non-clinical studies	0	Not applicable.
Clinical studies	2	**Study 2** Same as study 2 for the condition treatment of chemotherapy-induced neutropenia **Study 3**

		Same as study 3 for the condition treatment of chemotherapy-induced neutropenia
Extrapolation, modelling and simulation studies	1	**Study 4** Same as study 4 for the condition treatment of chemotherapy-induced neutropenia
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 October 2028
Deferral for one or more measures contained in the paediatric investigation plan:	Yes