

EMA/493094/2017

European Medicines Agency decision

P/0261/2017

of 4 September 2017

on the acceptance of a modification of an agreed paediatric investigation plan for lipegfilgrastim (Lonquex), (EMA-001019-PIP01-10-M04) 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 726/2004¹,

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 Agency²,

Having regard to the European Medicines Agency's decision P/112/2011 issued on 6 May 2011, the decision P/0028/2013 issued on 26 February 2013, the decision P/0116/2014 issued on 6 May 2014 and the decision P/0303/2015 issued on 21 December 2015,

Having regard to the application submitted by UAB "Sicor Biotech" on 27 April 2017 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 21 July 2017, 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.

² OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for lipegfilgrastim (Lonquex), solution for injection, subcutaneous 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 UAB "Sicor Biotech", Molėtų pl. 5, LT-08409 – Vilnius, Lithuania.

EMA/PDCO/285962/2017

London, 21 July 2017

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-001019-PIP01-10-M04

Scope of the application

Active substance(s):

Lipegfilgrastim

Invented name:

Lonquex

Condition(s):

Treatment of chemotherapy-induced neutropenia

Prevention of chemotherapy-induced febrile neutropenia

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Name / corporate name of the PIP applicant:

UAB "Sicor Biotech"

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, UAB "Sicor Biotech" submitted to the European Medicines Agency on 27 April 2017 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/112/2011 issued on 6 May 2011, the decision P/0028/2013 issued on 26 February 2013, the decision P/0116/2014 issued on 6 May 2014 and the decision P/0303/2015 issued on 21 December 2015.

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

The procedure started on 24 May 2017.

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 Norwegian Paediatric Committee member agrees 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.

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. Conditions

Treatment of chemotherapy-induced neutropenia

Prevention of chemotherapy-induced febrile neutropenia

2.1.1. Indication(s) targeted by the PIP

Treatment of neutropenia and reduction in the incidence of febrile neutropenia in patients treated with chemotherapy for malignancy.

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 studies	Description
Quality-related studies	1	Study 1 Development of single dose vial containing 6 mg of lipegfilgrastim in a 10mg/ml solution.
Non-clinical studies	0	Not applicable.
Clinical studies	2	Study 2 Open-label, multicentre, single dose trial to evaluate pharmacokinetics, pharmacodynamics, safety, tolerability, immunogenicity and efficacy (XM22-07). Study 3 Open-label, active controlled, randomised, multicentre, single dose trial to evaluate efficacy, safety, and tolerability of lipegfilgrastim (XM22-08).
Extrapolation, modelling & simulation studies	1	Study 4 Study to extrapolate efficacy to the paediatric population less than 2 years of age.

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:	Yes
Date of completion of the paediatric investigation plan:	By January 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 chemotherapy-induced neutropenia

Authorised indication(s):

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

2. Prevention of chemotherapy-induced febrile neutropenia

Authorised indication(s):

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

Authorised pharmaceutical form(s):

Solution for injection

Authorised route(s) of administration:

Subcutaneous use