EMA/565799/2017

European Medicines Agency decision

P/0267/2017

of 4 September 2017

on the acceptance of a modification of an agreed paediatric investigation plan for L-asparaginase encapsulated in erythrocytes (EMEA-000341-PIP02-09-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 726/2004[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/209/2010 issued on 29 October 2010, the decision P/0300/2014 issued on 24 November 2014 and the decision P/0188/2015 issued on 4 September 2015,

Having regard to the application submitted by ERYTECH Pharma S.A. on 3 August 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 18 August 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.

(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 L-asparaginase encapsulated in erythrocytes, suspension for injection, suspension for infusion, intravenous 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 ERYTECH Pharma S.A., Bâtiment Adénine - 60 Avenue Rockefeller, 69008 – Lyon, France.

EMA/PDCO/505893/2017 Corr
London, 18 August 2017

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

EMEA-000341-PIP02-09-M04

Scope of the application

Active substance(s):

L-asparaginase encapsulated in erythrocytes

Condition(s):

Treatment of acute lymphoblastic leukaemia

Pharmaceutical form(s):

Suspension for injection

Suspension for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

ERYTECH Pharma S.A.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, ERYTECH Pharma S.A. submitted to the European Medicines Agency on 3 August 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/209/2010 issued on 29 October 2010, the decision P/0300/2014 issued on 24 November 2014 and the decision P/0188/2015 issued on 4 September 2015.

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

The procedure started on 15 August 2017.

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Scope of the modification

A timeline of the Paediatric Investigation Plan has 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 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 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 acute lymphoblastic leukaemia

2.1.1. Indication(s) targeted by the PIP

Treatment of patients with acute lymphoblastic leukaemia

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)

Suspension for injection

Suspension for infusion

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable
Non-clinical studies	1	**Study 1:** To evaluate L-asparaginase activity in presence of specific neutralizing antibodies
Clinical studies	3	**Study 3:** Double-blind, dose-comparative, randomised, repeat-dose, multicentre, active-controlled trial to evaluate pharmacokinetics, pharmacodynamics, safety and immunogenicity of L-asparaginase encapsulated in erythrocytes in children from 1 years to less than 18 years (and in adults) with acute lymphoblastic leukaemia **Study 4:** Open-label, randomised, single-dose, multicentre, active-controlled trial to evaluate pharmacokinetics, safety, pharmacodynamic activity of L-asparaginase encapsulated in erythrocytes in children from 1 years to less than 18 years (and in adults) with first relapse of acute lymphoblastic leukaemia, with and without asparaginase hypersensitivity

		Study 5: Open-label, randomised, multicentre, active-controlled trial to evaluate safety, pharmacodynamic equivalence / comparative efficacy of L-asparaginase encapsulated in erythrocytes in children from birth to less than 18 years with newly-diagnosed acute lymphoblastic leukaemia
Extrapolation, modelling and simulation studies	0	Not applicable.
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 December 2020
Deferral for one or more measures contained in the paediatric investigation plan:	Yes