



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/656412/2010

European Medicines Agency decision P/209/2010

of 29 October 2010

on the agreement of a paediatric investigation plan and on the granting of a deferral for L-asparaginase encapsulated in erythrocytes, (EMEA-000341-PIP02-09) 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.



European Medicines Agency decision

P/209/2010

of 29 October 2010

on the agreement of a paediatric investigation plan and on the granting of a deferral for L-asparaginase encapsulated in erythrocytes (EMA-000341-PIP02-09) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 application submitted by ERYtech Pharma on 05 October 2009 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 10 September 2010, in accordance with Article 18 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 L-asparaginase encapsulated in erythrocytes, suspension for injection, suspension for infusion, intravenous 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 L-asparaginase encapsulated in erythrocytes, suspension for injection, suspension for infusion, intravenous 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 ERYtech Pharma, Bâtiment Adenine, 60 Avenue Rockefeller, 69008 Lyon, France.

Done at London, 29 October 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/493614/2010

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

EMA-000341-PIP02-09

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

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, ERYtech Pharma submitted for agreement to the European Medicines Agency on 05 October 2009 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 December 2009.

Supplementary information was provided by the applicant on 18 June 2010.



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.

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, 10 September 2010

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 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. Studies

Area	Number of studies	Description
Quality	0	Not applicable
Non-clinical	2	Study 1: To evaluate L-asparaginase activity in presence of specific neutralizing antibodies Study 2: To evaluate repeat-dose toxicity
Clinical	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

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By December 2016
Deferral for one or more studies contained in the paediatric investigation plan:	Yes