European Medicines Agency

Doc. Ref. EMEA/29650/2009
P/2/2009

EUROPEAN MEDICINES AGENCY DECISION

of 27 January 2009

on the acceptance of a modification of an agreed Paediatric Investigation Plan for recombinant L-asparaginase (EMEA-000013-PIP01-07-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006, as amended.

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THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

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 as amended 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 decision P/7/2008 of the European Medicines Agency on 1 February 2008.

Having regard to the application submitted by medac Gesellschaft für klinische Spezialpräparate on 26 September 2008 under Article 22 of Regulation (EC) No 1901/2006 as amended for changes to an agreed Paediatric Investigation Plan,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 12 December 2008, in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended,

Having regard to Article 25 of Regulation (EC) No 1901/2006 as amended,

WHEREAS:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to an agreed Paediatric Investigation Plan,

(2) It is therefore appropriate to adopt a Decision on the acceptance of changes to an 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 recombinant L-asparaginase, powder for solution for injection or infusion, intravenous and intramuscular 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, are hereby accepted.

Article 2

This decision, that supersedes previous decision of the European Medicines Agency P/7/2008 is addressed to medac Gesellschaft für klinische Spezialpräparate, Fehlandtstrasse 3, 20354 Hamburg, Germany.

Done at London, 27 January 2009

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMEA/29650/2009
EMEA-000013-PIP01-07-M01

OPINION OF THE PAEDIATRIC COMMITTEE ON THE ACCEPTANCE OF A MODIFICATION OF AN AGREED PAEDIATRIC INVESTIGATION PLAN

Scope of the application

Active substance:
Recombinant L-asparaginase

Conditions:
Acute lymphoblastic leukaemia
Lymphoblastic lymphoma

Pharmaceutical form:
Powder for solution for injection or infusion

Routes of administration:
Intravenous use
Intramuscular use

Name/corporate name of the PIP applicant:
medac Gesellschaft für klinische Spezialpräparate

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, medac Gesellschaft für klinische Spezialpräparate submitted to the EMEA on 26 September 2008 an application for modification of the agreed paediatric investigation plan as set out in the EMEA decision P/7/2008 of 1 February 2008.

The procedure started on 16 October 2008.

Scope of the modification

The modification concerned the timelines for initiation and completion of two clinical trials as well as the design and the definition of the primary endpoint of one clinical trial.

Opinion

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 the changes proposed by the applicant regarding the measures and the timelines of the paediatric investigation plan.

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 paediatric investigation plan are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the Agency, together with its annex(es) and appendix.

London, 12 December 2008

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

THE MEASURES AND TIMELINES OF THE AGREED PAEDIATRIC INVESTIGATION PLAN

A. CONDITION(S) / DISEASE(S)

Acute lymphoblastic leukaemia and lymphoblastic lymphoma

C. PAEDIATRIC INVESTIGATION PLAN

C.1. Conditions to be investigated

Acute lymphoblastic leukaemia and lymphoblastic lymphoma

- **Subset(s) covered**

All age subsets of the paediatric population

- **Formulation(s)**

Powder for solution for injection or infusion

- **Studies / Measures**

Area	Subarea	Number	Description
Clinical	Pharmacokinetic / pharmacodynamic	2	Randomised, parallel-group, blinded, single-centre, multiple-dose, comparative PK/PD and safety phase 2 study Non-controlled, multi-centre, PD, activity and safety phase 2 study of recombinant L-asparaginase
	Efficacy, safety	1	Randomised, multi-centre, double-blind, pharmaco-dynamic equivalence / comparative efficacy and safety phase 3 study

Need for a EU-RMP: Yes
Date of completion of the paediatric investigation plan: By December 2011
Deferral compared to submission date for non-paediatric data: No