European Medicines Agency

Doc. Ref. EMEA/258718/2008
P/23/2008

EUROPEAN MEDICINES AGENCY DECISION

of 23 May 2008

on the application for agreement of a Paediatric Investigation Plan for albumin interferon alfa-2b, EMEA-000017-PIP01-07, in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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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 application submitted by Novartis Europharm Ltd on 26 July 2007 under Article 16.1 of Regulation (EC) No 1901/2006 as amended also including a request for a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, formulated on 11 April 2008, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 21 of said Regulation,

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 a positive opinion,

(2) It is therefore appropriate to adopt a Decision following the Paediatric Committee's opinion on the 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 albumin interferon alfa-2b, powder and solvent for 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 albumin interferon alfa-2b, powder and solvent for solution for injection, subcutaneous use, the details of which are set out in the Opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to Novartis Europharm Ltd, Wimblehurst Road, RH125AB, Horsham.

Done at London, 23 May 2008

For the European Medicines Agency
Thomas Lönngren
Executive Director
(Signature on file)

European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

EMEA/258718/2008
EMEA-000017-PIP01-07

POSITIVE OPINION OF THE PAEDIATRIC COMMITTEE ON A REQUEST FOR AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN FOR

Scope of the application

Active substance:
Albumin interferon alfa-2b

Condition(s):
Chronic hepatitis C

Pharmaceutical form(s):
Powder and solvent for solution for injection.

Route(s) of administration:
Subcutaneous use.

Name/corporate name of the PIP applicant:
Novartis Europharm Ltd

Basis for opinion

Pursuant to Article 16.1 of Regulation (EC) No 1901/2006 as amended, Novartis Europharm Ltd submitted for agreement to the EMEA on 26 July 2007 a paediatric investigation plan for the above mentioned medicinal product.

The procedure started on 30 August 2007.

Supplementary information was provided by the applicant on 28 January 2008.

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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 Regulation (EC) No 1901/2006 as amended,
- to grant a deferral in accordance with Article 21 of Regulation (EC) No 1901/2006 as amended

The Norwegian 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 Agency, together with its annex and appendix.

London, 11 April 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)

Chronic hepatitis C

B. Waiver

Not applicable however before initiating the clinical trial in the paediatric subset below 3 years of age (study 2) the applicant must rediscuss with the PDCO the need to conduct such a study.

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Chronic hepatitis C

- **PIP indication**

Treatment of chronic hepatitis C, in combination with ribavirin, in children who have not previously been treated.

- **Subset(s) covered**

All age subsets of the paediatric population

- **Formulation(s)**

Powder and solvent for solution for injection

- **Studies / Measures**

Area	Subarea	Number	Description
Clinical	Pharmacokinetic, efficacy and safety	2	1) Multicentre, open-label, non-randomised, two-stage study, to assess safety, efficacy and pharmacokinetics of albinterferon plus ribavirin in children aged from 3 to 18 years of age diagnosed with chronic hepatitis C (genotype 1 and 2/3) who are treatment-naïve. 2) Multicentre, open-label, non-randomised, two-stage study, to assess safety, efficacy and pharmacokinetics of albinterferon plus ribavirin in children aged below 3-years diagnosed with chronic hepatitis C (genotype 1 and 2/3) who are treatment-naïve. The need for this study would have to be rediscussed with the PDCO.

Need for paediatric measures in a EU-Risk Management Plan: **Yes**
Date of completion of the paediatric investigation plan: **by December 2018**
A deferral has been granted: **Yes**