European Medicines Agency

Doc. Ref. EMEA/313283/2008
P/39/2008

EUROPEAN MEDICINES AGENCY DECISION

of 24 June 2008

on the application for agreement of a Paediatric Investigation Plan for taranabant (EMEA-000062-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)

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 70
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

EUROPEAN MEDICINES AGENCY DECISION

of 24 June 2008

on the application for agreement of a Paediatric Investigation Plan for taranabant (EMEA-000062-PIP01-07) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

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 Merck Sharp & Dohme (Europe) Inc on 15 October 2007 under Article 16(1) of Regulation (EC) No 1901/2006 as amended, also requesting a waiver under Article 13 of said Regulation, and a deferral under Article 20 of said Regulation;

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 8 May 2008, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 of said Regulation 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 waiver;

(4) 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 taranabant, soft capsules, oral 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 waiver for taranabant, soft capsules, oral 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

A deferral for taranabant, soft capsules, oral 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 4

This decision is addressed to Merck Sharp & Dohme (Europe) Inc., 5, Clos du Lynx, 1200 Brussels, Belgium.

Done at London, 24 June 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/PDCO/217173/2008
EMEA-000062-PIP01-07

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

Scope of the application

Active substance:
Taranabant

Condition:
Obesity

Pharmaceutical form:
Soft capsules

Route of administration:
Oral use

Name/corporate name of the PIP applicant:
Merck Sharp & Dohme (Europe) Inc

Basis for opinion

Pursuant to Article 16.1 of Regulation (EC) No 1901/2006 as amended, Merck Sharp & Dohme (Europe) Inc. submitted for agreement to the EMEA on 15 October 2007 a paediatric investigation plan for the above mentioned medicinal product.

The procedure started on 22 November 2007.

Supplementary information was provided by the applicant on 29 February 2008.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 75 23 70 40
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

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;
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended and concluded in accordance with Article 11(1)(a) of Regulation (EC) No 1901/2006 as amended, on the grounds that that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population.

The Norwegian and Icelandic Paediatric Committee members agree with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed paediatric investigation plan and the subset of the paediatric population and condition covered by the waiver 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, 8 May 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 AND THE SUBSET(S) OF THE PAEDIATRIC POPULATION AND CONDITION(S) COVERED BY THE WAIVER

A. CONDITION(S) / DISEASE(S)

Obesity

B. WAIVER

- **Condition**

Obesity

- **Subset of the paediatric population, pharmaceutical form and route of administration covered**

The waiver applies to:
Children aged 0 to less than 6 years, soft capsules, oral use

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Obesity

- **Paediatric investigation plan indication**

Treatment of obesity

- **Subset covered**

Children aged 6 to less than 18 years

- **Formulation**

Oral formulation, soft capsule

- **Studies / Measures**

#	Area	Subarea	Description
N	Non-clinical	Toxicology	Toxicity study in juvenile rats
1	Clinical	Pharmaco-kinetic	Randomized, Double-Blind, Placebo-Controlled Single-Dose Studies to Evaluate the Safety, Tolerability and Pharmacokinetic Profile of Taranabant in Obese Adolescents (from puberty to 17 years old) and in Obese Younger Children (6 years old to puberty)

2	Clinical	Pharmaco-kinetic	Randomized, Double-Blind, Placebo-Controlled Multiple-Dose Studies to Evaluate the Safety, Tolerability and Pharmacokinetic Profile of Taranabant in Obese Adolescents (from puberty to 17 years old) and in Obese Younger Children (6 years old to puberty)
3	Clinical	Safety and efficacy	Phase IIb Randomized, Placebo-Controlled Clinical Trial to Evaluate the Safety and Efficacy of Taranabant in Obese Adolescents, and in Overweight Adolescents with Obesity-Related Co-Morbidities
4	Clinical	Safety and efficacy	Phase III Randomized, Placebo-Controlled Clinical Trial to Evaluate the Safety and Efficacy of Taranabant in Obese Adolescents, and in Overweight Adolescents with Obesity-Related Co-Morbidities
5	Clinical	Safety and efficacy	Phase IIb Randomized, Placebo-Controlled Clinical Trial to Evaluate the Safety and Efficacy of Taranabant in Obese Younger Children, and in Overweight Younger Children with Obesity-Related Co-Morbidities
6	Clinical	Safety and efficacy	Phase III Randomized, Placebo-Controlled Clinical Trial to Evaluate the Safety and Efficacy of Taranabant in Obese Younger Children, and in Overweight Younger Children with Obesity-Related Co-Morbidities

Need for paediatric measures in a EU-Risk Management Plan: Yes

Date of completion of the paediatric investigation plan: November 2019
(to be confirmed with PDCO)

A deferral has been granted: Yes