



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/508721/2014

European Medicines Agency decision

P/0243/2014

of 29 September 2014

on the acceptance of a modification of an agreed paediatric investigation plan for 7-[4-(4-Benzo[b]thiophen-4-ylpiperazin-1-yl)butoxy]quinolin-2(1H)-one (OPC-34712) (EMEA-001185-PIP01-11-M01) 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 726/2004¹,

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 European Medicines Agency's decision P/0160/2012 issued on 25 July 2012,

Having regard to the application submitted by Otsuka Europe Development and Commercialisation Ltd, Zweigniederlassung Frankfurt am Main on 23 May 2014 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 15 August 2014, 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 and to the deferral.
- (2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the 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

Changes to the agreed paediatric investigation plan for 7-[4-(4-Benzo[b]thiophen-4-ylpiperazin-1-yl)butoxy]quinolin-2(1H)-one (OPC-34712), film-coated tablet, oral use, including changes to the deferral, 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 Otsuka Europe Development and Commercialisation Ltd,
Zweigniederlassung Frankfurt am Main, Europa-Allee 52, 60327 - Frankfurt, Germany.

Done at London, 29 September 2014

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/336833/2014

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

EMA-001185-PIP01-11-M01

Scope of the application

Active substance(s):

7-[4-(4-Benzo[b]thiophen-4-yl)piperazin-1-yl)butoxy]quinolin-2(1H)-one (OPC-34712)

Condition(s):

Treatment of schizophrenia

Pharmaceutical form(s):

Film-coated tablet

Route(s) of administration:

Oral use

Name / corporate name of the PIP applicant:

Otsuka Europe Development and Commercialisation Ltd, Zweigniederlassung Frankfurt am Main

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Otsuka Europe Development and Commercialisation Ltd, Zweigniederlassung Frankfurt am Main submitted to the European Medicines Agency on 23 May 2014 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0160/2012 issued on 25 July 2012.

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

The procedure started on 18 June 2014.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have 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 and to the deferral 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 and the subset(s) of the paediatric population and condition(s) covered by the waiver 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.

London, 15 August 2014

On behalf of the Paediatric Committee
Dr Dirk Mentzer, 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 (PIP)

1. Waiver

1.1. Condition:

Treatment of schizophrenia

The waiver applies to:

- all subsets of the paediatric population from birth to less than 13 years of age;
- for film-coated tablet for oral use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric Investigation Plan

2.1. Condition:

Treatment of schizophrenia

2.1.1. Indication(s) targeted by the PIP

Treatment of schizophrenia

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 13 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Film-coated tablet

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	3	Study 1: Open-label, multicenter, sequential cohort dose escalation trial to assess the safety, tolerability and pharmacokinetics of oral 7-[4-(4-Benzo[b]thiophen-4-yl)piperazin-1-yl)butoxy]quinolin-2(1H)-one in adolescents with schizophrenia spectrum or psychotic disorder, and with other psychiatric disorders for which antipsychotic treatments are used in specialist child and adolescent psychiatry clinical practice (331-10-233)

		Study 2: Randomised, multicenter, double-blind, placebo- and active-controlled trial to evaluate the efficacy of 7-[4-(4-Benzo[b]thiophen-4-ylpiperazin-1-yl)butoxy]quinolin-2(1H)-one monotherapy as acute and maintenance treatment in adolescents with schizophrenia (331-10-234) Study 3: Open-label, long-term, multicenter trial to evaluate the safety and tolerability of flexible-dose 7-[4-(4-Benzo[b]thiophen-4-ylpiperazin-1-yl)butoxy]quinolin-2(1H)-one as maintenance treatment in adolescents with schizophrenia (331-10-236)
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3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety or efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By December 2022
Deferral for one or more studies contained in the paediatric investigation plan:	Yes