EMA/591053/2014

# European Medicines Agency decision

P/0288/2014

Of 12 December 2014

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for (R)-7-Chloro-benzo[b]thiophene-2-carboxylic acid (1-aza-bicyclo[2.2.2]oct-3-yl)-amide hydrochloride hydrate (EVP-6124) (EMEA-001519-PIP01-13) 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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# European Medicines Agency decision

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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 726/2004[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 FORUM Pharmaceuticals, Inc. on 11 November 2013 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the revised opinion of the Paediatric Committee of the European Medicines Agency, issued on 4 November 2014, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation and Article 13 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 and on the granting of a waiver.

(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.

(4) It is therefore appropriate to adopt a decision granting a waiver.

[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 (R)-7-Chloro-benzo[b]thiophene-2-carboxylic acid (1-aza-bicyclo[2.2.2]oct-3-yl)-amide hydrochloride hydrate (EVP-6124), tablet, 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 deferral for (R)-7-Chloro-benzo[b]thiophene-2-carboxylic acid (1-aza-bicyclo[2.2.2]oct-3-yl)-amide hydrochloride hydrate (EVP-6124), tablet, 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 granted.

***Article 3***

A waiver for (R)-7-Chloro-benzo[b]thiophene-2-carboxylic acid (1-aza-bicyclo[2.2.2]oct-3-yl)-amide hydrochloride hydrate (EVP-6124), tablet, 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 granted.

***Article 4***

This decision is addressed to FORUM Pharmaceuticals, Inc., 500 Arsenal Street, MA 02472 – Watertown, United States.

Done at London, 12 December 2014

For the European Medicines Agency
Zaide Frias
Head of Division (ad interim)
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/403772/2014 Rev

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

EMEA-001519-PIP01-13

## Scope of the application

**Active substance(s):**

(R)-7-Chloro-benzo[b]thiophene-2-carboxylic acid (1-aza-bicyclo[2.2.2]oct-3-yl)-amide hydrochloride hydrate (EVP-6124)

**Condition(s):**

Treatment of schizophrenia

**Pharmaceutical form(s):**

Tablet

**Route(s) of administration:**

Oral use

**Name/corporate name of the PIP applicant:**

FORUM Pharmaceuticals, Inc.

## Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, FORUM Pharmaceuticals, Inc. submitted for agreement to the European Medicines Agency on 11 November 2013 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 18 December 2013.

Supplementary information was provided by the applicant on 19 June 2014. The applicant proposed modifications to the paediatric investigation plan.

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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 said Regulation;
   - to grant a deferral in accordance with Article 21 of said Regulation;
   - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population.

   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 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, 4 November 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:

- the paediatric population from  birth to less than 13 years of age;
- tablet, 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 cognitive impairment associated with schizophrenia (CIAS)

### 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)

Tablet

### 2.1.4. Measures

| Area | Number of measures | Description |
|---|---|---|
| Quality-related studies | 0 | Not applicable. |
| Non-clinical studies | 3 | **Study 1:**<br>Dose range-finding juvenile toxicity study (PC-RPT-0054-6124)<br>**Study 2:**<br>Dose range-finding juvenile toxicity study (PC-RPT-0055-6124)<br>**Study 3:**<br>Definitive juvenile toxicity study (PC-RPT-0053-6124) |

| Area | Number of measures | Description |
|---|---|---|
| Clinical studies | 2 | **Study 4:**<br><br>Randomised, double-blind, placebo-controlled, multiple ascending dose study of EVP-6124 as adjunctive to treatment with an atypical antipsychotic drug, to assess the safety, tolerability and PK of EVP-6124 tablets in adolescents with schizophrenia. (EVP-6124-029)<br><br>**Study 5:**<br><br>Two stage study to evaluate the efficacy and safety of adjunctive EVP-6124 as a pro-cognitive treatment in adolescent schizophrenia patients on chronic, stable, atypical antipsychotic therapy. (EVP-6124-030) |
| Extrapolation, modelling and simulation studies | 0 | Not applicable. |
| Other studies | 0 | Not applicable. |
| Other measures | 0 | Not applicable. |

## 3. Follow-up, completion and deferral of PIP

| | |
|---|---|
| Concerns on potential long term safety/efficacy issues in relation to paediatric use: | No |
| Date of completion of the paediatric investigation plan: | By June 2021 |
| Deferral for one or more measures contained in the paediatric investigation plan: | Yes |