EMA/591835/2019

European Medicines Agency decision

P/0391/2019

of 4 December 2019

on the acceptance of a modification of an agreed paediatric investigation plan for rubidium (82Rb) chloride (Ruby-Fill (82Sr/82Rb Generator)), (EMEA-000882-PIP03-11-M04) 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 726/2004[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 European Medicines Agency's decision P/0059/2012 issued on 26 March 2012, decision P/0048/2014 issued on 8 March 2014 and the decision P/0144/2017 issued on 7 June 2017,

Having regard to the application submitted by Jubilant DraxImage Inc. on 29 May 2019 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 18 October 2019, 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 rubidium (82Rb) chloride (Ruby-Fill (82Sr/82Rb Generator)), radionuclide generator, intravenous 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 Jubilant DraxImage Inc., 16751 Trans-Canada Highway, H9H 4J4 – Kirkland, Canada.

EMA/PDCO/416427/2019
Amsterdam, 18 October 2019

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

EMEA-000882-PIP03-11-M04

Scope of the application

Active substance(s):

Rubidium (82Rb) chloride

Invented name:

Ruby-Fill (82Sr/82Rb Generator)

Condition(s):

Visualisation of myocardial perfusion for diagnostic purposes

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Radionuclide generator

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Jubilant DraxImage Inc.

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Jubilant DraxImage Inc. submitted to the European Medicines Agency on 29 May 2019 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/0059/2012 issued on 26 March 2012, decision P/0048/2014 issued on 8 March 2014 and the decision P/0144/2017 issued on 7 June 2017.

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

The procedure started on 20 August 2019.

Scope of the modification

Some 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 annexes and appendix.

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:

Visualisation of myocardial perfusion for diagnostic purposes

The waiver applies to:

- preterm and term neonates (from birth to less than 28 days of age);
- radionuclide generator, intravenous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan

2.1. Condition:

Visualisation of myocardial perfusion for diagnostic purposes

2.1.1. Indication(s) targeted by the PIP

Assessment of myocardial perfusion abnormalities

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

From 1 month to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Radionuclide generator

2.1.4. Studies

Area	**Number of studies**	**Description**
Quality	0	Not applicable
Non-clinical	0	Not applicable
Clinical	1	**Study 1** Open-label, single centre, uncontrolled dosimetry, safety and tolerability trial of Rubidium (Rb82) chloride administered intravenously as contrast media for Positron Emission Tomography (PET) in paediatric patients from 1 month to less than 18 years of age at high risk of myocardial ischemia

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By August 2021
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Visualisation of myocardial perfusion for diagnostic purposes

Authorised indication(s):

- Rubidium (82RbCl) chloride injection is used with positron emission tomography (PET) for the assessment of myocardial perfusion and is indicated for the detection and localization of coronary artery disease in adult patients with known or suspected coronary artery disease.

Authorised pharmaceutical form(s):

Radionuclide generator

Authorised route(s) of administration:

Intravenous use