MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan and to the deferral

MHRA-100562-PIP01-22

Scope of the Application

Active Substance(s)

strontium-82 chloride/ rubidium-82 chloride

Condition(s)

Visualisation of myocardial perfusion for diagnostic purposes

Pharmaceutical Form(s)

Radionuclide generator

Route(s) of Administration

INTRAVENOUS USE

Name / Corporate name of the PIP applicant

Jubilant DraxImage Inc.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Jubilant DraxImage Inc. submitted to the licensing authority on 10/03/2023 17:43 GMT an application for a Paediatric Investigation Plan

The procedure started on 16/10/2023 17:14 BST

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to agree a paediatric investigation plan and grant a deferral

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-100562-PIP01-22

Of 13/02/2024 08:26 GMT

On the adopted decision for strontium-82 chloride/ rubidium-82 chloride (MHRA-100562-PIP01-22) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Paediatric Investigation Plan for strontium-82 chloride/ rubidium-82 chloride , Radionuclide generator , INTRAVENOUS USE .

This decision is addressed to Jubilant DraxImage Inc., 16751 TransCanada Hwy, Kirkland, CANADA, H9H4J4

ANNEX I

1. Waiver

1.1 Condition:

Visualisation of myocardial perfusion for diagnostic purposes The waiver applies / applied to: Paediatric Subset(s): Preterm and term newborn infants (from birth to less than 28 days) Pharmaceutical form(s): Radionuclide generator Route(s) of administration: INTRAVENOUS USE Reason for granting waiver: 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(s):

Visualisation of myocardial perfusion for diagnostic purposes

2.2 Indication(s) targeted by the PIP:

Assessment of myocardial perfusion abnormalities

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from 1 month to less than 18 years of age

2.4 Pharmaceutical Form(s):

Radionuclide generator

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	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.
Extrapolation, Modeling & Simulation Studies	0	Not applicable.
Other Studies	0	Not applicable.
Other Measures	0	Not applicable.

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	31/08/2022
Deferral of one or more studies contained in the paediatric investigation plan:	Yes