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 grant a product specific waiver

MHRA-100632-PIP01-22-M01

Scope of the Application

Active Substance(s)

FLUCICLOVINE (18F)

Condition(s)

Diagnosis of amino acid metabolism in solid malignant tumours

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

INTRAVENOUS USE

Name / Corporate name of the PIP applicant

Blue Earth Diagnostics Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Blue Earth Diagnostics Ltd submitted to the licensing authority on 27/07/2022 14:39 BST an application for a Modification

The procedure started on 23/01/2023 08:02 GMT

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 accept change(s) to the agreed paediatric investigation plan and to grant a product specific waiver

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-100632-PIP01-22-M01

Of 13/02/2023 15:23 GMT

On the adopted decision for FLUCICLOVINE (18F) (MHRA-100632-PIP01-22-M01) 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 Modification for FLUCICLOVINE (18F), Solution for injection , INTRAVENOUS USE .

This decision is addressed to Blue Earth Diagnostics Ltd, The Oxford Science Park, Magdalen Centre, Robert Robinson Avenue, Oxford, UNITED KINGDOM, OX4 4GA

ANNEX I

1. Waiver

1.1 Condition:

Diagnosis of amino acid metabolism in solid malignant tumours The waiver applies / applied to: Paediatric Subset(s): All subsets of the paediatric population from birth to less than 18 years of age Pharmaceutical form(s): Solution for injection 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 as the needs are already covered.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Not applicable

2.2 Indication(s) targeted by the PIP:

Not applicable

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

Not applicable

2.4 Pharmaceutical Form(s):

Not applicable

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable
Non-Clinical Studies	0	Not applicable
Clinical Studies	0	Not applicable
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:	Not applicable
Date of completion of the paediatric investigation plan:	
Deferral of one or more studies contained in the paediatric investigation plan:	Not applicable