

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

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## **Decision Cover Letter**

### **Decision of the licensing authority to:**

grant a product specific waiver

MHRA-100950-PIP01-23

### **Scope of the Application**

#### **Active Substance(s)**

lutetium-177 (177Lu) rhPSMA 10.1

#### **Condition(s)**

Treatment of prostate cancer

#### **Pharmaceutical Form(s)**

All pharmaceutical forms

#### **Route(s) of Administration**

All routes of administration

#### **Name / Corporate name of the PIP applicant**

Blue Earth Therapeutics Ltd

#### **Basis for the Decision**

Pursuant to the Human Medicines Regulations 2012, Blue Earth Therapeutics Ltd submitted to the licensing authority on 26/05/2023 16:36 BST an application for a Paediatric Investigation Plan

The procedure started on 10/10/2023 09:27 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 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-100950-PIP01-23

Of 27/11/2023 19:18 GMT

On the adopted decision for lutetium-177 (177Lu) rhPSMA 10.1 (MHRA-100950-PIP01-23) in accordance with the Human Medicines Regulations 2012.

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

Granting a waiver in all age groups for the listed condition(s)

This decision applies to a Paediatric Investigation Plan for lutetium-177 (177Lu) rhPSMA 10.1, All pharmaceutical forms , All routes of administration .

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

## ANNEX I

### 1. Waiver

#### 1.1 Condition:

Treatment of prostate cancer 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): All pharmaceutical forms Route(s) of administration: All routes of administration Reason for granting waiver: 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(s):

Not Applicable

**2.2 Indication(s) targeted by the PIP:**

Not Applicable
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**2.3 Subset(s) of the paediatric population concerned by the paediatric development:**

Not Applicable
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**2.4 Pharmaceutical Form(s):**

Not Applicable
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**2.5 Studies:**

<b>Study Type</b>	<b>Number of Studies</b>	<b>Study Description</b>
<b>Quality Measures</b>	0	Not Applicable
<b>Non-Clinical Studies</b>	0	Not Applicable
<b>Clinical Studies</b>	0	Not Applicable
<b>Extrapolation, Modeling &amp; Simulation Studies</b>	0	Not Applicable
<b>Other Studies</b>	0	Not Applicable
<b>Other Measures</b>	0	Not Applicable

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

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