# Phase I trial, BDD code: BDD21288

| Submission date   | Recruitment status   | Prospectively registered                      |
|-------------------|----------------------|---|
| 20/12/2023        | No longer recruiting | Protocol                                      |
| Registration date | Overall study status | Statistical analysis plan                     |
| 21/12/2023        | Deferred             | Results                                       |
| Last Edited       | Condition category   | Individual participant data                   |
| 21/12/2023        | Other                | <ul><li>Record updated in last year</li></ul> |

### Plain English summary of protocol

The sponsor has confirmed that the trial meets the criteria for deferral of publication of the full details of the trial. The full details will be added to the study record within 12 months after the trial has ended.

### Contact information

### Type(s)

Public, Scientific, Principal investigator

#### Contact name

Dr Lyn Corry

#### **ORCID ID**

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#### Contact details

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### Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

1007309

### ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

IRAS 1007309

# Study information

#### Scientific Title

Phase I trial, BDD code: BDD21288

### Study objectives

The Sponsor has confirmed that the trial meets the criteria for deferral of publication of the full details of the trial. The full details will be added to the study record within 12 months after the trial has ended.

### Ethics approval required

Ethics approval required

### Ethics approval(s)

approved 27/09/2023, London - Westminster Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8066; westminster.rec@hra.nhs.uk), ref: 23/LO/0126

### Study design

Pharmacoscintigraphic open-label crossover study

### Primary study design

Interventional

### Study type(s)

Other

### Health condition(s) or problem(s) studied

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#### **Interventions**

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#### Intervention Type

Drug

#### Phase

Phase I

### Drug/device/biological/vaccine name(s)

The sponsor has confirmed that the trial meets the criteria for deferral of publication of the full details of the trial. The full details will be added to the study record within 12 months after the trial has ended.

### Primary outcome(s)

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### Key secondary outcome(s))

The sponsor has confirmed that the trial meets the criteria for deferral of publication of the full details of the trial. The full details will be added to the study record within 12 months after the trial has ended.

### Completion date

07/12/2023

## Eligibility

### Key inclusion criteria

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### Participant type(s)

Healthy volunteer

### Healthy volunteers allowed

No

### Age group

Adult

### Lower age limit

18 years

### Upper age limit

60 years

#### Sex

Male

#### Total final enrolment

12

#### Key exclusion criteria

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### Date of first enrolment

30/10/2023

#### Date of final enrolment

23/11/2023

### Locations

#### Countries of recruitment

**United Kingdom** 

Scotland

# Study participating centre BDD Pharma Ltd

Glasgow Royal Infirmary 84 Castle Street Glasgow United Kingdom G4 0SF

# Sponsor information

### Organisation

BDD Pharma Ltd

# Funder(s)

### Funder type

Hospital/treatment centre

#### **Funder Name**

Cincinnati Children's Hospital Medical Center

#### Alternative Name(s)

Cincinnati Children's, Hospital Pediátrico y Centro Médico de Cincinnati, CCHMC

### **Funding Body Type**

Government organisation

### **Funding Body Subtype**

Other non-profit organizations

### Location

United States of America

## **Results and Publications**

### Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

### IPD sharing plan summary

Data sharing statement to be made available at a later date