ISRCTN97337444 https://doi.org/10.1186/ISRCTN97337444

Phase I study of PM534 to patients with advanced solid tumors

Submission date	Recruitment status	[_] Prospectively registered
14/05/2026	Recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/05/2026	Deferred	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
20/05/2026	Other	[X] Record updated in last year

Plain English summary of protocol
The Health Research Authority has approved a deferral. Full details will be added to the trial record on or before the deferral expiry date

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Additional identifiers

Clinical Trials Information System (CTIS)
2024-519013-57-00

Integrated Research Application System (IRAS)
1011534

Protocol number
PM534-A-002-24

Study information

Scientific Title
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Acronym
PM534A2

Study objectives
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Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 22/10/2025, East of England - Cambridgeshire and Hertfordshire (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 020 7104 8096; cambsandherts.rec@hra.nhs.uk), ref: 25/EE/0192

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
To identify the dose-limiting toxicities (DLTs), and to determine the maximum tolerated dose (MTD) and the recommended dose (RD) and to evaluate the antitumor activity in solid tumors

Study type(s)

Health condition(s) or problem(s) studied
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Interventions
The Health Research Authority has approved a deferral. Full details will be added to the trial record on or before the deferral expiry date.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
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Primary outcome(s)
1. [Outcome name] measured using [Metric or method of measurement] at [Timepoint(s)]

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Key secondary outcome(s)

Completion date
08/08/2028

Eligibility

Key inclusion criteria
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Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
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Date of first enrolment
10/04/2026

Date of final enrolment
30/07/2027

Locations

Countries of recruitment
United Kingdom

England

Spain

Study participating centre
University College London Hospitals NHS Foundation Trust
250 Euston Road

London
England
NW1 2PG

Sponsor information

Organisation
PharmaMar (Spain)

ROR
https://ror.org/02h694m69

Funder(s)

Funder type

Funder Name
PharmaMar

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Spain

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available