ISRCTN14340698 https://doi.org/10.1186/ISRCTN14340698

Phase I trial: Labcorp Drug Development Study: 8479217

Submission date 28/09/2022	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 14/10/2022	**Overall study status** Deferred	[_] Statistical analysis plan [_] Results
Last Edited 14/10/2022	**Condition category** Other	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

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Additional identifiers

EudraCT/CTIS number
202100563124

IRAS number
1004924

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 1004924, Labcorp Drug Development Study 8479217

Study information

Scientific Title
Phase I trial: Labcorp Drug Development Study: 8479217 [The full scientific title will be published within 30 months after the end of the trial]

Study objectives
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Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 06/07/2022, MHRA and HRA Fast track REC (10 South Colonnade, Canary Wharf, London, E14 4PU, UK; +44 (0)207 104 8012; fasttrack.rec@hra.nhs.uk), ref: CTA 42371/0009/001-0001, REC ref: 22/FT/0036

The HRA has approved deferral of publication of trial details.

Study design
A mass balance study and metabolic profile investigation

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format

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 Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

Primary outcome measure
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Secondary outcome measures

The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

Overall study start date
16/05/2022

Completion date
16/09/2022

Eligibility

Key inclusion criteria
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Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
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Key exclusion criteria
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Date of first enrolment
02/08/2022

Date of final enrolment
16/09/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Labcorp Clinical Research Unit Limited
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Sponsor information

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Bergenbio ASA

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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Bergenbio ASA

Results and Publications

Publication and dissemination plan
Publication of some trial details is deferred because of the high commercial sensitivity of this phase I study and the negligible benefit to the public of phase I information. Results will be posted on or after the date of publication of full trial details.

Intention to publish date
16/03/2025

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study are not expected to be made available because of their high commercial sensitivity and the negligible benefit to the public of publication of results of non therapeutic clinical trials.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No