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 [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 14/10/2022	**Overall study status** Deferred	
Last Edited 14/10/2022	**Condition category** Other	

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.

Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
202100563124

Integrated Research Application System (IRAS)
1004924

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

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)
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Primary outcome(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.

Key secondary outcome(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.

Completion date
16/09/2022

Eligibility

Key inclusion criteria
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Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre
Labcorp Clinical Research Unit Limited
Springfield House
Hyde Street
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LS2 9LH

Sponsor information

Organisation
Bergenbio ASA

Funder(s)

Funder type
Industry

Funder Name
Bergenbio ASA

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes