

Phase I trial code: PKM17308

Submission date 15/11/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 17/11/2023	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 17/11/2023	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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.

Contact information

Type(s)

Principal investigator

Contact name

Dr Litza Marie McKenzie

Contact details

Mere Way, Ruddington
Nottingham
United Kingdom
NG11 6JS
+44 (0)115 974 9000
litza.mckenzie@quotientsciences.com

Type(s)

Public, Scientific

Contact name

Dr Study Director Clinical Sciences & Operations Sanofi

Contact details

1 Avenue Pierre Brossolette
Chilly-Mazarin
France
91380
None provided
uk-medicalinformation@sanofi.com

Additional identifiers

Integrated Research Application System (IRAS)

1005387

Study information

Scientific Title

Phase I trial code: PKM17308

Study objectives

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Ethics approval required

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Ethics approval(s)

approved 10/06/2022, North West - Greater Manchester Central Research Ethics Committee (3rd Floor Barlow House 4 Minshull Street, Manchester, LM1 3DZ, United Kingdom; +44 (0)207 104 8244, (0)207 104 8004; gmcentral.rec@hra.nhs.uk), ref: 22/NW/0258

Study design

Pharmacokinetics (PK) study in 12 healthy participants

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Healthy volunteers

Interventions

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Intervention Type

Drug

Phase

Phase I

Drug/device/biological/vaccine name(s)

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Primary outcome(s)

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Key secondary outcome(s)

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Completion date

15/06/2023

Eligibility

Key inclusion criteria

Healthy human volunteer

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

All

Key exclusion criteria

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Date of first enrolment

24/04/2023

Date of final enrolment

15/06/2023

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Quotient Sciences - Nottingham

Mere Way, Ruddington

Nottingham

United Kingdom

NG11 6JS

Sponsor information

Organisation

Sanofi-Aventis Recherche & Développement

Funder(s)

Funder type

Industry

Funder Name

Sanofi-Aventis Recherche & Développement

Results and Publications

Individual participant data (IPD) sharing plan

Qualified researchers may request access to patient level data and related study documents including the clinical study report, study protocol with any amendments, blank case report form, statistical analysis plan, and dataset specifications. Patient level data will be anonymized and study documents will be redacted to protect the privacy of trial participants. Further details on Sanofi's data sharing criteria, eligible studies, and process for requesting access can be found at: <https://vivli.org>

IPD sharing plan summary

Not expected to be made available