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A long-term study testing the safety and effects of a new yearly antiviral treatment (CD388) in healthy people

Submission date
03/10/2025

Recruitment status
Recruiting

Registration date
21/11/2025

Overall study status
Ongoing

Last Edited
21/11/2025

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
In this study, participants who were previously enrolled in Study CD388.SQ.2.05 and received a single dose of CD388, will receive two annual doses of CD388 450mg. for 2 years. The study will enrol generally healthy participants without disease. The minimum age for participation for males or females is 18 years old and maximum age is 66 years old. The study will be carried out in the US and UK. The total target participants across both countries is 400. The maximum duration for each participant will be 18 months (± 2 months). Participants will be required to attend 1 screening visit and then will attend day 1 which is the treatment visit, at the study site. Participants will be observed for at least 30 minutes before discharge. The first follow-up period includes study site visits on day 8, 29, 85, 169, 197 and 280. The second follow-up period includes study site visits on day 8, 29, 85, 169 and 197.

Injection site pain, injection site swelling, injection site redness, muscle pain, joint pain, headache, fatigue (tiredness), chills, fever, diarrhoea.
Participants may experience an allergic reaction to the study drug even though this has not been seen in the previous study.
Symptoms of an allergic reaction may include the following; headache, rash, flushing, swelling, shortness of breath, nausea, and vomiting. Participants will be closely monitored for any side effects.
Blood drawing may cause pain/tenderness, bruising, bleeding, light-headedness, dizziness, fainting and, rarely, infection or nerve damage. Procedures will be in place to avoid injury. Blood tests may indicate that a participant has an infection or illness. The hVIVO doctor will provide a referral letter to the participants' GP with consent.

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Integrated Research Application System (IRAS)
1012942

Protocol serial number
CD388.SQ.2.07

Study information

Scientific Title

A phase 2, open-label, long-term study to evaluate the safety, pharmacokinetics, and occurrence of anti-drug antibodies in healthy participants following annual doses of CD388, a novel long-acting antiviral conjugate

Study objectives
1. To evaluate the occurrence of anti-drug antibodies (ADA) directed to CD388 during an 18-month period including administration of 2 annual doses of CD388
2. To evaluate the safety and tolerability of CD388
3. To evaluate the pharmacokinetics (PK) of CD388 in plasma following second and third doses of CD388 in participants who have previously received single CD388 doses of 150 mg, 300 mg, or 450 mg
4. To evaluate the PK/anti-CD388 antibody relationships for participants who have previously received single CD388 doses of 150 mg, 300 mg, or 450 mg

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 13/11/2025, South Central- Hampshire B Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8088; hampshireb.rec@hra.nhs.uk), ref: 25/SC/0349

Study design
Interventional non randomized

Primary study design
Interventional

Study type(s)
Safety

Health condition(s) or problem(s) studied
Influenza infection

Interventions
Participants identification codes will be assigned at screening. All participants will receive open-label CD388 450mg. Participants will receive investigational study intervention as 3 separate injections directly from the Investigator or designee. The dose of investigational study intervention and participant identification will be confirmed at the time of dosing by a member of the study site staff.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
CD388

Primary outcome(s)
Blood sample assessment will be taken via venepuncture at predose and 4,12,24 and 28 weeks following each annual dose to evaluate the treatment – emergent ADA and treatment-boosted ADA

Key secondary outcome(s))
1. Safety and tolerability, as assessed by adverse events (AEs), injection site reactions (ISRs), vital signs, and clinical laboratory parameters.
2. Plasma PK parameters of CD388 (eg, plasma concentrations at pre-dose, 8 days, and 4, 12, 24, and 28 weeks following each annual dose; trough plasma concentration at 24 weeks [Ctrough24w], maximum plasma concentration [Cmax], and area under the plasma concentration-time curve [AUC])
3. Plasma concentration-time data or PK parameter of CD388 and titer of anti-CD388 antibody, when present

Completion date
06/08/2027

Eligibility

Key inclusion criteria
1. Be willing and able to provide written informed consent and comply with scheduled visits, laboratory tests, and other study procedures.
2. Be a male or female adult aged 18 to 66 years of age who previously completed participation in Study CD388.SQ.2.05, having received a SQ CD388 dose of either 150 mg, 300 mg or 450 mg. (Note: Participants in this study may have received seasonal influenza vaccine prior to enrolment in this study and may receive influenza vaccine during this study, with certain exceptions)
3. Be in stable health at the time of screening and enrollment (in the Investigator's clinical judgment). Participants may not have a history of underlying hematologic, oncologic, renal, autoimmune, cardiac, or pulmonary conditions; or be considered at risk of developing complications from influenza infection per the CDC guidelines (chronic obstructive pulmonary disease [COPD], asthma, current immune-compromised cancer [except non-melanomatous skin cancer], or diabetes). Study participants will be included based on medical history and vital signs obtained during the screening process.
4. Have a body mass index (BMI) of ≥ 18.0 kg/m².
5. Must agree to the contraception requirements.
6. Must agree not to donate blood from Day 1 until 40 weeks after each administration of CD388.
7. Must be able to read, understand, and complete protocol questionnaires using the Sponsor-designated diary mode (eDiary or paper) and language, and be willing and able to adhere to the prohibitions and restrictions specified in this protocol. If eDiary is designated, the participant must be able to use a smartphone/tablet/computer. If an appropriate language version is not available in either eDiary or paper, the participant must not be enrolled. The diary mode and approved languages will be designated by the Sponsor prior to study start.
8. Must be willing to provide verifiable identification, has means to be contacted, and is able to contact the Investigator/study site and communicate reliably during participation in this study.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 years

Upper age limit
66 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Have a known or suspected allergy or history of anaphylaxis or other SAEs to zanamivir (following administration of inhaled or intravenous formulations), monoclonal antibodies (including Fc domains), or any of the components of CD388.
2. Have an acute illness (including acute respiratory illnesses) or body temperature ≥ 38.0 °C (≥ 100.4 °F) within 7 days prior to each administration of CD388. (Note: Enrollment and/or receipt of study intervention at a later date, subsequent to resolution of the illness [within the screening period], is permitted.)
3. Have a serious and/or clinically unstable condition, including but not limited to, a psychiatric condition including recent (within the past year) or active suicidal ideation/behavior, Alzheimer's disease, or any other condition which in the opinion of the Investigator might lead to hospitalization or death within this study period and for which enrollment would not be in the participant's best interest, or could prevent, confound, or limit the protocol-specified assessments.
4. Have any history of alcohol or substance abuse which in the opinion of the investigator might interfere with conduct of this study as planned.
5. Had major surgery (eg, cardiac, pulmonary, neurologic, or abdominal operations) within 4 weeks prior to screening, or will not have fully recovered from such prior surgery; or has major surgery planned during the time the participant is expected to participate in this study.
6. Had screening electrocardiogram (ECG) findings of prolonged QTcF interval (> 450 msec in males or > 470 msec in females), prolonged PR interval (> 220 msec), second- or third-degree heart block, or other clinically significant dysrhythmia.
7. Have any finding (at the time of screening) that may significantly increase the risk of participation in this study, affect the ability to participate in this study, or impair interpretation of the study data.
8. Have current or planned participation in another clinical study where study intervention is being administered while participating in this current study.
Note: Concurrent enrollment is allowed during the follow-up phase of the other clinical study or in case the study intervention in the other clinical study is a marketed product already approved for another indication – exception being if the other study requires study interventions that could affect the safety assessments of this present study (eg, clinical laboratory tests).
9. Have received any experimental drug, vaccine, or biologic agent within the past 90 days or 5 half-lives (whichever is longer) prior to study intervention administration.
10. Have a contraindication to SQ injections and venipunctures (eg, bleeding disorders).
11. Have donated ≥ 450 mL of blood product (1 unit) for any reason within 30 days of screening

or have plans to donate blood product during this study.
12. Are currently pregnant or breastfeeding, intends to become pregnant or breastfeed, or has a positive pregnancy test during the screening period.
13. Has direct involvement in this proposed study or other studies under the direction of the Investigator, sub-investigators, or study site personnel; is a family member of an individual with such direct involvement; or is an employee of the Sponsor.
14. Did not complete participation in protocol CD388.SQ.2.05, or experienced an SAE during that study, or was enrolled in CD388.SQ.2.05 despite not meeting that study's eligibility (one or more Inclusion Criteria not met or one or more Exclusion Criteria met), as determined on retrospective review, irrespective of completion status.
15. In the opinion of the Investigator, is unlikely to adhere to the requirements of this study.

Date of first enrolment
01/11/2025

Date of final enrolment
06/08/2027

Locations

Countries of recruitment
United Kingdom

Study participating centre
hVIVO Services Limited
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Sponsor information

Organisation
hVIVO Limited Services

Funder(s)

Funder type
Industry

Funder Name
Cidara Therapeutics, Inc.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date