Clinical Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of HT31-1 for Treating ARDS

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 65 years old

This study is also accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

Participants must meet all of the following criteria: 1. Age 18 to 65 years old, inclusive, at the time of consent. 2. Able and willing to provide written informed consent and to comply with all study procedures and requirements. 3. Healthy as determined by medical history, physical examination, and baseline investigations. No clinically significant abnormalities on physical exam. 4. Body Mass Index (BMI) between 18.0 and 32.0 kg/m², inclusive. 5. Vital signs and 12-lead ECG without clinically significant abnormalities, in the investigator's judgment, at screening (e.g., resting blood pressure and heart rate within normal limits). 6. Screening clinical laboratory tests (hematology, chemistry, liver and kidney function, etc.) within normal ranges or not clinically significant as judged by the investigator. 7. Female volunteers must be of non-childbearing potential (either surgically sterile by tubal ligation, bilateral oophorectomy or hysterectomy at least 6 months prior, or postmenopausal for ≥1 year) OR if of childbearing potential must agree to use 2 approved effective contraceptions from screening through at least 90 days after the last dose. Acceptable methods include hormonal contraception, intrauterine device, or barrier methods with spermicide. 8. Male volunteers with partners of childbearing potential must agree to use 2 approved effective contraception (e.g., condom plus spermicide) from screening through 90 days after their dose of study drug. 9. Able to communicate well with the investigator and comply with study requirements (e.g., availability for all follow-up visits).

Exclusion Criteria:

Participants will be excluded if they meet any of the following criteria: 1. History of any severe allergy or hypersensitivity to drugs, or known hypersensitivity to any monoclonal antibody (including prior biologic therapy reactions). 2. Known autoimmune disease or immunodeficiency condition, including a positive test for HIV at screening. 3. Active or chronic viral hepatitis infection: positive screening test for hepatitis B surface antigen (HBsAg) or hepatitis C antibody. 4. History of tetanus infection, or receipt of tetanus toxoid vaccine within 6 months prior to first dose of study drug. (Rationale: CitH3 is associated with NETs, and recent tetanus immunization may confound immune status or antibody responses). 5. Receipt of any live attenuated vaccine within 4 weeks prior to first dose, or any inactivated vaccine within 2 weeks prior to first dose. (This is to avoid confounding immune activation or risk to the volunteer's health). 6. History of any significant acute or chronic illness that, in the investigator's opinion, could interfere with the trial or pose additional risk in administering the investigational drug. Examples include significant cardiovascular, hepatic, renal, gastrointestinal, hematologic, neurologic, psychiatric, or respiratory conditions that are not well-controlled. 7. Recent major surgery (within 3 months prior to screening) or planned elective surgery during the study period. (Minor outpatient procedures are allowed at the investigator's discretion.) 8. Difficulty with venous access or an inability to tolerate blood draws, such that required PK sampling would be compromised. 9. History of drug or alcohol abuse: positive urine drug screen at screening for illicit substances, or a history of significant drug abuse in the past 5 years. Regular use of cannabis is also exclusionary unless stopped prior to study. 10. Positive screening alcohol breath test, or history of excessive alcohol intake (more than \~14 units per week; 1 unit = 360 mL beer, 150 mL wine, or 45 mL of 40% spirit) within 6 months. Any indication of alcoholism or inability to refrain from alcohol during study participation. 11. Use of any prescription or over-the-counter medications, herbal remedies, or supplements within 14 days prior to first dose, except hormonal contraceptives or occasional acetaminophen. (Any necessary medications may be reviewed by the investigator for approval if unlikely to interfere with study outcomes). 12. Participation in another clinical trial of an investigational drug or device within 4 weeks (or 5 half-lives of that investigational product, whichever is longer) prior to dosing. 13. Donation of \>400 mL of blood (or significant blood loss of similar volume) within 3 months prior to screening, or donation of \>200 mL within 1 month prior. (This is to avoid anemia or confounding volume loss). 14. Receipt of any blood products or immunoglobulin therapy within 90 days before dosing. 15. Chronic use of immunosuppressive medications (systemic corticosteroids, immunomodulators) within 45 days before dosing (inhaled/topical steroids for mild conditions may be permitted). 16. Regular use of nicotine products (smoking more than 5 cigarettes per day or equivalent) within 3 months prior to screening, or inability to refrain from tobacco/nicotine during the study. 17. Pregnant or breastfeeding women. (Female volunteers must have a negative pregnancy test and not be nursing.) 18. Any other condition that, in the opinion of the investigator, makes the volunteer unsuitable for study participation (e.g. inability to comply with protocol, or any factor that would jeopardize the volunteer's safety or the validity of the data).

Conditions & Interventions

Interventions:
DRUG: HT31-1, OTHER: Saline (0.9%, sterile, for infusion)
Conditions:
ARDS (Acute Respiratory Distress Syndrome)
Keywords:
Acute Respiratory Distress Syndrome (ARDS), Single Ascending Dose, Monoclonal Antibody

More Information

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