Study to Evaluate the Efficacy and Safety of Camidanlumab Tesirine (ADCT-301) in Patients With Relapsed or Refractory Hodgkin Lymphoma

Status: Recruiting
System ID: NCT04052997
Sex: All
Age: 16 Years and over
Healthy Volunteers: This study is NOT accepting healthy volunteers
Contact(s): sfinder@umn.edu
Phase: Phase 2
IRB Number:

Conditions & Interventions

Interventions:
Drug: Camidanlumab Tesirine

Conditions:
Relapsed Hodgkin Lymphoma, Refractory Hodgkin Lymphoma

Keywords:
Camidanlumab Tesirine, Relapsed or Refractory Hodkgins Lymphoma, Classical Hodkgins Lymphoma, Lymphoma

Eligibility Criteria

Inclusion Criteria:
1. Written informed consent must be obtained prior to any procedures. 2. Male or female participant aged 18 years or older. (16 years or older at US based sites) 3. Pathologic diagnosis of classical Hodkgin lymphoma (cHL). 4. Patients with relapsed or cHL, who have received at least 3 prior lines of systemic therapy (or at least 2 prior lines in HSCT ineligible patients) including Brentuximab vedotin and a checkpoint inhibitor approved for cHL (e.g., nivolumab or pembrolizumab). Note 1: Receipt of HSCT to be included in the number of prior therapies needed to meet eligibility. 5. Measurable disease as defined by the 2014 Lugano Classification. 6. Availability of formalin-fixed paraffin-embedded (FFPE) tumor tissue block (or minimum 10 freshly cut unstained slides if block is not available). Note 1: Any biopsy since initial diagnosis is acceptable, but if several samples are available, the most recent sample is preferred. Note 2: If a sufficient amount of tissue is not available, a fresh biopsy may be taken, provided the procedure is not deemed high-risk and is clinically feasible, and provided it is approved locally. 7. Eastern Cooperative Oncology Group (ECOG) performance status 0-2. 8. Adequate organ function as defined by Screening laboratory values within the following parameters: 1. Absolute neutrophil count (ANC) ≥ 1.0 × 10^3/μL (off growth factors at least 72 hours). Note 1: Patients known to be or having been infected with human immunodeficiency (HIV) virus, hepatitis B virus (HBV), or hepatitis C virus (HCV) and must be negative before initiating study treatment. 9. History of neuropathy considered of autoimmune origin (e.g., polyradiculopathy including mild [≤ Grade 1] chronic GVHD). 10. Participants known with known Graft-versus-host disease may have a total bilirubin up to 1.5 × ULN with direct bilirubin ≤ 1.5 × ULN. 5. Blood creatinine ≤ 3.0 × ULN or calculated creatinine clearance ≥ 30 mL/min by the Cockcroft-Gault equation. Note: A laboratory assessment may be repeated a maximum of two times during the Screening Period to confirm eligibility. 6. Post-transplantation lymphoproliferative disorders. 7. Absolute primary malignancy other than non-melanoma skin cancers, non-metastatic prostate cancer, in situ cervical cancer, ductal or lobular carcinoma in situ of the breast, or other malignancy that the Sponsor’s medical monitor and Investigator agree and document should not be exclusionary. 8. History of symptomatic autoimmune disease (e.g., rheumatoid arthritis, systemic progressive sclerosis [scleroderma], systemic lupus erythematosus, Sjögren’s syndrome, autoimmune vasculitis [e.g., Wegener’s granulomatosis]) or other central nervous system autoimmune disease (e.g., polymyositis, multiple sclerosis). 10. History of recent infection (within 4 weeks of Cycle 1, Day 1 [C1D1]) considered to be caused by one of the following pathogens: HSV1, HSV2, VZV, EBV, CMV, measles, Influenza A, Zika virus, Chikungunya virus, mycoplasma pneumonia, Campylobacter jejuni, or enterovirus D68, or severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Note: An influenza test and a pathogen-directed SARS CoV-2 test (such as polymerase chain reaction) are mandatory and must be negative before initiating study treatment (tests to be performed 3 days or less prior to dosing on C1D1; an additional 2 days are allowed in the event of logistical issues for receiving the results on time). 11. Participants known to be or having been infected with human immunodeficiency (HIV) virus, hepatitis B virus (HBV), or hepatitis C virus (HCV), and require anti-viral therapy or prophylaxis. Note: Serology testing is mandatory for patients with unknown status. 12. History of Stevens-Johnson syndrome or toxic epidermal necrolysis. 13. Failure to recover ≤ Grade 1 (Common Terminology Criteria for Adverse Events version 4.0 [CTCAE v4.0]) from acute non-hematologic toxicity (except ≤ Grade 2 neuropathy or alopecia), due to previous therapy, prior to screening. 14. Hodgkin lymphoma (HL) with central nervous system involvement, including leptomeningeal disease. 15. Clinically significant third space fluid accumulation (i.e., ascites requiring drainage or pleural effusion that is either requiring drainage or associated with shortness of breath). 16. Breastfeeding or pregnant. 17. Significant medical comorbidities, including uncontrolled hypertension (blood pressure [BP] ≥ 160/100 mmHg), unstable angina, congestive heart failure (greater than New York Heart Association class II), electrocardiographic evidence of acute ischemia, coronary angioplasty or myocardial infarction within 3 months prior to screening, severe uncontrolled atrial or ventricular cardiac arrhythmia, poorly controlled diabetes, or severe chronic pulmonary disease. 18. Major surgery, radiotherapy, chemotherapy, or other antineoplastic therapy, within 14 days prior to start of study drug, except shorter if approved by the Sponsor. 19. Use of any other experimental medication within 30 days prior to start of study drug. 20. Any live vaccine within 4 weeks prior to start of study drug and planned live vaccine administration after starting study drug. 21. Congenital long QT (measure between Q wave and T wave in the electrocardiogram) syndrome, or a corrected QTc interval of ≤ 480 ms, at screening (unless secondary to pacemaker or bundle branch block). 22. Any other significant medical illness, abnormality, or condition that would, in the Investigator’s judgment, make the participants inappropriate for study participation or put the participant at risk.

Exclusion Criteria:
1. Previous treatment with Camidanlumab Tesirine. 2. Participation in another investigational interventional study. Being in follow-up of another investigational study is allowed. 3. Known history of hypersensitivity to or positive serum human anti-drug antibody (ADA) to a CD25 antibody. 4. Allergic or autologous transplant within 60 days prior to start of study drug. 5. Active graft-versus-host disease (GVHD), except for non-neurologic symptoms as a manifestation of mild [≤ Grade 1] chronic GVHD. 6. Post-transplantation lymphoproliferative disorders. 7. Active second primary malignancy other than non-melanoma skin cancers, non-metastatic prostate cancer, in situ cervical cancer, ductal or lobular carcinoma in situ of the breast, or other malignancy that the Sponsor’s medical monitor and Investigator agree and document should not be exclusionary. 8. History of symptomatic autoimmune disease (e.g., rheumatoid arthritis, systemic progressive sclerosis [scleroderma], systemic lupus erythematosus, Sjögren’s syndrome, autoimmune vasculitis [e.g., Wegener’s granulomatosis]) (subjects with vitiligo, type 1 diabetes mellitus, residual hypothyroidism, hypophysitis due to autoimmune condition only requiring hormone replacement may be enrolled). 9. History of neuropathy considered of autoimmune origin (e.g., polyarthritis including Guillain-Barré syndrome and myasthenia gravis) or other central nervous system autoimmune disease (e.g., polymyositis, multiple sclerosis). 10. History of recent infection (within 4 weeks of Cycle 1, Day 1 [C1D1]) considered to be caused by one of the following pathogens: HSV1, HSV2, VZV, EBV, CMV, measles, Influenza A, Zika virus, Chikungunya virus, mycoplasma pneumonia, Campylobacter jejuni, or enterovirus D68, or severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Note: An influenza test and a pathogen-directed SARS CoV-2 test (such as polymerase chain reaction) are mandatory and must be negative before initiating study treatment (tests to be performed 3 days or less prior to dosing on C1D1; an additional 2 days are allowed in the event of logistical issues for receiving the results on time). 11. Participants known to be or having been infected with human immunodeficiency (HIV) virus, hepatitis B virus (HBV), or hepatitis C virus (HCV), and require anti-viral therapy or prophylaxis. Note: Serology testing is mandatory for patients with unknown status. 12. History of Stevens-Johnson syndrome or toxic epidermal necrolysis. 13. Failure to recover ≤ Grade 1 (Common Terminology Criteria for Adverse Events version 4.0 [CTCAE v4.0]) from acute non-hematologic toxicity (except ≤ Grade 2 neuropathy or alopecia), due to previous therapy, prior to screening. 14. Hodgkin lymphoma (HL) with central nervous system involvement, including leptomeningeal disease. 15. Clinically significant third space fluid accumulation (i.e., ascites requiring drainage or pleural effusion that is either requiring drainage or associated with shortness of breath). 16. Breastfeeding or pregnant. 17. Significant medical comorbidities, including uncontrolled hypertension (blood pressure [BP] ≥ 160/100 mmHg repeatably), unstable angina, congestive heart failure (greater than New York Heart Association class II), electrocardiographic evidence of acute ischemia, coronary angioplasty or myocardial infarction within 3 months prior to screening, severe uncontrolled atrial or ventricular cardiac arrhythmia, poorly controlled diabetes, or severe chronic pulmonary disease. 18. Major surgery, radiotherapy, chemotherapy, or other antineoplastic therapy, within 14 days prior to start of study drug, except shorter if approved by the Sponsor. 19. Use of any other experimental medication within 30 days prior to start of study drug. 20. Any live vaccine within 4 weeks prior to start of study drug and planned live vaccine administration after starting study drug. 21. Congenital long QT (measure between Q wave and T wave in the electrocardiogram) syndrome, or a corrected QTc interval of ≤ 480 ms, at screening (unless secondary to pacemaker or bundle branch block). 22. Any other significant medical illness, abnormality, or condition that would, in the Investigator’s judgment, make the participants inappropriate for study participation or put the participant at risk.

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