Comparing Rituximab and Mosunetuzumab Drug Treatments for People With Low Tumor Burden Follicular Lymphoma

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Participants must have a histologically confirmed diagnosis of classic follicular lymphoma (cFL). cFL was previously categorized as grade 1-3A per World Health Organization (WHO)-HAEM4R, but grading of classic follicular lymphoma (FL) is no longer mandatory. * NOTE: Participants with follicular lymphoma with uncommon features (uFL) are eligible, including FL with diffuse growth pattern (dFL). Diagnosis is as per local pathology. Lymphoma fluorescence in situ hybridization (FISH) is not required. Molecular testing is not required. * Participants must not have follicular lymphoma with "blastoid" or "large centrocyte" cytological features, or follicular large B-cell lymphoma (FLBL) (previously categorized as follicular lymphoma grade 3B) * Participants must have low-tumor burden follicular lymphoma defined as: * Nodal or extra-nodal tumor mass with diameter less than 7 cm in its greater diameter * Involvement of no more than 3 nodal or extra nodal sites with diameter greater than 3 cm. * Absence of B symptoms * No symptomatic splenomegaly * No compression syndrome (ureteral, orbital, gastrointestinal) * No pleural or peritoneal serous effusion related to follicular lymphoma Participants must have Ann Arbor stage II, III, or IV follicular lymphoma. Participants with stage I disease may be included if they do not wish to undergo radiation or are not candidates for radiation * Participants must either be experiencing distress due to their disease or would prefer active management of their disease rather than a watch and wait approach * Participants must have staging imaging performed within 49 days prior to registration, as follows. PET-CT baseline scans are preferred. If a baseline PET-CT scan cannot be obtained, CT scans of the chest, abdomen, and pelvis, along with a bone marrow biopsy, are acceptable. If CT scans are used for staging at baseline, a CT scan of the neck is recommended. All measurable dominant lesions must be assessed within 49 days prior to registration. Tests to assess non-measurable disease must be performed within 49 days prior to registration. All disease must be assessed and documented on the Baseline Tumor Assessment Form. * NOTE: if the initial evaluation is insufficient to detect measurable disease, treating investigators may obtain a CT scan with contrast * Participants must have bi-dimensionally measurable disease (at least one lesion with longest diameter \> 1.5 cm) * Participants must not have had prior systemic therapy for follicular lymphoma. Radiation therapy for a previous diagnosis of early-stage follicular lymphoma is allowed * Participant must be ≥ 18 years of age at the time of registration * Participant must have Zubrod performance status of 0-2 * Participant must have a complete medical history and physical exam within 28 days prior to registration * Leukocytes ≥ 3 x 10\^3/uL (within 28 days prior to registration) * Hemoglobin \> 9.0 g/dL (within 28 days prior to registration) * Absolute neutrophil count ≥ 1.5 x 10\^3/uL (within 28 days prior to registration) * Platelets ≥ 100 x 10\^3/uL (within 28 days prior to registration) * Total bilirubin ≤ 2 x institutional upper limit of normal (ULN) unless history of Gilbert's disease. Participants with history of Gilbert's disease must have total bilirubin ≤ 5 x institutional ULN (within 28 days prior to registration) * Aspartate aminotransferase (AST)/alanine aminotransferase (ALT) ≤ 3 × institutional ULN (within 28 days prior to registration) * Lactate dehydrogenase (LDH) \< institutional ULN (within 28 days prior to registration) * Participants must have a calculated creatinine clearance ≥ 30 mL/min using the following Cockcroft-Gault Formula. This specimen must have been collected and processed within 28 days prior to registration * Participants must not have an active or uncontrolled infection before initiation of study treatment in the opinion of the treating investigators * Participants must not have uncontrolled diabetes within 14 days prior to registration in the opinion of the treating investigators * Participants must not have uncontrolled blood pressure and hypertension within 14 days prior to registration in the opinion of the treating investigators * Participants with known human immunodeficiency virus (HIV)-infection must be on effective anti-retroviral therapy at registration and have undetectable viral load test on the most recent test results obtained within 6 months prior to registration * Participants with evidence of chronic hepatitis B virus (HBV) infection must have undetectable HBV viral load while on suppressive therapy on the most recent test results obtained within 6 months prior to registration, if indicated. Participants with a positive total hepatitis (Hep) B core antibody and negative hepatitis B virus surface antigen (HBsAg) at screening are at high risk for reactivation and should receive prophylactic antivirals (e.g., entecavir) before and throughout the treatment * Participants must not have active autoimmune disease requiring systemic therapy * Participants must not have had undergone organ transplants requiring ongoing systemic immunosuppressive therapy * Participants with a history of hepatitis C virus (HCV) infection must have been treated and cured. Participants currently being treated for HCV infection must have undetectable HCV viral load test on the most recent test results obtained within 6 months prior to registration, if indicated * Participants must not have known chronic active Epstein Barr Virus infection (CAEBV); testing in asymptomatic participants is not required * Participants must not have a positive test result for COVID-19 within seven (7) days prior to registration * Participants must not have a prior or concurrent malignancy whose natural history or treatment (in the opinion of the treating physician) has the potential to interfere with the safety or efficacy assessment of the investigational regimen * Participants must not have a history of confirmed progressive multifocal leukoencephalopathy (PML) * Participants must not have received allogeneic stem cell transplantation * Participants must not have a history of macrophage activation syndrome (MAS) or hemophagocytic lymphohistiocytosis (HLH) * Participants with known history or current symptoms of cardiac disease, or history of treatment with cardiotoxic agents, must have a clinical risk assessment of cardiac function using the New York Heart Association Functional Classification. Participant must not have significant cardiovascular disease such as class III or IV cardiac disease, myocardial infarction within 6 months prior to registration. Participants with unstable arrhythmias, or unstable angina, should be excluded * Participants must not be pregnant or nursing (nursing includes breast milk fed to an infant by any means, including from the breast, milk expressed by hand, or pumped). Individuals who are of reproductive potential must have agreed to use an effective contraceptive method with details provided as a part of the consent process. A person who has had menses at any time in the preceding 12 consecutive months or who has semen likely to contain sperm is considered to be of "reproductive potential." In addition to routine contraceptive methods, "effective contraception" also includes refraining from sexual activity that might result in pregnancy and surgery intended to prevent pregnancy (or with a side-effect of pregnancy prevention) including hysterectomy, bilateral oophorectomy, bilateral tubal ligation/occlusion, and vasectomy with testing showing no sperm in the semen * Participants must be offered the opportunity to participate in specimen banking. With participant consent, specimens must be collected and submitted via the Southwest Oncology Group (SWOG) Specimen Tracking System * NOTE: As a part of the Oncology Patient Enrollment Network (OPEN) registration process the treating institution's identity is provided in order to ensure that the current (within 365 days) date of institutional review board approval for this study has been entered in the system. * Participants must be informed of the investigational nature of this study and must sign and give informed consent in accordance with institutional and federal guidelines * For participants with impaired decision-making capabilities, legally authorized representatives may sign and give informed consent on behalf of study participants in accordance with applicable federal, local, and Central Institutional Review Board (CIRB) regulations

Conditions & Interventions

Interventions:

PROCEDURE: Biospecimen Collection, PROCEDURE: Computed Tomography, BIOLOGICAL: Mosunetuzumab, PROCEDURE: Positron Emission Tomography, BIOLOGICAL: Rituximab, BIOLOGICAL: Rituximab and Hyaluronidase Human

Conditions:

Classic Follicular Lymphoma, Follicular Lymphoma With Unusual Cytological Features

More Information

Contact(s): ctrrecruit@vcu.edu
Principal Investigator:
Phase: PHASE3
IRB
Number:
System ID: NCT06337318
