Testing Continuous Versus Intermittent Treatment With the Study Drug Zanubrutinib for Older Patients With Previously Untreated Mantle Cell Lymphoma

Status: RECRUITING

Eligibility Criteria

Age: 60 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* • Histologically confirmed mantle cell lymphoma with cyclin D1 (BCL1) expression by immunohistochemical stains and/or t(11;14) by cytogenetics or fluorescence in situ hybridization (FISH) as confirmed by the enrolling center * Any stage allowed (stage I-IV) * Presence of measurable disease, defined as \>= 1 nodal lesion that is \> 1.5 cm in longest diameter or \>= 1 extranodal lesion that is \> 1 cm in longest diameter * Steroids for management of mantle cell lymphoma are allowed up to a dose of prednisone 100mg/day (or equivalent) for up to 7 days * No prior systemic treatment for mantle cell lymphoma * No prior radiation treatment for stage I MCL * No prior exposure to a BTK inhibitor or anti-CD20 monoclonal antibody * No prior stem cell transplant * Age \>= 70 years OR age \>= 60 to \< 70 years with comorbidities precluding autologous stem cell transplantation (autoSCT) including at least one of the following: a) cardiac ejection fraction (EF) \< 45%, b) diffusing capacity for carbon monoxide \< 60% predicted; c) creatinine clearance \< 70 but \> 30ml/minute (min); d) Eastern Cooperative Oncology Group (ECOG) performance status of 2, which poses an unacceptable risk of toxicity for high-dose therapy and stem cell transplantation; or e) Cumulative Illness Rating Scales (CIRS) total score \> 6 * ECOG Performance Status 0-2 * Absolute neutrophil count (ANC) \>= 750/mm\^3 (without growth factor support within 7 days) * Platelet count \>= 75,000/mm\^3 (or \>= 50,000/mm\^3 for patients with bone marrow involvement of lymphoma) without growth factor support or transfusion within 7 days * Creatinine clearance \>= 30 mL/ min determined by either: a) Estimation using the Cockcroft-Gault equation or b) Measurement by nuclear medicine scan or 24 hour urine collection * Total bilirubin =\< 1.5 x upper limit of normal (ULN) (unless documented Gilbert's syndrome) * Aspartate transferase (AST) / alanine transaminase (ALT) =\< 3 x ULN * Patients should not be considered candidates for stem cell transplant or must have declined a stem cell transplant strategy * No clinically significant cardiovascular disease including the following * Unstable angina within 3 months before registration * New York Heart Association class III or IV congestive heart failure * History of clinically significant arrhythmias (eg, sustained ventricular tachycardia, ventricular fibrillation, torsades de pointes) * QT correction formula (QTcF) \> 480 msecs based on Fredericia's formula * History of Mobitz II second-degree or third-degree heart block without a permanent pacemaker in place * Human immunodeficiency virus (HIV)-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months are eligible for this trial * No active Hepatitis B or Hepatitis C infection. Patients with prior hepatitis B virus (HBV) exposure (positive HBV core antibody and/or surface antigen) are eligible if they have no detectable viral load, and are taking appropriate prophylactic antiviral therapy to prevent reactivation. Patients with history of hepatitis C virus (HCV) are eligible if they have an undetectable HCV viral load * Patients with a prior or concurrent malignancy whose natural history or treatment does not have the potential to interfere with the safety or efficacy assessment of the investigational regimen are eligible for this trial * No history of severe bleeding disorder such as hemophilia A, hemophilia B, von Willebrand disease, or history of spontaneous bleeding requiring blood transfusion or other medical intervention * No history of stroke or intracranial hemorrhage within 6 months prior to registration * No disease significantly affecting gastrointestinal function such as malabsorption syndrome, resection of the stomach or small bowel, bariatric surgery procedures, symptomatic inflammatory bowel disease, or partial or complete bowel obstruction. Patient must be able to swallow pills * Potential trial participants should have recovered from major surgery * No vaccination with a live vaccine within 35 days prior to registration * No hypersensitivity to zanubrutinib or rituximab or any of the other ingredients of the study drugs * Chronic concomitant treatment with strong inhibitors of CYP3A4 is not allowed on this study. Patients on strong CYP3A4 inhibitors must discontinue the drug for 14 days prior to registration on the study. * Chronic concomitant treatment with strong CYP3A4 inducers is not allowed. Patients must discontinue the drug 14 days prior to the start of study treatment * Avoid use of moderate CYP3A4 inhibitors, PGP inhibitors, and moderate CYP3A4 inducers * Archival tissue must be available for submission in all patients for histopathology review, though participation in correlative substudies is optional

Conditions & Interventions

Interventions:

DRUG: Zanubrutinib, BIOLOGICAL: Rituximab, OTHER: Patient Observation, PROCEDURE: Bone Marrow Biopsy, OTHER: Fludeoxyglucose F-18, PROCEDURE: Positron Emission Tomography, PROCEDURE: Computed Tomography, PROCEDURE: Magnetic Resonance Imaging, PROCEDURE: Esophagogastroduodenoscopy, PROCEDURE: Colonoscopy, PROCEDURE: Biospecimen Collection, OTHER: Questionnaire Administration

Conditions:

Mantle Cell Lymphoma

More Information

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Principal Investigator:

Phase: PHASE3

IRB

Number:

System ID: NCT05976763