Testing the Effectiveness of a Combination Targeted Therapy (ViPOR) for Patients With Relapsed and/or Refractory Aggressive B-cell Lymphoma

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Patient must be ≥ 18 years of age * Patient must have histologically or cytologically confirmed aggressive B-cell lymphoma as follows: * Cohort 1: CD10-negative DLBCL, which includes: * CD10-negative non-GCB DLBCL, not otherwise specified (NOS) (i.e., CD10-/BCL6- or CD10-/BCL6+/MUM1+ DLBCL) * CD10-negative GCB DLBCL, NOS (i.e., CD10-/BCL6+/MUM1- DLBCL) * CD10-negative HGBCL with MYC and BCL6 (without BCL2) translocations (HGBCL-DH-BCL6) * CD10-negative HGBCL, NOS (without MYC and BCL2 translocations) * CD10-negative T-cell/histiocyte-rich large B-cell lymphoma (THRLBCL) OR * Cohort 2: CD10-positive or negative HGBCL with MYC and BCL2 rearrangements (with or without BCL6 rearrangement) (HGBCL-DH-BCL2) * NOTE: The site principal investigator must review and verify the pathology report findings to ensure the patient is eligible and is assigned to the respective cohort at the time of registration * Patient must have relapsed and/or refractory disease after at least 1 prior anthracycline and anti-CD20 antibody-containing regimen * Patient must not have confirmed or suspected primary mediastinal large B-cell lymphoma (PMBL) * Patient must not be pregnant due to the potential harm to an unborn fetus with the treatment regimens being used. * All patients of childbearing potential must have a serum or urine study with a sensitivity of at least 25 mIU/mL within 14 days prior to registration to rule out pregnancy and again within 24 hours prior to starting cycle 1 day 1 of treatment. * A patient of childbearing potential is defined as anyone, regardless of whether they have undergone tubal ligation, who meets the following criteria: 1) has achieved menarche at some point, 2) has not undergone a hysterectomy or bilateral oophorectomy; or 3) has not been naturally postmenopausal (amenorrhea following cancer therapy does not rule out childbearing potential) for at least 24 consecutive months (i.e., has had menses at any time in the preceding 24 consecutive months) * Patients of childbearing potential must not expect to conceive children by abstaining from sexual intercourse or by using accepted and effective methods of contraception throughout the entire duration of protocol treatment, including during dose interruptions, and for 6 months after the last dose of protocol treatment. Male patients must not father children by abstaining from sexual intercourse or by using a condom during sexual contact with pregnant partners or partners of childbearing potential throughout the entire duration of protocol treatment, including dose interruptions, and for 6 months after the last dose of protocol treatment even if they have had a successful vasectomy * Male patients must agree to not donate semen or sperm during the entire duration of protocol treatment or for at least 28 days after the last dose of lenalidomide * Patient must agree to abstain from breastfeeding during the entire duration of protocol treatment and for at least 6 months after the last dose of protocol treatment * Patient must agree to abstain from donating blood during the entire duration of protocol treatment and for at least 28 days after the last dose of lenalidomide * Patient must have the ability to understand and the willingness to sign a written informed consent document. Patients with impaired decision-making capacity (IDMC) who have a legally authorized representative (LAR) or caregiver and/or family member available will also be considered eligible * Absolute neutrophil count (ANC) ≥ 1,000/mcL without requirement for granulocyte colony stimulating factor (G-CSF) support (obtained ≤ 7 days prior to registration) * Hemoglobin ≥ 8 g/dL (obtained ≤ 7 days prior to registration) * Platelets ≥ 75,000/mcL without requirement for platelet transfusion support (obtained ≤ 7 days prior to registration) * Total bilirubin ≤ 1.5 x institutional upper limit of normal (ULN) (or ≤ 3.0 x institutional ULN for patients with documented Gilberts syndrome) (obtained ≤ 7 days prior to registration) * Aspartate aminotransferase (AST) (serum glutamic oxaloacetic transaminase \[SGOT\])/alanine aminotransferase (ALT) (serum glutamic pyruvic transaminase \[SGPT\]) ≤ 3.0 x institutional ULN (obtained ≤ 7 days prior to registration) * Creatinine ≤ 1.5 mg/dL OR creatinine clearance ≥ 30 mL/min/1.73 m\^2 (estimated by Cockcroft-Gault method or measured) (obtained ≤ 7 days prior to registration) * Human immunodeficiency virus (HIV)-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months of registration are eligible for this trial * For patients with evidence of chronic hepatitis B virus (HBV) infection, the HBV viral load must be undetectable on suppressive therapy, if indicated * Patients with a history of hepatitis C virus (HCV) infection must have been treated and cured. For patients with HCV infection who are currently on treatment, they are eligible if they have an undetectable HCV viral load * Patient must not have confirmed or suspected primary DLBCL of the central nervous system (CNS) (PCNSL) * Patients with history of secondary CNS lymphoma (SCNSL) are eligible if follow-up brain imaging after central nervous system (CNS)-directed therapy shows no evidence of progression * 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 * Patient must not have taken or require warfarin or other strong CYP3A inhibitors or inducers within 7 days prior to registration. * NOTE: Antiplatelet agents, other anticoagulants aside from warfarin, as well as mild or moderate CYP3A inhibitors or inducers are permitted on study but should be used with caution * Patient must not have an uncontrolled intercurrent illness that would interfere with the safety or efficacy assessment of this protocol * Patient must not have evidence of an active infection at the time of registration * Patient must not have the following current or prior anti-cancer treatment: * Any chemotherapy, targeted therapy, anti-cancer antibodies, antibody-drug conjugates, or bi-specific antibodies received within 2 weeks prior to registration * NOTE: Short courses of corticosteroids or palliative external beam radiation therapy (XRT) prior to registration are permitted * More than 3 prior lines of cytotoxic chemotherapy, excluding targeted therapy, anti-cancer antibodies, antibody-drug conjugates, bi-specific antibodies, and radio- or toxin-immunoconjugates * NOTE: Cytoreductive chemotherapy followed by autologous stem cell transplant (ASCT) counts as 1 line of cytotoxic therapy. Similarly, cytoreductive chemotherapy (either pre-T-cell collection or as bridging therapy) followed by pre-conditioning therapy/chimeric antigen receptor T-cell (CAR-T) counts as 1 line of therapy, as long as no disease progression occurs between interventions. For both therapies, if progressive disease is documented between 2 distinct regimens, then they should be counted as 2 lines of cytotoxic chemotherapy * Radio- or toxin-immunoconjugates within 10 weeks prior to registration * Previous treatment with more than one of the following study agents: venetoclax, ibrutinib, or lenalidomide * Prior autologous stem cell transplant (ASCT), chimeric antigen receptor T-cell (CAR-T) therapy, or allogeneic stem cell (or other organ) transplant within 3 months prior to registration * Any evidence of active graft-versus-host disease or requirement for immunosuppressants within 28 days prior to registration * NOTE: In addition, patient must have recovered (i.e., ≤ grade 1 or baseline) from all adverse events due to previously administered anti-cancer treatment, surgery, or procedure * NOTE: Exceptions to this include events not considered to place the patient at unacceptable risk of participation in the opinion of the treating investigator (i.e., alopecia) * Patients with known history or current symptoms of cardiac disease, or history of treatment with cardiotoxic agents, should have a clinical risk assessment of cardiac function using the New York Heart Association Functional Classification. To be eligible for this trial, patients should be class 2B or better * Patient must have adequate formalin fixed paraffin embedded (FFPE) tumor tissue specimen from the initial diagnostic biopsy or on-study repeat tumor tissue biopsy for molecular analysis * NOTE: Excisional tumor biopsy is preferred. Core needle biopsies will be considered adequate if there is enough tissue for the mandatory molecular analysis. Submission of an entire FFPE tumor block is preferred, but if unavailable 10 x 10um FFPE scrolls may be submitted as an alternative. If adequate archived FFPE tumor tissue is unavailable, the patient must be willing to undergo research biopsy for molecular analysis * Patient must have measurable disease * Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status 0-2

Conditions & Interventions

Interventions:

PROCEDURE: Biopsy Procedure, PROCEDURE: Biospecimen Collection, PROCEDURE: Bone Marrow Aspiration, PROCEDURE: Bone Marrow Biopsy, PROCEDURE: Computed Tomography, DRUG: Ibrutinib, DRUG: Lenalidomide, PROCEDURE: Magnetic Resonance Imaging, BIOLOGICAL: Obinutuzumab, PROCEDURE: Positron Emission Tomography, DRUG: Prednisone, DRUG: Venetoclax

Conditions:

Conditions:
High Grade B-Cell Lymphoma With MYC and BCL6 Rearrangements, Recurrent Diffuse Large B-Cell Lymphoma, Recurrent Diffuse Large B-Cell Lymphoma Germinal Center B-Cell Type, Recurrent Diffuse Large B-Cell Lymphoma, Not Otherwise Specified, Recurrent High Grade B-Cell Lymphoma With MYC and BCL2 or BCL6 Rearrangements, Recurrent High Grade B-Cell Lymphoma With MYC, BCL2, and BCL6 Rearrangements, Recurrent High Grade B-Cell Lymphoma, Not Otherwise Specified, Recurrent T-Cell/Histiocyte-Rich Large B-Cell Lymphoma, Refractory Diffuse Large B-Cell Lymphoma, Refractory Diffuse Large B-Cell Lymphoma Germinal Center B-Cell Type, Refractory Diffuse Large B-Cell Lymphoma, Not Otherwise Specified, Refractory High Grade B-Cell Lymphoma With MYC and BCL2 or BCL6 Rearrangements, Refractory High Grade B-Cell Lymphoma With MYC, BCL2, and BCL6 Rearrangements, Refractory High Grade B-Cell Lymphoma, Not Otherwise Specified, Refractory T-Cell/Histiocyte-Rich Large B-Cell Lymphoma

More Information

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