Comparing the Effectiveness of the Immunotherapy Agents Rituximab or Mosunetuzumab in Patients With Nodular Lymphocyte-Predominant Hodgkin Lymphoma, NORM Trial

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Histopathologically confirmed diagnosis of NLPHL as confirmed by local pathologist's expert review. * Untreated NLPHL: stage IB to IV according to Cotswolds. The proportion of patients with stages I or II treated with consolidative radiotherapy will be capped at 40%. * Previously treated NLPHL, any stage. * According to the treating physician, the patient should not be observed and needs therapy, notably because of B-symptoms (unexplained fever \[temperature \> 38 degrees Celsius (\> 100.4 degrees Fahrenheit)\], weight loss \[unexplained loss of \> 10 percent of body weight over the past six months\], or drenching night sweats), symptomatic nodal or extranodal disease, or patient preferences. * Patients must have measurable disease according to the Lugano/Lymphoma Response to Immunomodulatory Therapy Criteria (LYRIC) classification. * Age \>= 18 years. Because no dosing or adverse event (AE) data are currently available on the use of mosunetuzumab in patients \< 18 years of age, children are excluded from this study. * Eastern Cooperative Oncology Group performance status =\< 2 (Karnofsky \>= 60%). * Absolute neutrophil count \>= 1,000/mcL. * Platelets \>= 100,000/mcL. * Total bilirubin =\< 1.5 institutional upper limit of normal (ULN), except in patients with Gilbert's syndrome as defined by \> 80% unconjugated bilirubin. * Aspartate aminotransferase (AST)(serum glutamic-oxaloacetic transaminase \[SGOT\])/alanine transaminase (ALT)(serum glutamic-pyruvic transaminase \[SGPT\]) =\< 3 x institutional ULN. * Glomerular filtration rate (GFR) \>= 40mL /min= GFR (mL/Min/1.73 m\^2) * body surface area (BSA)/1.73. * Human immunodeficiency virus-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months 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. * 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. * 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. * The effects of mosunetuzumab on the developing human fetus are unknown. For this reason and because other therapeutic agents used in this trial are known to be teratogenic, women of childbearing potential and men must agree to use adequate contraception (hormonal and/or barrier method of birth control; abstinence) (both hormonal and barrier method of birth control are required for participants in Canada) prior to study entry and for the duration of study participation. Should a woman become pregnant or suspect she is pregnant while she or her partner is participating in this study, she should inform her treating physician immediately. Men and women treated or enrolled on this protocol must also agree to use adequate contraception prior to the study, for the duration of study participation, and 3 months after completion of mosunetuzumab administration and 12 months after completion of rituximab administration. * Ability to understand and the willingness to sign a written informed consent document. Legally authorized representatives may sign and give informed consent on behalf of study participants.

Exclusion Criteria:

* Classical Hodgkin lymphoma (cHL) or composite lymphoma. * Transformed NLPHL, concerns of the treating physician of an occult transformation or concerns of the treating physician that the patient needs cytotoxic therapy. * NLPHL relapse less than 6 months after rituximab or rituximab-containing therapy. * Patients who have not recovered from AEs due to prior anticancer therapy (i.e., have residual toxicities \> grade 1) with the exception of alopecia. * Patients who are receiving any other investigational agents. * Patients with central nervous system (CNS) involvement as a result of lymphoma. * History of allergic reactions attributed to compounds of similar chemical or biologic composition to mosunetuzumab or rituximab. * Patients with uncontrolled intercurrent illness or any other significant condition(s) that would make participation in this protocol unreasonably hazardous. * Pregnant women are excluded from this study because there is an unknown but potential risk for AEs in nursing infants secondary to treatment of the mother with mosunetuzumab; breastfeeding should be discontinued if the mother is treated with mosunetuzumab or rituximab. These potential risks may also apply to other agents used in this study. * Prior allogeneic stem cell or solid organ transplantation. * Participants who have received a live, attenuated vaccine within 4 weeks before first dose of study treatment or anticipation that such a live, attenuated vaccine will be required during the study. Participants must not receive live, attenuated vaccines (e.g., FluMist \[registered trademark\]) while receiving study treatment and after the last dose until B-cell recovery to the normal ranges. Killed vaccines or toxoids should be given at least 4 weeks prior to the first dose of study treatment to allow development of sufficient immunity. * Any other anti-cancer therapy, whether investigational or approved, including but not limited to chemotherapy, within 4 weeks or 5 half-lives of the drug, whichever is shorter, prior to initiation of study treatment. * Evidence of any significant, concomitant disease that could affect compliance with the protocol or interpretation of results as judged by the investigator, including, but not limited to: * Significant cardiovascular disease (e.g., New York Heart Association class III or IV cardiac disease, myocardial infarction within the previous 6 months, unstable arrhythmia, or unstable angina). * Significant pulmonary disease (such as obstructive pulmonary disease or history of bronchospasm). * Current or past history of CNS disease, such as stroke, epilepsy, CNS vasculitis, or neurodegenerative disease. * Participants with a history of stroke who have not experienced a stroke or transient ischemic attack in the past 1 year and have no residual neurologic deficits as judged by the investigator are allowed. * Participants with a history of epilepsy who have had no seizures in the past 2 years with or without anti-epileptic medications can be eligible only for the expansion cohort. * History of confirmed progressive multifocal leukoencephalopathy (PML). * Participants with infections requiring IV treatment with antibiotics or hospitalization (grade 3 or 4) within the last 4 weeks prior to enrollment or known active bacterial, viral (including SARS-CoV-2), fungal, mycobacterial, parasitic, or other infection (excluding fungal infections of nail beds) at study enrollment. * Systemic immunosuppressive medications (including, but not limited to, cyclophosphamide, azathioprine, methotrexate, thalidomide, and anti-tumor necrosis factor agents) within 2 weeks prior to first dose of study treatment. * Known or suspected chronic active Epstein-Barr virus (EBV) or cytomegalovirus (CMV) infection. * Known or suspected history of hemophagocytic lymphohistiocytosis (HLH).

Conditions & Interventions

Interventions:

PROCEDURE: Biopsy Procedure, PROCEDURE: Biospecimen Collection, PROCEDURE: Bone Marrow Biopsy, PROCEDURE: Computed Tomography, OTHER: Fludeoxyglucose F-18, BIOLOGICAL: Mosunetuzumab, PROCEDURE: Positron Emission Tomography, BIOLOGICAL: Rituximab, BIOLOGICAL: Rituximab and Hyaluronidase Human

Conditions:

Nodular Lymphocyte Predominant B-Cell Lymphoma, Recurrent Nodular Lymphocyte Predominant B-Cell Lymphoma, Refractory Nodular Lymphocyte Predominant B-Cell Lymphoma

More Information

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Principal Investigator:
Phase: PHASE2
IRB
Number:
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