Testing Early Treatment for Patients With High-Risk Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Leukemia (SLL), EVOLVE CLL/SLL Study

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Participants must have a confirmed diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) (collectively referred to as CLL throughout) according to the 2018 International Workshop on CLL. Participants must have been diagnosed within 18 months prior to registration * Participants must have CLL-International Prognostic Index (CLL-IPI) score \>= 4 and/or complex cytogenetics (defined as 3+ chromosomal abnormalities) * Cytogenetic AND/OR FISH analyses must be completed at a Clinical Laboratory Improvement Act (CLIA)-approved (or laboratories accredited under Accreditation Canada Diagnostics to conduct FISH analyses) laboratory within 18 months prior to registration. At minimum, FISH panel should use probes to detect for abnormalities in chromosomes 13q, 12, 11q, and 17p * TP53 gene mutation analysis performed at any CLIA-approved (or laboratories accredited under Accreditation Canada Diagnostics) lab (if completed) must be obtained within 18 months prior to registration. This sequencing test is distinct from FISH studies for del(17p) * Note: TP53 gene mutation analysis is recommended but not required if the participant meets disease-related study criteria via a combination of risk factors that totals a score of 4 on the CLL-IPI score and/or has complex cytogenetics completed * Immunoglobulin heavy chain locus variable (IgVH) gene mutation analysis performed at any CLIA-approved lab (or laboratories accredited under Accreditation Canada Diagnostics) must be obtained prior to registration (at any time prior to registration) * Serum beta-2 microglobulin level must be obtained within 28 days prior to registration * Participants must not meet any of the IWCLL specified criteria for active CLL therapy * Treatment with high dose corticosteroids and/or intravenous immunoglobulin for autoimmune complications of CLL must be complete at least 4 weeks prior to enrollment * Steroids used for treatment of conditions other than CLL/SLL must be at a dose of at most 20 mg/day of prednisone or equivalent corticosteroid at the time of registration * Prior therapy with anti CD20 monoclonal antibodies is not allowed * Participants must not have received or be currently receiving any prior CLL-directed therapy, including non-protocol-related therapy, anti-cancer immunotherapy, experimental therapy (with exception of agents approved for emergency access use for the prevention or treatment of COVID-19), or radiotherapy * Participants must not be receiving or planning to receive any other investigational agents before completing protocol therapy * Participants must be \>= 18 years of age * Participants must have Eastern Cooperative Oncology Group (ECOG) performance status =\< 2 * Platelet count \>= 100,000/mm\^3 within 28 days prior to registration * Absolute neutrophil count (ANC) \>= 1,000/mm\^3 within 28 days prior to registration * Creatinine clearance \>= 30mL/min (by Cockcroft Gault) within 28 days prior to registration * Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) \< 3.0 x upper limit of normal (ULN) within 28 days prior to registration * Total bilirubin =\< 2.0 x ULN (or 5.0 x ULN if the participant has a history of Gilbert's disease), within 28 days prior to registration * Participants must be able to take oral medications * Human immunodeficiency virus (HIV)-infected participants on effective anti-retroviral therapy with undetectable viral load within 6 months are eligible for this trial * Participants with history of malignancy are allowed providing the cancer has not required active treatment within 2 years prior to registration (hormonal therapy is permissible). The following exceptions are permissible: basal cell, squamous cell skin, or non-melanomatous skin cancer, in situ cervical cancer, superficial bladder cancer not treated with intravesical chemotherapy or Bacillus Calmette-Guerin (BCG) within 6 months, localized prostate cancer requiring no more than chronic hormonal therapy, or localized breast cancer requiring no more than chronic hormonal therapy * Participants must not have current, clinically significant gastrointestinal malabsorption, in the opinion of treating doctor * Participants must not have cirrhosis * Obinutuzumab has been associated with hepatitis reactivation. Participants must not have uncontrolled active infection with hepatitis B or C. Participants with latent hepatitis B infection must agree to take prophylaxis during and for 6 months following active protocol therapy with V-O. * Active infection with hepatitis B or C: * Active infection is defined as detectable hepatitis B deoxyribonucleic acid (DNA) or hepatitis C ribonucleic acid (RNA) by quantitative polymerase chain reaction (PCR). * Latent infection with hepatitis B: * Latent infection is defined as meeting all of the following criteria: * Hepatitis B surface antigen positive * Anti-hepatitis B total core antibody positive * Anti-hepatitis IgM core antibody undetectable * Hepatitis B PCR undetectable * Participants with latent hepatitis B infection must agree to take prophylaxis with anti-hepatitis agents during and for 6 months following active protocol therapy with V-O. * Participants who have received intravenous immunoglobulin (IVIG) therapy within 6 months who are hepatitis B core total antibody positive but PCR undetectable are not mandated to take prophylaxis * Participants must not have had major surgery within 30 days prior registration or minor surgery within 7 days prior to registration. Examples of major surgery include neurosurgical procedures, joint replacements, and surgeries that occur inside the thoracic or abdomino-pelvic cavities. Examples of minor surgery include dental surgery, insertion of a venous access device, skin biopsy, or aspiration of a joint. If a participant has had a bone marrow biopsy for diagnosis or evaluation of CLL, this will not exclude the participant from registration to the study. If there is a question about whether a surgery is major or minor, this should be discussed with the Study Chair * Participants must not have known bleeding disorders (e.g., von Willebrand's disease or hemophilia) * Participants must not have a history of stroke or intracranial hemorrhage within 6 months prior to enrollment * Participants must not require continued therapy with a strong inhibitor or inducer of CYP3A4/5, as venetoclax is extensively metabolized by CYP3A4/5 * Participants must not have uncontrolled autoimmune hemolytic anemia or idiopathic thrombocytopenia purpura * Participants must not have any currently active, clinically significant cardiovascular disease, such as uncontrolled arrhythmia or class 3 or 4 congestive heart failure as defined by the New York Heart Association Functional Classification * Participants must not have a history of myocardial infarction, unstable angina, or acute coronary syndrome within 6 months prior to enrollment * Participants must not be pregnant or nursing, as there are no safety data available for these drug regimens during pregnancy. Women/men of reproductive potential must have agreed to use an effective contraceptive method. A woman is considered to be of "reproductive potential" if she has had menses at any time in the preceding 12 consecutive months. In addition to routine contraceptive methods, "effective contraception" also includes heterosexual celibacy and surgery intended to prevent pregnancy (or with a side-effect of pregnancy prevention) defined as a hysterectomy, bilateral oophorectomy or bilateral tubal ligation. However, if at any point a previously celibate patient chooses to become heterosexually active during the time period for use of contraceptive measures outlined in the protocol, he/she is responsible for beginning contraceptive measures * Participants must agree to have specimens submitted for translational medicine (MRD) as outlined * Participants must be offered the opportunity to participate in specimen banking for future research as outlined. * NOTE: With participant's consent, the site must follow through with specimen submission as outlined * Participants who are able to complete patient reported outcome (PRO) forms in English, Spanish, French, German, Russian or Mandarin must agree to participate in the quality of life assessments. (Those participants who are unable to read and write in English, Spanish, French, German, Russian or Mandarin may be registered to S1925 without contributing to the quality of life portion of the study.) * Participants must be informed of the investigational nature of this study and must sign and give written informed consent in accordance with institutional and federal guidelines * 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

Conditions & Interventions

Interventions:

PROCEDURE: Biospecimen Collection, PROCEDURE: Bone Marrow Aspiration, PROCEDURE: Bone Marrow Biopsy, PROCEDURE: Computed Tomography, BIOLOGICAL: Obinutuzumab, OTHER: Questionnaire Administration, DRUG: Venetoclax

Conditions:

Chronic Lymphocytic Leukemia, Small Lymphocytic Lymphoma

More Information

Contact(s): ctrrecruit@vcu.edu
Principal Investigator:
Phase: PHASE3
IRB
Number:
System ID: NCT04269902
