ForPatients
by Roche

Chronic Lymphocytic Leukemia

A study to look at the safety and efficacy of obinutuzumab with bendamustine in people with a type of blood cancer called ‘chronic lymphocytic leukemia’ (GIBB)

A Study of Obinutuzumab + Bendamustine (BG) in Participants With Previously Untreated Chronic Lymphocytic Leukemia (CLL)

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT02320487 ML29538

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase II, Open-Label Study of Obinutuzumab Plus Bendamustine (BG) in Patients With Previously Untreated Chronic Lymphocytic Leukemia

Trial Summary:

This is a Phase 2, open-label, multicenter study to evaluate the safety and efficacy of BG induction therapy in participants with previously untreated CLL. The anticipated time on study treatment is 24 weeks.

Genentech, Inc. Sponsor	**Phase 2** Phase

NCT02320487 ML29538
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Participants must satisfy one of the criteria for treatment initiation, as outlined in the iwCLL NCI-WG guidelines. The criteria include: (a) Evidence of progressive marrow failure as manifested by the development of, or worsening of, anemia and/or thrombocytopenia, (b) Massive (i.e., greater

than or equal to [>=] 6 centimeters [cm] below the left costal margin) or progressive or symptomatic splenomegaly, (c) Massive nodes (i.e., >= 10 cm in longest diameter) or progressive or symptomatic lymphadenopathy, (d) Progressive lymphocytosis with an increase of greater than (>) 50 percent (%) over a 2-month period or lymphocyte doubling time (LDT) of less than (<) 6 months, (e) Autoimmune anemia and/or thrombocytopenia that is poorly responsive to corticosteroids or other standard therapy, (f) Constitutional symptoms, defined as any one or more of the following disease-related symptoms or signs: unintentional weight loss of >=10% within the previous 6 months, significant fatigue (i.e., Eastern Cooperative Oncology Group Performance Status [ECOG PS] of 2 or worse or the inability to work or perform usual activities), fevers higher than 100.5 degrees Fahrenheit (°F)/38.0 degrees Celsius (°C) for >= 2 weeks without other evidence of infection, or night sweats for >1 month without evidence of infection

- Absolute neutrophil count (ANC) >=1.5 × 10^9 per liter (/L) and platelets >=75 × 10^9/L unless cytopenia is caused by the underlying disease, i.e., no evidence of additional bone marrow dysfunction (e.g., myelodysplastic syndrome, hypoplastic bone marrow)
- Life expectancy >6 months
- ECOG PS of 0, 1, or 2
- Willing to use acceptable contraceptive measures as defined by the protocol during and at least for 6 months (male participants) or 12 months (female participants) after the last dose of study drug

Exclusion Criteria:

- Pregnant or lactating, or intending to become pregnant during the study: Women who are not postmenopausal (>=12 months of non-therapy-induced amenorrhea) or surgically sterile must have a negative serum pregnancy test result within 14 days prior to initiation of study drug
- Participants who have received previous CLL therapy, including investigational therapies
- Transformation of CLL to aggressive non-Hodgkin's lymphoma (Richter's transformation)
- Inadequate renal function
- Inadequate liver function: National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) Grade 3 liver function tests (aspartate aminotransferase [AST] or alanine aminotransferase [ALT] >5× upper limit of normal [ULN] for >2 weeks; bilirubin >3× ULN) unless due to underlying disease
- History of other malignancy, which could affect compliance with the protocol or interpretation of results
- Participants with active bacterial, viral, or fungal infection requiring systemic treatment
- Participants with known infection with human immunodeficiency virus (HIV) or human T-cell leukemia virus 1 (HTLV-1)
- Positive hepatitis serology: (a) Participants with positive serology for hepatitis B, defined as positivity for hepatitis B surface antigen (HBsAg), or participants who are HBsAg negative but are hepatitis B core antibody (anti-HBc) positive, (b) Participants positive for anti-HBc, but with negative hepatitis B Virus (HBV) deoxyribonucleic acid (DNA), will be considered for inclusion by the Medical Monitor on a case-by-case basis in order to ensure feasibility of monthly DNA testing and availability of appropriate care in case of hepatitis B reactivation, (c) Participants with positive serology for hepatitis C (HCV) unless HCV (by ribonucleic acid [RNA]) is confirmed negative
- History of severe allergic or anaphylactic reactions to monoclonal antibodies
- Evidence of significant, uncontrolled concomitant diseases that could affect compliance with the protocol or interpretation of results, including significant cardiovascular disease (such as New York Heart Association Class III or IV cardiac disease, myocardial infarction within the previous 6 months, unstable arrhythmias, or unstable angina) or pulmonary disease (including obstructive pulmonary disease and history of symptomatic bronchospasm)
- Vaccination with a live vaccine a minimum of 30 days prior to study treatment
- Use of investigational agents of any kind within 30 days before study treatment