Phase 3b VENICE 1 (M15-550): Study Design and Endpoints

A study to evaluate the efficacy of venetoclax in relapsed/refractory participants with Chronic Lymphocytic Leukemia (CLL)

Key Inclusion Criteria

- Relapsed/refractory CLL patients including those with the 17p deletion or TP53 mutation, or those who have received prior B-cell receptor therapy
- Adequate bone marrow function: platelets ≥ 25,000/mm³ (without transfusion support within 2 weeks of screening); hemoglobin ≥ 8.0 g/dL
- Adequate renal function (calculated CrCl >50 mL/min)
- No transformed disease i.e. Richter’s Transformation or Prolymphocytic leukemia (PLL), no prior allogeneic transplant, no active or uncontrolled autoimmune hemolytic anemia or idiopathic thrombocytopenia purpura

Endpoints

Primary
Complete Remission Rate (CR + CRi) as assessed by the investigator

Secondary
• Overall Response Rate (ORR)
• Duration of Overall Response (DoR)
• Time to Progression (TTP)
• Progression-Free Survival (PFS)
• Overall Survival (OS)
• CR Rate in BCRi treated subjects
• Level of Minimal Residual Disease (MRD)

Treatment and Follow-up Periods

Treatment Period
Venetoclax administered orally once daily with meal and water. Subjects will titrate to 400mg and may continue to receive venetoclax up to 2 years.

Follow-up Period
After treatment discontinuation, subjects will be followed for disease progression and survival. Post-treatment calls will be performed every 6 months for 2 years.

Venetoclax is being investigated for indications that have not been approved by Regulatory Agencies. Safety and Efficacy have not been established in unapproved indications.


To learn more about these studies, please visit https://ClinicalTrials.gov or email abbbvieclinicaltrials@abbvie.com