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Gilead leukemia study gets complete response

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Singapore: Gilead Sciences' phase II study (Study 101-08) evaluating idelalisib (formerly GS-1101), an investigational, targeted, oral inhibitor of PI3K delta, in combination with rituximab for older patients with treatment-naÃ¯ve chronic lymphocytic leukemia (CLL) has achieved a complete response (CR) rate of 19 percent and an overall response rate (ORR) of 97 percent, with estimated progression-free survival (PFS) at 24 months of 93 percent.

CLL is a slow-growing cancer that induces the production of too many mature white blood cells. It is the second most common type of leukemia in the United States and can lead to life-threatening complications, including serious infection. Currently, patients with CLL are usually treated first with rituximab in combination with one or more chemotherapy agents.

"New therapies that can drive CLL into remission while potentially avoiding or delaying the need for chemotherapy would represent a much needed clinical advance," said Dr Susan M O'Brien, Ashbel Smith Professor of Medicine in the Department of Leukemia at the University of Texas MD Anderson Cancer Center in Houston and a principal investigator of the study.

"The high overall response rate and durable disease control observed in this Phase 2 study suggest that idelalisib in combination with rituximab could become an important therapeutic option for CLL patients new to treatment," she said.

"These results demonstrate for the first time idelalisib's potential benefit for patients with a previously untreated hematological malignancy," said Dr Roy D Baynes, senior VP of Oncology and Inflammation Therapeutics at Gilead Sciences. "Based on these promising data, we are now evaluating Phase 3 study designs for idelalisib as part of a frontline treatment regimen for CLL patients."