

Three-Drug Combination Therapy Effective in Patients with High-Risk Leukemia

Targeted therapy combo sent chronic lymphocytic leukemia into deep remission in people with high-risk forms of the disease.

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A three-drug combination that sent chronic lymphocytic leukemia (CLL) into deep remissions in a broad group of patients in a clinical trial is highly effective in patients with high-risk forms of the disease, a new, phase 2 clinical trial led by Dana-Farber Cancer Institute investigators indicates.

The initial cohort of the trial, which included patients with any subtype of CLL, found that a regimen of acalabrutinib, venetoclax, and obinutuzumab produced deep remissions in 89% of participants. The new cohort, which exclusively included patients with high-risk CLL, found a similar deep-remission rate of 83%.

The study's lead author, Christine Ryan, MD, of Dana-Farber, [presented] the findings at the American Society of Hematology (ASH) Annual Meeting.

The trial, conducted at Dana-Farber, Beth Israel Deaconess Medical Center, Stamford (Conn.) Hospital, and Lifespan Health System, in Rhode Island, involves 68 patients with previously untreated CLL, 41 of whom have a mutation and/or deletion in the TP53 gene in their tumor cells – an abnormality associated with an aggressive form of the disease. Patients are treated with acalabrutinib [Calquence] (a targeted drug), obinutuzumab [Gazyva] (an antibody therapy), and venetoclax [Venclexta] (a targeted agent) on a specified schedule that can continue for up to 16 cycles.

At a median follow-up of 35 months, 83% of the high-risk patients had undetectable minimal residual disease (MRD) – no detectable CLL cells per 100,000 white blood cells – in their bone marrow. And 45% had the deepest measurable response to the treatment: complete remission and undetectable MRD in the bone marrow.

Overall, the treatment was well-tolerated, researchers found, with low rates of cardiovascular problems and infections. After nearly three years of follow-up, 93% of the trial participants were

alive with no advance of their disease. The study has in part supported the development of a large, phase III trial of the regimen for patients with CLL without high-risk disease that has the potential to lead to FDA approval of the regimen.

“Our data provide foundational support for using this triplet therapy in patients with high-risk CLL patients,” says study senior author and principal investigator Matthew Davids, MD, MMSC, of Dana-Farber.

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