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# Drug combination yields results in patients with forms of leukemia or lymphoma

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A combination of two targeted agents - one approved by the Food and Drug Administration and one undergoing testing - has demonstrated safety as well as encouraging signs of effectiveness in a phase 1 clinical trial in patients with relapsed or hard-to-treat chronic lymphocytic leukemia (CLL) or mantle cell lymphoma (MCL). Dana-Farber Cancer Institute researchers will report the findings at the 58th annual meeting of the American Society of Hematology (ASH).

The combination of the approved drug ibrutinib and the novel agent TGR-1202 is being tested in patients to determine if the two agents can be safely given at the same time and whether they lead to more durable remissions in CLL and MCL compared to ibrutinib alone. While ibrutinib, which targets the cell protein BTK, often reduces the amount of cancer in patients with relapsed or drug-resistant CLL or MCL, it rarely eliminates the cancer or generates long-lasting results in MCL or high-risk forms of CLL. By pairing it with TGR-1202, which blocks the P13K-delta protein, researchers hope to disable two key parts of cancer cells' growth circuitry.

As of late July, investigators had treated 28 patients - 17 with CLL, 11 with MCL - with the tandem therapy. The regimen was shown to be safe, with an 800 mg dose of TGR-1202 found to be suitable for further study.

"The efficacy of the combination looks promising as well," said Dana-Farber's Matthew Davids, MD, principal investigator of the investigator-

initiated trial. Davids will present the findings Monday, December 5, at 8 a.m. in Room 5AB of the San Diego Convention Center. "We have already seen a complete response - no evidence of cancer - in one patient with CLL, and several other patients are approaching complete response," Davids added.

Another potential benefit of the two-drug combination is that it could offer greater flexibility in treatment, Davids remarked. Patients who need to discontinue one of the drugs because of temporary complications could continue with the other and resume the two-drug regimen when the complications subside.

While enrollment of patients with CLL in the trial is complete, openings remain for patients with MCL, and the study is open at several sites across the country through the Blood Cancer Research Partnership, a Dana-Farber-led hematologic malignancies research consortium funded through the Leukemia & Lymphoma Society.

Provided by Dana-Farber Cancer Institute