

# **Combination therapy more effective than chemotherapy alone for many newly diagnosed leukemia patients**

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A multi-institutional, Phase II study led by The University of Texas MD Anderson Cancer Center showed that pairing standard chemotherapy azacitidine (AZA) with a drug called enasidenib (ENA) measurably

boosts complete remission in patients newly diagnosed with a specific form of acute myeloid leukemia (AML).

Findings from the randomized, open-label study were presented Dec. 9 at the 61st American Society of Hematology Annual Meeting & Exposition in Orlando, Fla.

"This study looked at AML involving mutations in a gene known as isocitrate dehydrogenase or IDH2," said Courtney DiNardo, M.D., associate professor of Leukemia.. "IDH2 mutations occur in 8% to 19% of patients with AML. This is the first report of interim outcomes from this study, which represent at least one year of follow up for all participating patients. In general, the [combination therapy](#) was well tolerated."

ENA, an oral, small-molecule inhibitor, was approved by the Food and Drug Administration in August 2017 for relapsed or refractory AML in people with specific IDH2 mutations. AZA is a hypomethylating chemotherapy agent that is the [standard treatment](#) for [older patients](#) newly diagnosed with AML.

Between October 2016 and August 2018, 101 patients were randomized to receive either ENA plus AZA, or AZA alone. Median ages were 74 years for the combination group, and 75 years for the AZA only cohort.

Overall response rates for patients receiving both therapies was 68% versus 42% for those receiving AZA alone. Complete remissions were reported in 50% of the combination group versus 12% in the AZA only group. Grade 3-4 [side effects](#) were observed, including low white blood cell count, low platelet count, anemia, IDH differentiation syndrome and low-grade infections.

"These findings are significant, given that the older a patient is, the more

likely they are to have an IDH2 mutation," said DiNardo. "This [combination](#) treatment may offer an alternative option for older patients who may not be candidates for intensive chemotherapy or who have relapsed disease."

Provided by University of Texas M. D. Anderson Cancer Center

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