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Combination therapy shown as effective for higher-risk MDS/AML patients

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A phase two study that investigated the potential of the drugs azacitidine (AZA) and lenalidomide (LEN), demonstrated that the two therapies in combination may be an effective frontline treatment regimen for patients with higher-risk forms of myelodysplastic syndrome and acute myeloid leukemia.

Myelodysplastic syndrome (MDS) is a type of cancer in which the bone marrow does not make enough healthy blood cells, resulting in abnormal (blast) cells in the blood and/or bone marrow. Higher-risk patients experience an unusually large percentage of blasts in their blood. Patients often develop infections, anemia, or excessive bleeding. Acute myeloid leukemia (AML) is a blood cell cancer and is the most common acute leukemia affecting adults, with incidences increasing with age.

The study, led by Guillermo Garcia-Manero, M.D., professor of leukemia at The University of Texas MD Anderson Cancer Center, shed new light on effective dosage schedule and amounts for the drugs, something previously unknown. The combination therapy was well tolerated in the study of 88 patients.

The study results were presented today by Courtney Dinardo, M.D., assistant professor of leukemia, at the 56th Annual Meeting of the American Society of Hematology (ASH) annual conference in San Francisco and were published in the Dec. 5 issue of the ASH journal *Blood*.

"Hypomethylating (HMA) agents such as AZA and LEN are currently the front line of therapeutic choice for patients with higher-risk MDS, and also frequently employed in elderly AML patients not otherwise eligible for standard intensive therapy," said DiNardo. "A number of combination strategies are under development to improve the results of HMA therapy. Given what we know about the effectiveness of AZA and LEN in patients with MDS and AML, a scientific rationale existed to explore this therapeutic combination strategy."

DiNardo's team evaluated the administration of AZA and LEN on days 6 to 10 of a 28-day cycle of treatment. The combination therapy appeared to be effective in patients presenting with as high as 30 percent blasts or abnormal blood/bone marrow cells.

"The responses were rapid with a median of two cycles for the drugs to be effective. Treatment with this dosage and schedule was well tolerated," said DiNardo.

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