Drug combination improves or stabilizes disease for relapsed multiple myeloma patients

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Mayo Clinic researchers have found that a new combination of medications designed to maximize immune functions improved or stabilized multiple myeloma for 76 percent of patients who had relapsed after previous treatment.

Interim results of an ongoing clinical trial evaluating pomalidomide, a new immunomodulatory agent, combined with dexamethasone (pom/dex), were presented today at the 50th Annual Meeting of the American Society of Hematology in San Francisco. Pomalidomide, also referred to as CC-4047, is the latest in the class of immunomodulatory agents that also includes thalidomide and lenalidomide.

Multiple myeloma (http://www.mayoclinic.org/multiple-myeloma/) is a cancer of the plasma cells, a type of white blood cells in the bone marrow, that affects approximately 3 in 100,000 people each year. There is no cure. While the condition can be managed, often with good results, the disease can lead to erosion of the bones, causing bone pain and fractures.

Immunomodulatory drugs work by interfering with cancer cell growth and by stimulating the immune system to attack the cancer cells. The Food and Drug Administration (FDA) has approved the use of thalidomide and lenalidomide to be given with dexamethasone for previously treated cases of multiple myeloma.

The study opened in November 2007 and has accrued 60 patients. To date, 58 percent of patients have responded to therapy with at least a 50 percent drop in the detectable tumor burden as measured by blood protein levels, a marker for myeloma. This included one patient who achieved a complete remission -- no signs of the cancer -- and 14 patients (23 percent) who achieved at least a 90 percent drop in blood proteins. Eleven other patients (18 percent) remained stable.

"These are high remission rates, and they happened quickly," says Martha Lacy, M.D., Mayo Clinic hematologist and lead researcher on the study. Also encouraging, says Dr. Lacy, is that treatment did not cause significant side effects in most patients. Side effects included anemia and declines in blood counts, most often mild in both.

In the study, patients took pomalidomide (2 milligrams [mg]) orally daily for a 28-day cycle. Dexamethasone (40 mg) was taken orally on days 1, 8, 15 and 22 of each cycle. Patients also took 325 mg of aspirin daily to prevent blood clots, a concern associated with immunomodulatory agents. Blood clots can occur with use of any IMiD, but the risk increases as the dose of dexamethasone increases.

The dosage of dexamethasone in the current trial is one-third of the dose that was used in the registration trial that led to FDA approval for lenalidomide in previously treated myeloma patients. "We're getting good results with less toxicity compared to what we've seen in the past," says Dr. Lacy. "And, so far, no patients have had blood clots."

Another key finding was that pom/dex was helpful for 29 percent of patients who previously did not respond to treatment with lenalidomide.

"We are excited about the potential of this drug combination to significantly help patients with myeloma," says Dr. Lacy. "Based on these encouraging results, we are expanding the study to include other

patient populations that may benefit from this therapy."

Source: Mayo Clinic