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New drug improves survival in multiple myeloma relapse

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Researchers at Moffitt Cancer Center and colleagues have investigated the safety, efficacy and the maximum tolerated dose of pomalidomide for patients with multiple myeloma who have disease relapsed after treatments with other drugs, such as bortezomib and lenalidomide. This phase I clinical trial enrolled 38 patients, and pomalidomide provided a minimal or better response for 42 percent of the patients, a partial response or better for 21 percent, and a complete response for 3 percent.

The study, a collaborative effort among researchers from Moffitt, Dana-Farber Cancer Institute, Hackensack University Medical Center, Multiple Myeloma Research Consortium, and Celgene Corporation, appeared in the Dec. 14 issue of *Blood*, the journal of the American Society of Hematology.

According to the authors, almost all multiple myeloma patients treated with bortezomib, lenalidomide or thalidomide relapse, and survival times shorten progressively with each subsequent relapse. Effective new treatments that re-establish tumor response are urgently required to improve outcomes for these patients.

"This open-label, phase I, dose-escalation study was primarily conducted to evaluate the maximum tolerated dose of pomalidomide," said study co-author Daniel Sullivan, M.D., associate center director for clinical investigations at Moffitt. "The secondary objective was to assess safety of pomalidomide when given with or without dexamethasone."

The researchers found that pomalidomide, given in escalating doses (from 2 to 5 mg per day for 21 of 28 days) in combination with low doses of dexamethasone, demonstrated "encouraging activity with manageable toxicity." The researchers noted that there was a low incidence of peripheral neuropathy in their study patients, all of whom had eventually failed past treatment with drugs known to be associated with neurotoxicity. Common adverse events included neutropenia, anemia, thrombocytopenia and fatigue. These adverse events were generally manageable and are not unexpected in this clinical situation.

Ongoing phase II studies have confirmed the safety and efficacy of this drug in patients with relapsed myeloma. The Food and Drug Administration is considering the drug for approval for this patient population.

More information: bloodjournal.hematologylibrary …2-08-450742.full.pdf

Provided by H. Lee Moffitt Cancer Center & Research Institute