

Lenalidomide plus rituximab produces durable responses in mantle cell lymphoma patients

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New research from Moffitt Cancer Center and its collaborators find that the drug combination rituximab plus lenalidomide was effective and produced long-term responses in patients with mantle cell lymphoma. The results from the multicenter phase 2 study were published in the Nov. 5 issue of *The New England Journal of Medicine*.

Mantle [cell lymphoma](#) is a rare form of B-cell non-Hodgkin lymphoma that has a median survival of only 4 to 5 years. The most common type of treatment is an aggressive form of chemotherapy with or without the addition of a drug called rituximab that targets a specific protein on B-cells called CD20. However, these intensive treatments are often associated with significant side effects and are less often used in older patients. Researchers and clinicians hope to improve initial therapies by using more targeted, biological-based regimens to reduce toxicity.

Lenalidomide is an oral drug with different anti-tumor activity, including expansion of immune cells and stimulation of tumor cell death.

Lenalidomide is currently approved by the Food and Drug Administration to treat patients with mantle cell lymphoma whose disease has either relapsed or progressed following two prior therapies.

Moffitt researchers, along with collaborators at Weill Cornell Medical College, assessed the combination of lenalidomide plus rituximab in patients with mantle cell lymphoma who had not received prior

treatment. The patients received the combination treatment for approximately a year followed by a period of low-dose treatment for up to three years to maintain an anti-tumor response.

A total of 38 patients were enrolled in the study from July 2011 through April 2014 at cancer centers throughout the United States.

The combination of lenalidomide and rituximab was very effective in previously untreated [mantle cell lymphoma](#) patients. Ninety-two percent of patients who could be evaluated had either a complete response or a partial response to therapy, with 64 percent of patients achieving a complete response.

The responses to treatment were also durable. Eighty-five percent of patients were alive two years after therapy without experiencing any disease progression.

The most common high-grade immune-associated toxicities during treatment included reduced levels of neutrophils in 50 percent of patients, reduced levels of platelets (13 percent) and anemia (11 percent). The most common non-immune related toxicities were rash in 29 percent of patients, tumor flare (11 percent), and fatigue and pneumonia (8 percent each).

These results are encouraging. "The lenalidomide plus rituximab regimen stands out because it is a low intensity therapy. Usually, standard [treatment](#) with this disease is intensive chemotherapy or aggressive stem cell transplants. We were able to avoid both of those," said Bijal D. Shah, M.D., assistant member of the Malignant Hematology Department at Moffitt.

Lenalidomide is also approved to treat [patients](#) with either multiple myeloma or myelodysplastic syndromes (MDS), and is currently being

investigated in a number of other hematologic malignancies, including chronic lymphocytic leukemia. Moffitt researchers, led by Alan F. List, M.D., CEO of Moffitt Cancer Center, were instrumental in the clinical development and FDA approval of lenalidomide in MDS.

Provided by H. Lee Moffitt Cancer Center & Research Institute

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