

In Part 1 of the phase 2 [STORM \(Selinexor Treatment Of Refractory Myeloma\) study](#), selinexor was administered in combination with dexamethasone to patients with myeloma refractory to either four or five drugs. Based on a median overall response rate of 21 percent, selinexor was then examined in a more uniform population with stringent eligibility criteria in Part 2 of the STORM study, which included 122 patients at 60 sites in the U.S. and Europe. The *New England Journal of Medicine* article reports on the results of Part 2 of the STORM study.

The response rate in this pivotal study was 26.2 percent. Among the responders, efficacy was consistent across subgroups, including patients with high-risk cytogenetics. The trial allowed enrollment of patients with reduced renal function, thrombocytopenia, and neutropenia. Patients had been heavily pretreated with a median of seven prior regimens including up to 10 anti-myeloma agents, and had rapidly progressing disease burden. These characteristics are typical of the growing population of patients with refractory disease who have exhausted available therapies but want to continue treatment.

"STORM Part 2 represents the largest, most heavily pretreated population with MM in a prospective clinical trial to date," said Dr. Chari. "Patients received a median of seven prior therapies over 6.6 years. These patients have no known available therapies with clinical benefit."

"This study proved that a novel, first-in-class drug with a new mechanism of action can kill a patient's cancer cells," said Dr. Jagannath. "This proved that the drug worked in patients who had exhausted every other treatment and who would have been placed on hospice care otherwise."

Results of the STORM Part 2 protocol led the U.S. Food and Drug Administration to grant [accelerated approval to selinexor](#) on July 3.

[Joshua Richter, MD](#), who provided clinical contributions, and [Samir Parekh, MD](#), whose lab performed some of the critical translational research work discussed, are co-authors on the report.

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