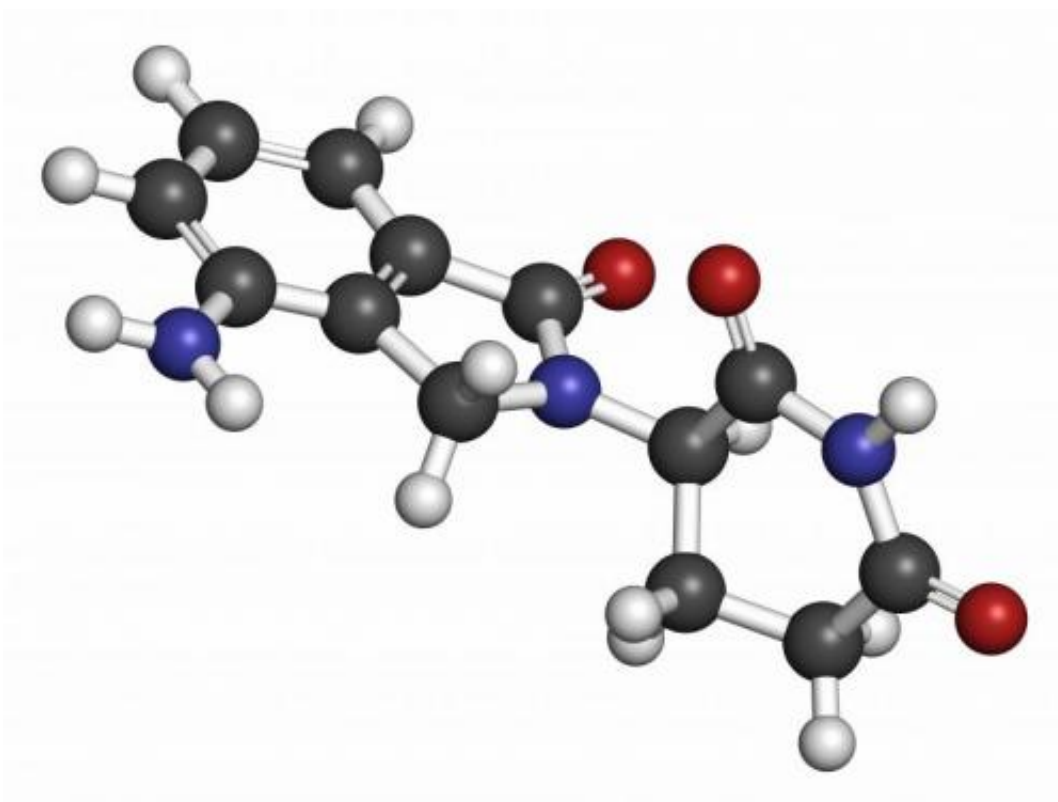


Investigational oral drug combo shows promise for newly diagnosed multiple myeloma

November 17 2014



The investigational drug ixazomib taken orally in combination with lenalidomide and dexamethasone shows promise in patients with newly diagnosed multiple myeloma, according to the results of a phase 1/2

study published in the journal *Lancet Oncology*.

"Ixazomib is an investigational, oral proteasome inhibitor with promising anti-myeloma effects and low rates of peripheral neuropathy," says Shaji Kumar, M.D., a hematologist at Mayo Clinic and lead author of the study. "While it is well known that a combination of bortezomib, lenalidomide and [dexamethasone](#) is highly effective in treating newly diagnosed [multiple myeloma](#), we wanted to study the safety, tolerability and activity of ixazomib in combination with lenalidomide and dexamethasone in newly diagnosed multiple myeloma."

Dr. Kumar and colleagues enrolled 65 patients (15 to phase 1 and 50 to phase 2) between November 2010 and February 2012. Researchers established 2.97 mg/m² as the maximum tolerated dose of ixazomib and recommended the phase 2 dose should be 2.23 mg/m², which was converted to a 4.0 mg fixed dose based on population pharmacokinetic results. Population pharmacokinetics is the study of the sources of variability in drug concentrations among patients receiving the drug based on demographics, body weight, metabolism and other medications.

There were 41 grade 3 or higher [adverse events](#) reported, including skin and subcutaneous tissue disorders neutropenia and thrombocytopenia and drug-related [peripheral neuropathy](#). Five patients discontinued therapy because of adverse events. In 64 response-evaluable patients, 59 (92 percent) had a partial response, including 37 who had a very good partial response or better.

Atoms are represented as spheres with conventional color coding: hydrogen (white), carbon (grey), oxygen (red), nitrogen (blue)."The all-oral combination of weekly ixazomib plus lenalidomide and dexamethasone was generally well tolerated and appeared active in patients with newly diagnosed multiple myeloma," Dr. Kumar says. "Our results support the development of a phase 3 trial studying this

combination for multiple myeloma."

Provided by Mayo Clinic

Citation: Investigational oral drug combo shows promise for newly diagnosed multiple myeloma (2014, November 17) retrieved 29 March 2023 from

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