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## Triple Drug Combination Beats Standard Treatment in Myeloma Trial

A SWOG trial shows bortezomib, lenalidomide, and dexamethasone delays recurrence and lengthens life for myeloma patients, indicating a possible new standard of care

**Portland, Oregon, Dec. 5, 2015** – The addition of bortezomib to a standard two-drug regimen for myeloma patients significantly lengthened the time before their cancer returned, and significantly lengthened their lives, according to new clinical trial results announced today.

The randomized, phase III trial, conducted by SWOG, a publicly funded international cancer clinical trials network, compared the effectiveness of two drug regimes in patients undergoing their first round of treatment for myeloma, a type of bone marrow cancer. One regime used in the study was lenalidomide with dexamethasone, a standard first-line treatment for myeloma patients. The other drug regimen also included bortezomib, a second-line drug typically given to myeloma patients whose cancer progresses after initial therapy.

SWOG researchers found that the addition of bortezomib earlier made a difference for myeloma patients, giving them about another year of remission and another year of life compared to the standard two-drug regime.

Patients receiving bortezomib, along with lenalidomide and dexamethasone, in their first six months of treatment had a median remission time of 43 months compared to a median remission of 30 months for patients who received lenalidomide and dexamethasone alone. Researchers also found that patients who received bortezomib lived a median of 75 months, or about six years, after their initial treatment. Patients who received the standard two-drug treatment lived a median of 64 months, or about five years, after initial treatment.

"Our results are clear," said study principal investigator Brian G.M. Durie, M.D., a physician at Cedars-Sinai Outpatient Cancer Center in Los Angeles and chairman of the board at the International Myeloma Foundation. "Using bortezomib in combination with lenalidomide and dexamethasone in front-line treatment – hitting the disease early and hard – makes a meaningful difference for myeloma patients. Our results represent a potential new standard of care."

Results of the SWOG study, S0777, were presented this morning at the 57<sup>th</sup> Annual Meeting of the American Society of Hematology (ASH) held in Orlando, Florida.



Researchers enrolled 474 eligible adult patients in S0777 between February 2008 and February 2012 at 139 institutions throughout the NCI's National Cancer Trials Network, which includes SWOG, the Alliance for Clinical Trials in Oncology, ECOG-ACRIN Cancer Research Group, and NRG Oncology.

Patients ranged in age from 28 to 87, had active myeloma, and had not had a stem-cell transplant or any prior treatment for their disease. Patients were randomized into two groups. One group received the standard two-drug treatment for six cycles over six months. The other group received a three-drug combination that included bortezomib, a proteasome inhibitor marketed as Velcade by Millennium Pharmaceuticals. These patients received the triple combination therapy for eight cycles over six months.

Despite the increased remission and longevity, the three-drug combination did have a drawback: Patients who received bortezomib were much more likely to experience sensory neuropathy, or tingling, pain, numbness or weakness in their hands and feet. For more study details, see the ASH abstract at <a href="https://ash.confex.com/ash/2015/webprogram/Paper79014.html">https://ash.confex.com/ash/2015/webprogram/Paper79014.html</a>

According to National Cancer Institute (NCI) statistics, in 2015 an estimated 26,850 new cases of myeloma will be diagnosed and 11,240 people will die of the disease.

The NCI provided primary grant funding for S0777 and was the sponsor of the study. Millennium Pharmaceuticals, Inc., The Takeda Oncology Company, and Celgene Corporation provided the study drugs under their respective Cooperative Research and Development Agreements with the NCI.

A national team of SWOG researchers led S0777. Along with Durie, they include: Antje Hoering, Ph.D, of Cancer Research And Biostatistics; S. Vincent Rajkumar, M.D., of Mayo Clinic; Muneer H. Abidi, M.D., of Spectrum Health and Michigan State University; Joshua Epstein, DS.c, of University of Arkansas for Medical Sciences; Stephen P. Kahanic, M.D., of Souixland Regional Cancer Center; Mohan C. Thakuri, M.D., of Southeast Clinical Oncology Research Consortium NCORP; Frederic J. Reu, M.D., of Cleveland Clinic; Christopher M. Reynolds, M.D., of Michigan Cancer Research Consortium NCORP; Rachael Sexton, M.S., of Cancer Research And Biostatistics; Robert Z. Orlowski, M.D., Ph.D, of MD Anderson Cancer Center; Bart Barlogie, M.D., Ph.D, of University of Arkansas for Medical Sciences; and Angela Dispenzieri, M.D., of Mayo Clinic.

**SWOG** is a publicly funded worldwide network of researchers that design and conduct cancer clinical trials. The group's goal is to change medical practice so it improves the lives of people with cancer. The approximately 6,000 physician-researchers in the network practice at more than 950 institutions nationwide and in six other countries. SWOG is part of the NCI's National Clinical Trials Network and is supported primarily through NCI research funding. Learn more at swog.org.