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Results of Major Myeloma Treatment Trial Published in *The Lancet*

A SWOG trial shows that the addition of bortezomib to the standard chemotherapy treatment for myeloma delays recurrence and lengthens life, indicating a possible new standard of care

Portland, Oregon, Dec. 21, 2016 – The addition of bortezomib to a standard two-drug regimen for multiple myeloma patients significantly lengthened the time before their cancer returned, and significantly lengthened their lives, according to clinical trial results in *The Lancet*.

Investigators from SWOG, the international cancer clinical trials network funded by the National Cancer Institute (NCI), compared the effectiveness of two drug regimens in newly diagnosed patients undergoing their first round of treatment for multiple myeloma, a type of bone marrow cancer. One regimen used in the study was lenalidomide with dexamethasone, a standard first-line treatment. 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 made a significant difference for myeloma patients, giving them about another year of remission and another year of life.

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.

“There’s a lot of excitement about these research findings and this treatment option, which helps myeloma patients stay healthier longer and gives them more time to spend with people they love,” said SWOG 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. “Because the research was so solid, and the findings so strong, we’re looking at a potential new standard of care.”

Results of the SWOG study, S0777, first gained attention in December 2015 at the 57th Annual Meeting of the American Society of Hematology (ASH) held in Orlando, Florida. Myeloma is

the second most common blood cancer in the world. According to NCI statistics, in 2016 an estimated 30,330 new cases of myeloma will be diagnosed and 12,650 people will die of the disease in the U.S. In recent years, new drugs have brought new hope, and life expectancy for people diagnosed with multiple myeloma is slowly rising.

SWOG researchers enrolled 471 eligible and consented adult patients in S0777 between February 2008 and February 2012 at 139 institutions throughout the National Cancer Trials Network (NCTN), the nation's oldest and largest publicly funded cancer research network. The NCTN includes SWOG, the Alliance for Clinical Trials in Oncology, ECOG-ACRIN Cancer Research Group, and NRG Oncology, which all enrolled patients to S0777, as well as the Children's Oncology Group, which focuses on pediatric cancers.

S0777 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. That includes lenalidomide, an immunomodulating therapy marketed as Revlimid by Celgene Corporation. 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.

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 global network of researchers that design and conduct cancer clinical trials, and, as part of the Nation Cancer Institute's National Clinical Trials Network, is a major part of the cancer research infrastructure in the U.S. and the world. The group's goal is to change medical practice so it improves the lives of people with cancer. Founded in 1956, SWOG's 1,300 trials have led to the approval of 14 cancer drugs, changed the standard of cancer care more than 100 times, and saved more than 2 million years of human life. Learn more at swog.org.*