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New multiple myeloma drug shows promise in treating people with advanced disease

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A new oral agent under review by the U.S. Food and Drug Administration (FDA) is safe and effective in treating relapsed and treatment-resistant multiple myeloma, according to a multicenter, Phase II study presented by Mount Sinai School of Medicine researchers at the American Society of Hematology (ASH) Annual Meeting. The meeting is taking place December 8-11, 2012 in Atlanta.

A multi-center research team evaluated 113 patients with multiple myeloma who had received at least two prior therapies and had subsequent disease progression to determine safety and efficacy of pomalidomide, a new immunomodulatory drug under review by the FDA. They found significant increases in progression-free survival and overall survival.

"When multiple myeloma no longer responds to two major classes of drugs the average patient survival is only nine months and progression-free survival only five months, representing a significant unmet need for patients with advanced disease," said Sundar Jagannath, MD, Director of the Multiple Myeloma Program and Professor of Medicine at The Tisch Cancer Institute at The Mount Sinai Medical Center and first author on the trial, who presented the trial in an oral abstract session at ASH. "Pomalidomide represents an exciting development for our patients."

Patients were administered four mg/day of pomalidomide plus 40 mg/week of dexamethasone, a steroid used in standard treatment, for 21 days of a 28-day cycle. Progression-free survival was 4.6 months and

overall survival was 16.5 months. The scientists also conducted a subanalysis of this group based on age, as treating older people with multiple myeloma is especially difficult. Progression-free survival was 4.7 months in people under 65 and 3.7 months in people over 65, and overall survival was 19.7 months in people under 65 and 11.8 months in people over 65.

"We have made great strides in prolonging the lives of people with multiple myeloma, increasing overall survival from three years to as high as seven years in less than a decade," said Dr. Jagannath. "These results show that pomalidomide in combination with dexamethasone is a promising new option to extend survival even longer, including in older patients."

Pomalidomide was well-tolerated, with patients experiencing side effects common to this drug class, including low white blood cell count, anemia, pneumonia, and low blood platelet count.

The FDA is expected to decide whether to approve pomalidomide in early 2013.

Dr. Jagannath leads one of the largest multiple myeloma research and treatment programs in the world. He and his team, which includes Ajai Chari, MD, Assistant Professor of Medicine in the Division of Hematology and Oncology, seek to explore new treatments for this deadly cancer and extend survival in patients such that it becomes a chronic disease.

The Multiple Myeloma Program at Mount Sinai is one of the leading programs in the country for the diagnosis and treatment of multiple myeloma and sees patients from around the world. The interdisciplinary approach to patient care means that patients are seen by a team of specialists with expertise in the care of patients with multiple myeloma

and other hematologic malignancies. The program conducted clinical trials with Lenalidomide and Bortezomib, two novel drugs that are now standard of care. As a result, multiple myeloma patients now have access to highly promising clinical studies and the latest treatment breakthroughs.

Dr. Jagannath receives compensation from Celgene Corporation as a scientific and clinical advisor.

Provided by The Mount Sinai Hospital