Novel Daratumumab-Based Regimen Slows Multiple Myeloma Progression

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Contact
Kelly Baldwin
571-483-1365
kelly.baldwin@asco.org

ASCO Perspective

"Here, we’ve seen what can happen for patients when we select the treatment based on a common target in multiple myeloma. The new treatment regimen appears to rapidly slow cancer growth in many patients. This study affirms the efficacy of daratumumab that was seen in earlier, smaller clinical trials in this setting," said ASCO President Julie M. Vose, MD, MBA, FASCO.

CHICAGO – Initial findings from a pivotal phase III trial showed that daratumumab (DARZALEX) added to a standard two-drug regimen (bortezomib and dexamethasone) markedly improved outcomes for patients with recurrent or refractory multiple myeloma.

The daratumumab combination reduced the risk of cancer progression by 70%, and doubled both very good partial response rates from 29% to 59% and complete response rates from 9% to 19%. Daratumumab, the first monoclonal antibody approved for multiple myeloma, targets a protein on the surface of cancer cells called CD-38.

These data will be presented in ASCO’s Plenary Session, which features four abstracts deemed to have the greatest potential to impact patient care, out of the more than 5,000 abstracts featured as part of the ASCO Annual Meeting.

“We’ve suspected for a long time that CD-38 is the major treatment target for multiple myeloma, but these results are unprecedented in this cancer," said lead study author Antonio Palumbo, MD, a chief of the Myeloma Unit at the Department of Oncology, University of Torino in Torino, Italy. “It’s clear now that we’ll be moving to a three-drug regimen with daratumumab as the standard of care.”

About the Study

This first randomized clinical trial of daratumumab included nearly 500 patients with relapsed or
refractory multiple myeloma. Patients received eight cycles of either regimen, followed by daratumumab maintenance therapy for patients in the daratumumab group.

“Daratumumab is a fast-acting drug ? in many cases tumors shrank in just a month. As a result of shrinkage and slower tumor growth, patients had less pain and a better quality of life,” said Dr. Palumbo.

He noted that daratumumab did not substantially worsen the most common side effects of the standard regimen. Patients in the daratumumab group experienced slightly higher rates of hematologic toxicity, infections, and peripheral neuropathy.

Next Steps

Longer patient follow-up is needed to determine the impact of this daratumumab combination on patient survival. A clinical trial that combines daratumumab with another standard therapy for recurrent multiple myeloma is underway. Additional clinical trials are testing various daratumumab-based regimens for patients with newly diagnosed multiple myeloma.

About Daratumumab

Daratumumab is one of the first drugs with the ability to directly kill myeloma cells and at the same time stimulate the immune system response to attack the tumor. The direct effect explains rapid tumor shrinkage, whereas the immune effect sustains prolonged responses to the treatment. The US Food and Drug Administration granted daratumumab accelerated approval in November 2015 based on results from a non-randomized phase II trial.

About Multiple Myeloma

Myeloma is a cancer of plasma cells, which make antibodies to fight infections. Abnormal plasma cells can crowd out or suppress the growth of other cells in the bone marrow. This suppression may result in anemia, excessive bleeding, and a decreased ability to fight infection.

Multiple myeloma is an uncommon cancer. This year, an estimated 30,300 people\textsuperscript{1} in the United States will be diagnosed with multiple myeloma and 114,250\textsuperscript{2} were diagnosed worldwide in 2012. This study received funding from the Janssen Research & Development.

View the full abstract.

For Your Readers:

- Guide to Multiple Myeloma
- Understanding Targeted Therapy
View the disclosures for the 2016 ASCO Annual Meeting News Planning Team.

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