Injectable Darzalex Combo Delays Multiple Myeloma Progression

The injectable formulation can cut administration time from two or more hours to just five minutes.

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Darzalex Faspro, an injectable formulation of daratumumab, nearly doubled progression-free survival time when used as part of a three-drug regimen for people with relapsed or refractory multiple myeloma, researchers reported at the virtual American Society of Hematology (ASH) Annual Meeting.

Darzalex Faspro plus oral Pomalyst (pomalidomide) and dexamethasone reduced the risk of disease progression or death by 37% compared with Pomalyst and dexamethasone alone. What's more, administration of injectable Darzalex takes just five minutes on average, compared with at least two hours—and sometimes the better part of a day—when using the older IV formulation.

"Subcutaneous daratumumab is much easier for the patient and reduces the time they need to spend at the outpatient chemotherapy unit," said presenter Meletios Dimopoulos, MD, of National and Kapodistrian University of Athens.

Darzalex is a monoclonal antibody that binds to the CD38 protein on myeloma cells and helps the immune system recognize and attack the cancer. IV Darzalex plus Pomalyst and dexamethasone is widely used to treat relapsed multiple myeloma. The Food and Drug Administration approved Darzalex Faspro earlier this year, after a study showed that subcutaneous injections work as well as IV infusions and reduce infusion-related reactions.

Dimopoulos presented findings from the Phase III APOLLO study (ClinicalTrials.gov NCT03180736), which compared a three-drug regimen of Darzalex, Pomalyst and low-dose dexamethasone versus Pomalyst and dexamethasone alone. Response rates with Pomalyst and dexamethasone are around 30% to 40%, and median progression-free survival time is about six months, he noted as background.

The trial enrolled 304 people with a median age of 67 who had received at least one prior line of therapy for multiple myeloma, not including Pomalyst or other CD38 inhibitors. Most had developed resistance to Revlimid (lenalidomide), a proteasome inhibitor or both.

The study initially used IV Darzalex, but after a protocol amendment, everyone randomized to the Darzalex arm received the injectable formulation. Injections were given weekly for the first two 28-day cycles, every other week for the next four cycles and then every four weeks. Pomalyst and dexamethasone were taken as pills. Participants were treated until they experienced disease progression or unacceptable side effects.

People who received Darzalex Faspro plus Pomalyst and dexamethasone had a median progression-free survival time of 12.4 months versus 6.9 months for those treated with the two-drug regimen. Overall survival also appeared to improve, but these data are not yet mature and follow-up is continuing.

The overall response rate, meaning complete or partial remission, was 69% with the triple regimen versus 46% with Pomalyst and dexamethasone alone. Very good partial response rates were 51% versus 20%, respectively, and 25% versus 4% had a complete response. People using the triple combination were over four times more likely to achieve minimal residual disease negativity, meaning no evidence of remaining cancer according to the most sensitive tests (9% versus 2%).

Treatment was generally safe, although side effects were common. People who added Darzalex Faspro were more likely than dual therapy recipients to have severe white blood cell deficiencies, including neutropenia (68% versus 51%), and pneumonia (13% versus 7%). Rates of anemia and platelet deficiency were similar in the two groups. However, few people stopped treatment due to side effects in either group (2% versus 3%). About 5% of patients using injectable Darzalex had mild to moderate infusion-related reactions, and 2% had mild local injection site reactions.

“The infusion-related reaction rate was low, and administration duration was short, thus increasing convenience for patients and decreasing treatment burden,” Dimopoulos and colleagues concluded.

Lisa Hicks, MD, of St. Michael’s Hospital and the University of Toronto, who moderated an ASH press conference on this and other studies, noted that injectable Darzalex could relieve the treatment burden for patients as well as saving time for clinic staff.

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