Superior results for myeloma drug that's added earlier in treatment

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(HealthDay)—A recently approved immunotherapy drug for a blood

cancer called multiple myeloma can provide even better benefits if patients receive it earlier in their treatment, new clinical trial results show.

Darzalex (daratumumab) reduced patients' risk of cancer progression by 70 percent when added to a standard two-drug regimen for people with recurring myeloma, said lead researcher Dr. Antonio Palumbo. He is chief of the myeloma unit at the University of Torino department of oncology in Italy.

The new drug essentially doubled the response that doctors expect from the standard regimen of bortezomib (another immunotherapy drug) and dexamethasone (a steroid drug).

About 19 percent of patients given Darzalex had their cancer go into full remission, compared with just 9 percent of those taking the standard treatment, researchers found. "Very good" response rates doubled to 59 percent in the Darzalex group from 29 percent in the standard treatment group.

"It's clear now that we'll be moving to a three-drug regimen, with daratumumab as the standard of care," Palumbo said.

Multiple myeloma is a cancer of the plasma cells that make infection-fighting antibodies, researchers said in background information.

Abnormal plasma cells grow out of control in myeloma, crowding out other blood-generating cells in a person's bone marrow. Anemia, excessive bleeding, and a decreased ability to stave off infections are the result.

Myeloma is relatively uncommon. About 30,330 new cases are expected in 2016, and about 12,650 deaths, the American Cancer Society

estimates.

The U.S. Food and Drug Administration granted accelerated approval to Darzalex last November, for treatment of multiple myeloma patients who have undergone at least three prior rounds of treatment.

Darzalex targets a protein on the surface of cancer cells called CD-38, and appears to attack cancer cells in several ways, said Dr. Amrita Krishnan, a hematologist/oncologist at City of Hope National Medical Center in Duarte, Calif.

The drug stimulates the immune system's ability to attack tumor cells, Krishnan said. At the same time, it can directly kill myeloma cells, causing rapid tumor shrinkage, the researchers said.

Palumbo and his colleagues suspected that Darzalex might produce even stronger results if included earlier in treatment. The team recruited nearly 500 patients who had undergone one or more prior rounds of therapy. Participants were randomly assigned to receive either a three-drug regimen that included Darzalex or the usual two-drug combination.

Patients received eight cycles of either drug regimen, followed by Darzalex maintenance therapy for patients assigned to the three-drug group.

Not only did Darzalex produce superior results, but it did so in a very short period of time, Palumbo said.

"In many cases, tumors shrank in less than a month," he said. "As a result of shrinkage and slower tumor growth, patients had less pain and a better quality of life."

Adding the drug did not substantially worsen the most common side

effects from the standard two-drug regimen, Palumbo added. However, patients receiving Darzalex did have slightly higher rates of blood toxicity, including anemia, infections, and damage to peripheral nerves, the study found.

Krishnan said the clinical trial "sets a new paradigm, suggesting that this is something that should be considered earlier in the course of a patient's therapy."

While it's too soon to tell if Darzalex will provide a significant life-extending benefit to patients, "I do think it is going to be explored as a front-line therapy," Krishnan added.

Palumbo presented the clinical trial findings Sunday at the American Society of Clinical Oncology meeting in Chicago. The study received funding from the drug's marketer, Janssen Biotech of Horsham, Pa.

Research presented at meetings is generally considered preliminary until it's peer-reviewed.

More information: For more on multiple myeloma, visit the American Cancer Society.