Adding Monjuvi Cuts Risk of Follicular Lymphoma Disease Progression

Patients treated with tafasitamab plus two standard drugs saw a 57% reduction in the risk of disease progression or death.

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Patients with follicular lymphoma [who] did not respond to or recurred after prior therapy experienced a 57% reduction in the risk of disease progression, relapse, or death when treated with tafasitamab [Monjuvi] in addition to two standard drugs compared with patients who received a placebo plus these two drugs. This is according to findings presented during the 66th American Society of Hematology (ASH) Annual Meeting and Exposition.

“Addition of the novel immunotherapy agent tafasitamab to a standard regimen that paired another immunotherapy agent, rituximab, with lenalidomide resulted in clinically meaningful improvement in the number of patients benefiting from treatment and in the duration of benefit,” said principal investigator Laurie H. Sehn, MD, MPH, a clinical professor with the BC Cancer Centre for Lymphoid Cancer and the University of British Columbia in Vancouver, Canada. “This regimen represents a potential new standard of care option for patients with relapsed or refractory follicular lymphoma.”

Lymphoma is a type of cancer that begins in the lymph nodes, part of the body’s immune system. Follicular lymphoma is the most common slow-growing form of B-cell lymphoma, Dr. Sehn said. B cells are white blood cells that play a key role in helping the immune system fight infection. The average patient age at diagnosis is about 60. In its early stages, follicular lymphoma may have no symptoms. By the time patients develop symptoms (such as fatigue, fever, unintentional weight loss, and swelling in the neck, armpit, or groin), the disease may be at an advanced stage.

While several treatment options are available for follicular lymphoma, Dr. Sehn said, none of them cure the disease. Although no clear standard of care currently exists for treating patients with relapsed or refractory disease, the two-drug combination of lenalidomide and rituximab is commonly used in this setting, she said.

The goal of this Phase III study, known as the inMIND trial, was to test whether adding tafasitamab to lenalidomide and rituximab would increase both the duration of remission and the number of patients achieving it, she said. Like rituximab, tafasitamab is a monoclonal antibody, a protein

made in a laboratory. Monoclonal antibodies stimulate the immune system to look for, latch onto, and kill cancer cells. Tafasitamab is currently approved by the U.S. Food and Drug Administration for use with lenalidomide to treat diffuse large B-cell lymphoma. Like most monoclonal antibodies, it is given as an intravenous infusion.

A total of 548 patients in 28 countries were enrolled in the inMIND trial. Patients' median age was 64 years and 55% were men; 45% had relapsed or refractory follicular lymphoma having received at least one prior therapy. Many patients' cancer had features making it challenging to treat, such as having come back less than two years after initial diagnosis or after multiple prior therapies, or proven refractory to prior anti-CD20 monoclonal antibody therapy.

All patients received lenalidomide and rituximab and were randomly assigned to additional treatment with either tafasitamab or a placebo. The trial was double-blinded, meaning that neither the patients nor their doctors knew who was in which treatment group until the end of the study.

The trial's primary endpoint was progression-free survival (PFS), defined as the time from start of treatment until a patient's lymphoma worsened, had come back after an initial response, or the patient's death due to any cause. Secondary endpoints included the overall response rate, the proportion of patients who showed no evidence of cancer on a positron emission tomography (PET) scan, the safety of treatment, and overall survival.

After a median follow-up of 14.1 months, the median PFS for patients in the tafasitamab group was 22.4 months, compared with 13.9 months for those in the placebo group, representing a 57% improvement in PFS. Improvement in PFS was consistent across subgroups of patients such as those whose cancer had returned within two years and those who had received multiple prior therapies.

Among patients who received tafasitamab, 83.5% responded to treatment, compared with 72.4% of those who received the placebo. In the tafasitamab group, 49.4% showed no evidence of cancer on a PET scan, compared with 39.8% of those in the placebo group. Rates of adverse events were comparable in the two groups.

Longer follow-up is needed to analyze overall survival, Dr. Sehn said. The investigators will continue to follow the patients in the study for five years, she said.

This study was funded by Incyte, the manufacturer of tafasitamab.

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