Venclexta Provides Sustained Benefit for People With Leukemia

Venclexta alone or in combination with Rituxan improved progression-free survival in patients with chronic lymphocytic leukemia.

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The targeted therapy Venclexta (venetoclax), used alone or in combination with Rituxan (rituxumab), delayed disease progression more than chemotherapy in people with chronic lymphocytic leukemia (CLL), according to studies presented at the American Society of Hematology (ASH) annual meeting last month in San Diego.

CLL, the most common type of adult leukemia, involves overproduction of abnormal white blood cells, usually antibody-producing B cells. These cells can crowd out normal blood cells, leading to anemia, increased susceptibility to infections and other complications.

Although traditional chemotherapy can sometimes put CLL into remission, relapse is common. While chemotherapy works against all fast-growing cells, targeted therapy is directed against cancer cells with specific characteristics. Venclexta blocks the B-cell lymphoma 2 (BCL-2) regulatory protein, which interferes with the normal cell death cycle and allows uncontrolled cancer cell growth.

Venclexta and Minimal Residual Disease

William Wierda, MD, PhD, of the University of Texas MD Anderson Cancer Center in Houston, presented results from an analysis of minimal residual disease (MRD) status in a pair of Phase II clinical trials that evaluated Venclexta monotherapy for people with relapsed or refractory (nonresponsive) CLL.

MRD refers to traces of cancer cells that remain after treatment. Out of 285 total participants in the two studies, 161 had available data on MRD status in their bone marrow or peripheral blood.

Just over half (52 percent) achieved undetectable MRD in their blood and another 38 percent had low-level MRD, Wierda reported. Among those with available bone marrow data, 36 percent had undetectable MRD and 32 percent had low MRD. More than 90 percent of patients had concordant, or matching, blood and bone marrow MRD results. This differs from chemotherapy, where MRD is typically 10 times higher in the bone marrow than in the peripheral blood, the researchers noted.

Undetectable or low-level MRD in the blood and bone marrow was associated with longer progression-free survival (PFS). Two years after starting treatment, 90 percent of people with undetectable MRD and 72 percent of those with low MRD in their blood were still alive without disease progression, compared with 34 percent of those with high blood MRD.

Venclexta Plus Rituxan

Two ASH presentations described findings from the Phase III MURANO trial, which compared Venclexta versus the chemotherapy drug bendamustine, both in combination with Rituxan, a monoclonal antibody that targets the CD20 receptor on malignant B cells. Venclexta is a once-daily pill while Rituxan and bendamustine are given by IV infusion.

The study included 389 people with relapsed or refractory CLL. Half were randomly assigned to take Venclexta plus Rituxan for six monthly cycles, followed by Venclexta alone for a total of two years of treatment. The others received bendamustine plus Rituxan for six cycles.

Previously reported interim results showed that people randomly assigned to Venclexta plus Rituxan had improved progression-free survival compared with those who used the chemotherapy regimen. At ASH, Arnon Kater, MD, of the University of Amsterdam, and John Seymour, MBBS, PhD, of Royal Melbourne Hospital in Australia, presented updated findings after all participants had finished treatment. Study results were also published in the Journal of Clinical Oncology.

The new results showed continued benefit with the Venclexta combination. After a median follow-up period of three years, the PFS rate was nearly five times higher in the Venclexta plus Rituxan group compared with the bendamustine plus Rituxan group (71 percent versus 15 percent, respectively). The median progression-free survival duration was 17 months in the chemotherapy arm but was not reached in the Venclexta arm because a majority of patients were still doing well.

People who took the Venclexta regimen were more likely than those in the chemotherapy group to have undetectable MRD in their blood—defined as less than one leukemia cell per 100,000 white blood cells—at the end of combination therapy (62 percent versus 13 percent). The difference was even greater at the end of all therapy at two years (48 percent versus 2 percent, respectively).

People with undetectable MRD at the end of combination therapy had improved PFS compared with those who had low-level MRD, who in turn did better than those with high-level MRD. Just 2 percent of Venclexta recipients with undetectable MRD experienced disease progression, compared with 13 percent of those with low-level MRD and 79 percent of those with high-level MRD. Here too, there was 90 percent agreement between MRD status in the peripheral blood and bone marrow.

“Undetectable MRD rates were durable and predicted longer PFS,” the researchers concluded. “Low conversion to detectable MRD and sustained PFS after completion of two years of venetoclax-rituximab demonstrate the feasibility of this regimen.”

Click here for the MURANO study report in the Journal of Clinical Oncology.

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