FDA Approves Targeted Therapy Combo for Leukemia

Imbruvica plus Gazyva is the first chemotherapy-free regimen for chronic lymphocytic leukemia.

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On January 28, the Food and Drug Administration approved a combination of two targeted therapies, Imbruvica (ibrutinib) and Gazyva (obinutuzumab), as the first non-chemotherapy initial regimen for people with chronic lymphocytic leukemia (CLL) and the similar blood cancer small lymphocytic lymphoma (SLL).

The approval—the 10th for Imbruvica—was based on a study showing that the combination significantly improved progression-free survival compared with standard therapy.

CLL is the most common type of leukemia in adults. More than 15,000 people—mostly older adults—will be diagnosed with CLL this year, according to the American Cancer Society. This type of 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. SLL is a slow-growing type of lymphoma in which immature white blood cells build up in lymph nodes.

Imbruvica is an inhibitor of Bruton's tyrosine kinase (BTK), which plays a role in the development of B cells that grow out of control in people with leukemia. It was approved as a secondary treatment for CLL in 2014 and for first-line therapy in 2016; it is also approved for certain other blood cancers. Gazyva is a monoclonal antibody that targets the CD20 receptor on malignant B cells. Imbruvica is taken as a once-daily pill while Gazyva requires IV infusion in monthly cycles.

As reported at the recent 2018 American Society of Hematology Annual Meeting and in Lancet Oncology, the Phase III iLLUMINATE trial compared Imbruvica plus Gazyva versus Gazyva plus the chemotherapy drug chlorambucil in 229 previously untreated patients with CLL or SLL who were either 65 or older or had coexisting conditions that made it difficult to tolerate intensive chemotherapy.

The study showed that Imbruvica plus Gazyva reduced the risk of disease progression or death by 77 percent. The reduction was even greater, at 85 percent, for a subset of patients with genetic risk factors for disease progression.

The median progression-free survival, meaning participants were still alive without worsening of disease, was 19 months in the Gazyva/chlorambucil group but was not reached in the Imbruvica/Gazyva group because a majority of patients were still doing well. The estimated 30-month progression-free survival rates were 31 percent and 79 percent, respectively. The median overall survival has not yet been reached in either group.

The overall response rate was 88 percent (including 19 percent complete response) in the Imbruvica/Gazyva group compared with 73 percent (including 8 percent complete response) in the Gazyva/chlorambucil group. Just over a third of people taking Imbruvica/Gazyva and a quarter of those taking Gazyva/chlorambucil achieved undetectable minimal residual disease status, meaning no detectable cancer cells remained in the bone marrow or circulating blood.

Treatment with Imbruvica plus Gazyva was safe, though side effects were frequent. The most common adverse events included diarrhea, rash, infusion reactions, muscle and joint pain and depletion of white blood cells (neutropenia) and platelets (thrombocytopenia), which can lead to infections and easy bleeding. Potentially serious side effects include severe bleeding, heart rhythm abnormalities and tumor lysis syndrome (metabolic abnormalities that can occur when many cancer cells are killed at once).

“This latest Imbruvica FDA approval gives the health care community the first chemotherapy-free, anti-CD20 combination to treat CLL and SLL patients who have not yet started therapy. Also, and importantly, this new treatment combination helps reduce the need for chemotherapy,” iLLUMINATE lead investigator Carol Moreno, MD, PhD, of Hospital de la Santa Creu Sant Pau in Barcelona, said in a press release from AbbVie, which developed Imbruvica in collaboration with Janssen.

Researchers are currently evaluating a chemotherapy-sparing triple combination of Imbruvica, Gazyva and Venclexta (venetoclax) in two Phase III studies (NCT03737981 and NCT03701282).

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