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The U.S. Food and Drug Administration today approved Gazyva (obinutuzumab) for use in combination with chlorambucil to treat patients with previously untreated chronic lymphocytic leukemia (CLL).

CLL is a blood and bone marrow disease that usually gets worse slowly. According to the National Cancer Institute, 15,680 Americans will be diagnosed and 4,580 will die from the disease this year.

Gazyva works by helping certain cells in the immune system attack cancer cells. Gazyva is intended to be used with chlorambucil, another drug used to treat patients with CLL.

Gazyva is the first drug with breakthrough therapy designation to receive FDA approval. This designation was requested by the sponsor and granted soon after the biologic license application to support marketing approval was submitted to the FDA. The FDA can designate a drug a breakthrough therapy at the request of the sponsor if preliminary clinical evidence indicates the drug may offer a substantial improvement over available therapies for patients with serious or life-threatening diseases.

The FDA also granted Gazyva priority review because the drug demonstrated the potential to be a significant improvement in safety or effectiveness in the treatment of a serious condition. And the FDA granted Gazyva orphan product designation because it is intended to treat a rare disease.

“Today’s approval represents an important new addition to the treatments for patients with CLL,” said Richard Pazdur, M.D., director of the Office of Hematology and Oncology Products in the FDA’s Center for Drug Evaluation and Research. “This approval reflects the promise of the Breakthrough Therapy Designation program, allowing us to work collaboratively with companies to expedite the development, review and availability of important new drugs.”

Gazyva’s approval for CLL is based on a study of 356 participants in a randomized open-label multicenter trial comparing Gazyva in combination with chlorambucil to chlorambucil alone in participants with previously untreated CLL. Participants receiving Gazyva in combination with chlorambucil demonstrated a significant improvement in progression free survival: an average of 23 months compared with 11.1 months with chlorambucil alone.

The most common side effects observed in participants receiving Gazyva in combination with chlorambucil were infusion-related reactions, a decrease in infection-fighting white blood cells (neutropenia), a low level of platelets in the blood (thrombocytopenia), low red

blood cells (anemia), pain in the muscles and bones (musculoskeletal pain), and fever (pyrexia).

Gazyva is being approved with a boxed warning regarding Hepatitis B virus reactivation and a rare disorder that damages the material that covers and protects nerves in the white matter of the brain (progressive multifocal leukoencephalopathy). These are known risks with other monoclonal antibodies in this class and rare cases were identified in participants on other trials of Gazyva. Patients should be advised of these risks and assessed for Hepatitis B virus and reactivation risk.

Gazyva is marketed by Genentech, a member of the Roche Group, based in South San Francisco, Calif.

For more information:

FDA: Office of Hematology and Oncology Products
FDA: Breakthrough Therapies
FDA: Drug Innovation
FDA: Approved Drugs: Questions and Answers
NCI: Chronic Lymphocytic Leukemia

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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