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New treatment for adults with relapsed or refractory acute lymphoblastic leukemia

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Besponsa is a targeted therapy that is thought to work by binding to B-cell ALL cancer cells that express the CD22 antigen, blocking the growth of cancerous cells.



Singapore- The U.S. Food and Drug Administration today approved Besponsa (inotuzumab ozogamicin) for the treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

"For adult patients with B-cell ALL whose cancer has not responded to initial treatment or has returned after treatment, life expectancy is typically low," said Richard Pazdur, M.D., director of the FDA's Oncology Center of Excellence and acting director of the Office of Hematology and Oncology Products in the FDA's Center for Drug Evaluation and Research. "These patients have few treatments available and today's approval provides a new, targeted treatment option."

B-cell precursor ALL is a rapidly progressing type of cancer in which the bone marrow makes too many B-cell lymphocytes, an immature type of white blood cell. The National Cancer Institute estimates that approximately 5,970 people in the United States will be diagnosed with ALL this year and approximately 1,440 will die from the disease.

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The FDA granted this application Priority Review and Breakthrough Therapy designations. Besponsa also received Orphan Drug designation, which provides incentives to assist and encourage the development of drugs for rare diseases.

The FDA granted the approval of Besponsa to Pfizer Inc.