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Pfizer has announced that investigational antibody-drug conjugate (ADC) inotuzumab ozogamicin received Breakthrough Therapy designation from the U.S. Food and Drug Administration (FDA) for acute lymphoblastic leukemia (ALL).

The Breakthrough Therapy designation was based on the results of the Phase 3 INO-VATE ALL trial, which enrolled 326 adult patients with relapsed or refractory CD22-positive ALL and compared inotuzumab ozogamicin to standard of care chemotherapy. Topline results from the trial were announced in April 2015 and also presented at the 20th Congress of the European Hematology Association (EHA).

"Inotuzumab ozogamicin is the third Pfizer oncology medicine to be granted Breakthrough Therapy designation by the FDA, underscoring our commitment to innovative research and development that addresses significant unmet needs. Breakthrough Therapy designation will allow us to work more closely with the FDA to bring this important therapy to patients as rapidly as possible," said Dr Mace Rothenberg, senior vice-president of Clinical Development and Medical Affairs and chief medical officer for Pfizer Oncology. He added, "Advancing therapies for patients with adult acute lymphoblastic leukemia is crucial as only 10 percent of adults with ALL who relapse after first-line therapy survive five years or more with current treatment options."

Enacted as part of the 2012 FDA Safety and Innovation Act (FDASIA), Breakthrough Therapy designation is intended to expedite the development and review of a potential new medicine if it is "intended to treat a serious or life-threatening disease and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies." The Breakthrough Therapy designation is distinct from the FDA's other mechanisms to expedite drug development and review.