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Antibody-based drug helps 'bridge' leukemia patients to curative treatment

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In a randomized Phase III study of the drug inotuzumab ozogamicin, a statistically significant percentage of patients with acute lymphoblastic leukemia (ALL) whose disease had relapsed following standard therapies, qualified for stem cell transplants.

Inotuzumab ozogamicin, also known as CMC-544, links an antibody that targets CD22, a protein found on the surface of more than 90 percent of ALL cells. Once the drug connects to CD22, the ALL cell draws it inside and dies.

The study, which revealed complete remission rates of nearly 81 percent and significantly longer progression-free and higher overall survival rates than with standard therapies, was conducted at The University of Texas MD Anderson Cancer Center. Study findings were reported in the June 12 online issue of the *New England Journal of Medicine*.

"Forty-one percent of ALL patients in the study were able to proceed to transplant after receiving inotuzumab ozogamicin compared with the 11 percent we have seen qualify through standard chemotherapy," said Hagop Kantarjian, M.D., chair of Leukemia. "Given that stem cell transplant is considered the only curative treatment option, the ability of inotuzumab ozogamicin to increase the number of patients able to bridge to transplant is encouraging."

Donor stem cell transplants generally are considered curative for this aggressive form of leukemia with more than 6,500 American adults

expected to be diagnosed with the disease in 2016. However, patients must be in complete remission before they are eligible for transplant.

Current therapies for adults with newly diagnosed B-cell ALL result in complete remission rates (CR) of 60 to 90 percent. However, many of those patients will relapse and only about 30 to 50 percent will achieve long-term, disease-free survival lasting more than three years.

"Standard chemotherapy regimens result in complete remission in 31 to 41 percent of patients who relapse earlier, and just 18 to 25 percent in those who relapse later," said Kantarjian. "Patients in the inotuzumab ozogamicin study had remission rates of 58 percent, higher than previously reported, possibly due to patients being treated later in the disease course."

The study reported moderate side effects, the most common being cytopenia, a disorder that reduces blood cell production, and liver toxicity. Funding was provided by Pfizer, Inc.

Provided by University of Texas M. D. Anderson Cancer Center