

Rituxan approved for most common type of leukemia

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Last night, the Food and Drug Administration announced its approval of [Rituxan](#) (rituximab) in combination with fludarabine and cyclophosphamide (FC) for the treatment of CD20-positive chronic lymphocytic leukemia. The combination can be given to CLL patients who have not received previous treatment as well as those whose cancer has not responded to other drugs.

The agency based its decision on two phase 3 studies. The first trial showed progression-free survival--the amount of time patients lived without the disease getting worse--was eight months longer (39.8 months versus 31.5 months) in patients who received Rituxan plus FC compared with patients who received FC alone. In the second study, patients on the Rituxan combo lived five months longer without disease progression than patients receiving chemotherapy alone (26.7 months versus 21.7 months).

Already approved for non-Hodgkin lymphoma, Rituxan is a monoclonal antibody that works by targeting the CD20 protein that is found at high levels on cancerous B cells. Side effects of the drug can include fever, chills, headache, and, rarely, infusion reactions (Rituxan is administered intravenously).

About 16,000 people in the U.S. are diagnosed with CLL each year, making it the most common type of adult leukemia.

Rituxan becomes the third drug approved for CLL in the past two years. The FDA gave the green light to Arzerra (ofatumumab) last October for patients whose cancer stopped responding to other forms of chemotherapy, and Treanda (bendamustine) received the FDA's OK in March 2008 for patients who had not received prior treatment.

Watch for our feature on CLL in *CURE's* Summer issue, which drops in June. And for more, visit our [leukemia](#) page.