MedicalXpress

Blincyto approved for rare leukemia

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(HealthDay)—Blincyto (blinatumomab) has been approved by the U.S. Food and Drug Administration to treat Philadelphia chromosome-negative precursor B-cell acute lymphoblastic leukemia, a rare cancer of the bone marrow.

The cancer occurs when the bone marrow makes too many B-cell lymphoblasts, a type of white blood cell. Some 6,000 Americans are projected to contract acute lymphoblastic leukemia this year, and more than 1,400 will die from it, the U.S. National Cancer Institute estimates.

Blincyto spurs the body's immune system to fight the disease, the FDA said Wednesday in a news release. It's the first approved drug that engages the body's disease-fighting T-cells to destroy leukemia cells, the agency said. The drug is sanctioned for people who have tried at least one previous therapy or who have seen their cancer return.

The drug's safety and effectiveness were evaluated in a clinical study involving 185 adults with the disease. After at least four weeks of treatment, 32 percent of participants had no evidence of the cancer for about six months.

"Immunotherapies, especially Blincyto with its unique mechanism of action, are particularly promising for patients with leukemia," said Dr. Richard Pazdur, director of the Office of Hematology and Oncology Products in the FDA's Center for Drug Evaluation and Research.

Blincyto's label includes a boxed warning that some clinical trial

participants had low blood pressure and difficulty breathing, or had nervous system impairment including difficulty thinking, the FDA said. More common side effects included fever, headache, tissue swelling, low white blood cell count, nausea, low potassium level, fatigue, constipation, diarrhea and tremor.

The drug is marketed by Amgen, based in Thousand Oaks, Calif.

More information: The FDA has more about this approval.