Experimental agent may help older people with chronic leukemia

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The experimental drug ibrutinib (PCI-32765) shows great promise for the treatment of elderly patients with chronic lymphocytic leukemia (CLL), according to interim findings from a clinical trial.

The phase I/II trial, co-led by researchers at the Ohio State University Comprehensive Cancer Center – Arthur G. James Cancer Hospital and Richard J. Solove Research Institute (OSUCCC – James) and MD Anderson Cancer Center, indicates that the oral agent has few side effects and a high one-year survival rate in older patients.

Ibrutinib is the first drug designed to target Bruton's tyrosine kinase, a protein that is essential for CLL-cell survival and proliferation. CLL is the most common form of leukemia, with about 16,000 new cases occurring annually in the United States. About 4,600 Americans die each year of the disease, which is incurable.

Study co-leader Dr. John C. Byrd, director of the division of hematology and a CLL specialist at OSUCCC – James, will present the findings at the 2012 annual meeting of the American Society of Clinical Oncology (ASCO) in Chicago.

"This interim report indicates that older patients respond well to this oral, targeted therapy, which lacks many of the side effects of chemotherapy and produces a quite dramatic one-year progression-free survival," says Byrd.

"The high overall response rate and lack of side effects suggests that ibrutinib deserves further study as a first-line treatment in elderly CLL patients," he says.

Standard treatment for CLL involves use of the chemotherapeutic drug fludarabine, Byrd says. These regimens can effectively control the disease until drug resistance arises, but fludarabine has serious side effects, and sometimes causes death, in older patients. For these reasons, new treatment approaches are needed for older CLL patients.

The study involves 31 patients aged 65 or older with active CLL who require stem-cell transplantation for treatment. Of these patients, 26 were randomized to receive a drug dose of 420 milligrams (mg) and five received a drug dose of 840 mg.

Of patients receiving 420 mg, 8 percent had no sign of disease and 65 percent showed improvement in their disease, and an estimated 93 percent would show no change in their condition.

Provided by Ohio State University Medical Center