MedicalXpress

Novel experimental agent is highly active in CLL patients, interim study shows

December 11 2011

An interim analysis of a phase Ib/II clinical trial indicates that a novel experimental agent for chronic lymphocytic leukemia (CLL) is highly active and well tolerated in patients who have relapsed and are resistant to other therapy. The agent, called PCI-32765, is the first drug designed to target Bruton's tyrosine kinase, a protein essential for CLL-cell survival and proliferation. CLL is the most common form of leukemia, with about 15,000 new cases annually in the U.S. About 4,400 Americans die of the disease each year.

Study co-leader Dr. John C. Byrd, director of the division of hematology at Ohio State University Comprehensive Cancer Center – Arthur G. James Cancer Hospital and Richard J. Solove Research Institute (OSUCCC – James) is available to discuss the findings that were presented today (12/13) at the 53rd Annual Meeting of the American Society of Hematology in San Diego.

Study co-leader Dr. Susan O'Brien of The University of Texas M.D. Anderson Cancer Center reported the analysis, which involves 61 patients who have relapsed and whose cancer no longer responds to standard CLL therapy. Of these patients, 27 received a drug dose of 420 milligrams (mg) and 34 received a drug dose of 840 mg.

This study found that 70 percent of patients in the 420-mg group had either a complete or partial remission to treatment after 10 months of follow-up.

"These interim findings are truly exciting because they provide additional evidence that PCI-32765 is a highly active oral therapeutic that produces a high rate of durable remissions – the remissions last months on end – with acceptable toxicity in relapsed and refractory CLL," Byrd says. "These responses last for many months in part because patients are willing to remain on the drug since the side effects are very tolerable," he notes.

Complete remission means there is no detectable CLL anywhere in the body; partial remission means that the individual's disease volume has decreased 50 percent or more in a sustained manner.

Patients enrolled in this cohort of the ongoing phase II clinical trial are individuals with relapsed CLL, all of whom had two or more earlier treatments followed by recurrent disease.

"Usually patients with highly resistant and refractory CLL would have progressed and possibly died by this time, but 82 percent remain on PCI-32765 and continue to improve." Byrd says.

Provided by Ohio State University Medical Center