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

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An interim analysis of a phase II clinical trial indicates that a novel experimental agent for chronic lymphocytic leukemia (CLL) is highly active and well tolerated both in patients who are undergoing treatment for the first time and those 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, whose function is essential for CLL-cell survival and proliferation.

Study 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) presented the findings June 5 at the 2011 American Society of Clinical Oncology annual meeting in Chicago

The analysis involved the first 21 cases in the untreated-patient group and the first 27 individuals in the relapsed/refractory-patient group. One patient in each group had a complete remission, and 13 patients (62 percent) in the previously untreated group and 12 patients (44 percent) in the relapsed group had partial remissions.

"We are excited about these early findings because they suggest 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.

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

"It is exciting to see a drug that was shown to be active in the laboratory translate to clinical benefit for CLL patients," says researcher Dr. Amy Johnson, assistant professor of medicine at the OSUCCC – James. Johnson co-led the pre-clinical CLL work at Ohio State with Byrd and now coordinates several correlative studies for this clinical trial.

Byrd stresses that the patients show several benefits of the treatment, such as higher platelet counts and hemoglobin levels, and that many report that they feel dramatically better overall with less fatigue, factors that are difficult to measure and report as a number.

"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.

The ongoing phase II clinical trial involves 78 patients with previously untreated or relapsed and refractory CLL or small lymphocytic leukemia . The previously untreated patients were all age 65 or older; individuals in the relapsed group all had two or more earlier treatments followed by recurrent disease.

"These are early findings, so patients with partial remissions could improve to complete remissions with further observation," Byrd says. "Usually patients with highly resistant and refractory CLL would have progressed and possibly died by this time, but 85 percent remain on PCI-32765 and continue to improve."

Provided by Ohio State University Medical Center