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

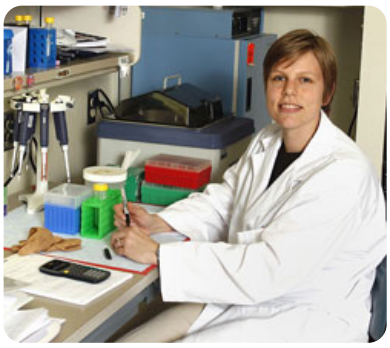
An interim analysis of a phase II clinical trial indicates that a novel experimental agent for chron lymphocytic leukaemia (CLL) is highly active and well tolerated both in patients who are undergoing treatment for the first time and those who have relapsed and are resistant to other therapy.

Study leader Dr. John C. Byrd: "Early findings suggest that PCI-32765 is a highly active oral therapeutic that produces a high rate of durable remissions."

The agent, called PCI-32765, is the first drug designed to target Bruton's tyrosine kinase, whose function essential for CLL-cell survival and proliferation.

Study leader Dr. John C. Byrd, director of the division of haematology at Ohio State University Comprehensive Cancer Centre - Arthur G. James Cancer Hospital and Richard J. Solove Research Institu (OSUCCC - James) presented the findings 5 June at the 2011 American Society of Clinical Oncology annual meeting in Chicago.

Early findings excite



Dr. Amy Johnson: “It is exciting to see a drug that was shown to be active in the laboratory translate to clinical benefit for CLL patients.”

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%) in the previously untreated group and 12 patients (44%) in the relapsed group had partial remission

"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 t the individual's disease volume has decreased 50% 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.

Several benefits from the treatment

Byrd stresses that the patients show several benefits of the treatment, such as higher platelet counts and haemoglobin 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 th 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 leukaemia. 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% remain on PCI-32765 and continue to improve."

Funding from Pharmacyclics, Inc., supported the clinical trial reported here. Funding from the D. Warren Brown Foundation, Leukaemia and Lymphoma Society, National Cancer Institute, and the Harry Mangurian Foundation supported the pre-clinical work with PCI-32765 in CLL performed by Byrd and Johnson.

John Byrd is an unpaid consultant and member of the scientific advisory board for Pharmacyclics, Inc.

The Ohio State University Comprehensive Cancer Centre - Arthur G. James Cancer Hospital and Richard Solove Research Institute (http://cancer.osu.edu) is one of only 40 Comprehensive Cancer Centres in the United States designated by the National Cancer Institute. Ranked by US News & World Report among th top cancer hospitals in the nation, The James is the 205-bed adult patient-care component of the cancer program at The Ohio State University. The OSUCCC-James is one of only seven programs in the country funded by the NCI to conduct both Phase I and Phase II clinical trials.

Source: Ohio State University