

New cancer treatment gives hope to lymphoma and leukemia patients

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Cancer researchers have high hopes for a new therapy for patients with certain types of lymphoma and leukemia.

PCI-32765 is a new drug being assessed in a Phase I clinical trial at the Virginia G. Piper Cancer Center in collaboration with the Clinical Division of the Translational Genomics Research Institute (TGen).

This is one of 35 such trials under way through a partnership between the Virginia G. Piper Cancer Center at Scottsdale Healthcare and TGen, which enables molecular and genomic discoveries to reach patients through Phase I trials as quickly as possible.

"Progress in developing new treatments for cancer has been painfully slow as only 2-4 percent of all cancer patients enroll in clinical trials. This is especially true for uncommon cancers such as leukemia's and lymphomas," said Dr. Raoul Tibes, Director of the Hematological Malignancies Program at the Virginia G. Piper Cancer Center and an Associate Investigator at TGen.

Clinical trials test the safety and effectiveness of new drugs prior to approval by the U.S. Food and Drug Administration. Participants are volunteers for whom other cancer treatments have failed. Arizona is one of many states in which clinical trials often are covered by health insurance.

"This study is going very well. It is a very promising agent," Dr. Tibes



said of PCI-32765, which uniquely targets the molecular abnormalities of lymphoma cells. "This is a recently identified cancer mechanism that we are going after with this drug in <u>lymphoma cells</u>."

Bruton-tyrosine-kinase, or Btk, is an enzyme needed to maintain Blymphocytes function. B- lymphocytes are the cells that make antibodies for the immune system.

Too little Btk causes a disease called Bruton's agammaglobulinemia, in which the B-lymphocytes fail to mature and produce antibodies, leading to infections.

Too much Btk is involved in constantly stimulating the proliferation and spread of lymphoma and <u>leukemia cells</u>.

PCI-32765, produced by Pharmacyclics of Sunnyvale, Calif., inhibits Btk. Preclinical studies showed PCI-32765 arrested cancer cell growth and caused cancer cell death.

"This is the Yin and Yang of two diseases," said Dr. Tibes. In one there is not enough Btk; in the other, too much. "We are exploiting a natural occurring phenomenon, an enzyme that is turned around in <u>cancer</u>, and now we have a drug against it."

Dr. Tibes, the principal investigator for the clinical trial, said PCI-32765 is at the frontier of research and offers a new therapy option for patients with advanced lymphomas and chronic lymphocytic leukemia.

Patients with a variety of lymphomas can participate in the clinical trial, including those with aggressive diffuse large B-Cell and mantle cell lymphoma, as well as patients with follicular lymphoma.

"Perhaps there is a genetic context under which certain patients may be



more responsive. We want to find those patients and explore the possibilities for their benefit in this ongoing study," said Dr. Ramesh K. Ramanathan, research medical director.

Provided by The Translational Genomics Research Institute

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