

KineMed Reports Data Demonstrating New Insights into the Cellular Progression of Chronic Lymphocytic Leukemia (CLL)

Tuesday March 1, 7:30 am ET

Results Could Alter How CLL is Treated in the Future

EMERYVILLE, Calif., March 1 /PRNewswire/ -- KineMed, Inc., a platform-based drug development and advanced medical diagnostics company, today announced the publication of data in the March 1 print issue, February 10 online issue, of the Journal of Clinical Investigation demonstrating new insights into the natural history and progression of chronic lymphocytic leukemia (CLL). Data generated by KineMed and reported in this article show for the first time that CLL is not a static disease that results from the accumulation of long-lived lymphocytes but rather it is a dynamic process composed of cells that proliferate, die and reproduce at an aggressive rate. Prior to the publication of this paper it was believed that CLL cells proliferate at a very slow rate and do not die.

"We believe that these results have the potential to change the way we currently treat CLL by helping us identify the form of the disease that someone has in its early stages of development," said Nicholas Chiorazzi, MD, lead author and director and CEO of the Institute for Medical Research, which is part of the North Shore-Long Island Jewish Health System in Manhasset, N.Y. "Furthermore, researchers may now have a new target for drug therapies by interrupting the reproduction of CLL cells. Old ideas need to be revised based on new information that the heavy water studies have provided."

About the Study: the kinetics of cells in living organisms including humans

In the study, investigators used an assay referred to as the KineMarker(TM) test, developed by researchers at KineMed and the University of California at Berkeley. This assay measures the rates of proliferation and death of CLL cells in vivo. A total of nineteen people with CLL were given a solution of "heavy" water to drink. Heavy water is a safe, non-radioactive substance that is identical to normal tap water except that it contains an atom of deuterium, a non-radioactive substance detectable by mass spectrometry. Cells that divide in vivo incorporate the deuterium label into newly synthesized DNA. This technique is easily administered, well tolerated, and without toxicities. Heavy water can be taken for weeks or months, thereby allowing the dynamic behavior of CLL cells to be monitored over extended periods. The study volunteers drank two ounces of the heavy water every day for 84 days. The researchers also took blood samples for an additional three months, which allowed them to track the death and birth rates (cellular kinetics) of CLL cells.

Study Results

The results demonstrated that CLL cells of each patient had definable and often substantial birth rates. This observation ran counter to the classic dogma in the CLL field, as CLL has generally been envisioned as a disorder characterized by an impairment of cell death, thereby resulting in the slow accumulation over time of long-lived cells. Moreover, those patients with more aggressive birth rates were much more likely to exhibit active or to develop progressive disease than those with lower birth rates. This study highlights the dynamic nature of CLL cells and shows for the first time sizable rates of birth and death in these cells.

"It is gratifying that our technology has again revealed, in another disease state, a new understanding of pathogenesis," commented David Fineman, President and CEO of KineMed.

"Our proprietary technology is also being used to gain insights into other disease states in areas, such as neurobiology, immunology, and metabolic diseases. In the case of CLL, a common and important disease, this test arms the physician with the information necessary to make better decisions. The KineMarker(TM) technology also provides drug developers information to advance compounds rapidly and efficiently to approvals."

About Chronic Lymphocytic Leukemia (CLL)

Chronic Lymphocytic Leukemia (CLL) is a monoclonal disorder characterized by an accumulation of abnormal lymphocytes, a type of white blood cell, in the blood and the bone marrow. The lymphocytes in CLL cannot fight infection effectively, and as the number of lymphocytes increases, there is less room for healthy white blood cells, red blood cells, and platelets. This may result in immune deficiency, infection, anemia, and easy bleeding.

CLL is the most common form of leukemia, worldwide. The American Cancer Society estimates that 9,730 new cases of chronic lymphocytic leukemia will be diagnosed in the United States during 2005. About 4,600 people in the United States will die of CLL during 2005. The average patient is about 70 years of age; CLL is rarely seen in people under age 40.

About KineMarker(TM) Assays

Kinetic biomarkers, or KineMarkers(TM), provide the only commercially available tools for measuring the flux of molecules through pathways in living systems. This platform technology measures the response of complex, interconnected physiologic systems to drug treatment. The outputs measured by KineMed's ultra-sensitive stable isotope/mass spectrometric techniques represent the rate of flux through the central or critical pathway involved in the etiology of the disease of interest. In the case of CLL, this pathway comprises the birth and death of CLL tumor cells in the body. With this technology, KineMed measures the integrated response of the complex pathway involving all associated genes and proteins. A kinetic biomarker thereby provides an authentic, quantitative metric of activity aggressiveness or therapeutic response of complex diseases.

About KineMed, Inc.

KineMed, Inc. is a platform-based drug development and advanced medical diagnostics company that merges the insights and methods of systems biology with the precision and specificity of physical chemistry. KineMed's technology measures the flow of molecules through the critical pathways that lead to disease, in vivo in animals and humans, by use of proprietary techniques involving mass spectrometry. KineMed's assays combine high throughput (due to the precision and automation of mass spectrometry) with high predictive capacity for clinical response (due to the intrinsic functional significance of the measured molecular fluxes through critical pathways in living organisms). These biomarkers represent a systematic screening/filtering technology for identifying activities of agents. As such, KineMed is active in repurposing of drugs (identifying new uses of agents). The Company has negotiated equity positions in a number of agents that have been given to man (Phase I-III studies) for a specific indication, in return for discovering new uses and advancing the agents rapidly through Phase II data. KineMed has also begun a systematic screening initiative of approved agents. In addition, KineMed has developed powerful diagnostic tests, most notably in the area of metabolic syndrome/insulin resistance, with potential for widespread use in the doctor's office or clinical laboratory.