

## UCSD Moores Cancer Center Studying Novel Leukemia Vaccine for High-Risk Patients

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**R**esearchers at the Moores Cancer Center at the University of California, San Diego (UCSD) are conducting clinical trials of a novel therapy aimed at revving up the immune system to combat a particularly difficult-to-treat form of leukemia.

The experimental therapy is being offered to patients with chronic lymphocytic leukemia (CLL) whose cancer did not respond or was resistant to initial treatment or harbors a particular chromosomal abnormality called a 17p deletion. In most of these cases, the cancer has failed to respond to further conventional therapy.

In this clinical trial, patients will receive a vaccine of an immune-boosting molecule, ISF35 (Immune Stimulatory Factor 35) followed by three courses of rituximab, a monoclonal antibody, and the chemotherapy drugs fludarabine and cyclophosphamide (FCR). The trial is termed Phase I, meaning that it is aimed at testing the safety of the combination of repeat infusions of ISF35 and FCR, the latter being considered the standard and best possible CLL treatment.

"This approach – activating immune cells followed by chemotherapy – may lead to new strategies that could be applied to other cancers," said Januario E. Castro, M.D., assistant clinical professor of medicine at the UC San Diego School of Medicine and the Moores UCSD Cancer Center, who leads the work. The vaccine therapy approach makes it possible to target the cancer cells and activate the immune system by making the cancerous leukemia B cells more visible. The activated immune system can then find and eliminate the cancer cells.

CLL can be especially hard to treat. Though chemotherapy can beat back the disease initially, and patients may do well for years, the disease invariably returns, frequently resistant to further treatment. The American Cancer Society estimates that about 15,100 new cases of CLL will occur this year in the United States, with about 4,390 deaths from the disease.

"Standard strategies for CLL involve drugs and drug combinations that result in serious toxicities, little or no improvement in survival, and poor tolerance by the elderly," Castro said. "Almost all

patients eventually experience disease relapse and become less responsive to therapy. Clearly we need novel therapeutic approaches for CLL, and ISF35 therapy represents such an innovation."

According to Castro, the latest study builds on previous trials completed at UCSD and M.D. Anderson Cancer Center in Houston. "Those trials showed remarkable results for ISF35 in patients with high-risk and treatment-resistant CLL," he said, particularly when combined with chemotherapy.

Castro said that ISF35 also has the "potential to treat a range of blood cancers including lymphomas and even certain types of breast and lung cancers and melanoma," adding that future clinical trials are being planned.

This trial is sponsored by Memgen, LLC, which is headquartered in Dallas, TX, and is funded by Memgen and the Leukemia & Lymphoma Society Therapy Acceleration Program. ISF35 is based on technology discovered by Thomas J. Kipps, M.D., Ph.D., professor of medicine and Deputy Director for Research at the Moores UCSD Cancer Center. This technology has been patented by the University of California and licensed to Memgen for the treatment of CLL and other cancers.

For more information about the trial, contact Denise Darrah, 858-822-5354, or [ddarrah@ucsd.edu](mailto:ddarrah@ucsd.edu).

The Moores UCSD Cancer Center is one of the nation's 41 National Cancer Institute-designated Comprehensive Cancer Centers, combining research, clinical care and community outreach to advance the prevention, treatment and cure of cancer.

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