UCSD Launches Vaccine Trial for Chronic Lymphocytic Leukemia

December 04, 2007 |

Patients with chronic lymphocytic leukemia (CLL) who have failed chemotherapy or have chosen to forego chemotherapy have an opportunity to participate in a new clinical trial for a CLL vaccine being conducted at the Moores Cancer Center at the University of California, San Diego (UCSD).

Study participants will receive Memgen's ISF35, an immune therapy product, or vaccine. Based on the results of previous studies, ISF35 has the potential to stimulate the immune system to act against CLL cells and fight them naturally. Memgen, a biomedical company headquartered in Dallas, Texas, licensed the technology for the ISF35 molecule from UCSD and continues clinical development of the molecule.

"Traditionally, CLL patients do not have a lasting response to chemotherapy," said immunotherapy expert Januario E. Castro, M.D., associate professor of medicine in the UCSD Department of Medicine and the trial's principal investigator. "Innovative immune therapies like ISF35 offer a potentially effective alternative. This clinical trial is the first of its kind in that participants will receive a single injection of the immune therapy product directly into affected lymph nodes."

ISF35 is an abbreviation for Immune Stimulatory Factor 35, which is an offspring of technology discovered by Thomas J. Kipps, M.D., Ph.D., professor in the UCSD Department of Medicine and deputy director for research at the Moores Cancer Center.

"ISF35 gene therapy represents the next generation of leukemia-targeting vaccine strategies for patients with CLL," said Kipps. "It is designed to activate dormant leukemia B-cells and rally T-cells to selectively attack blood- and tissue-based leukemia cells."

In previous research, Kipps had found that T cells – the sentries of the immune system– could not 'see' the leukemic B cells and so did not alert the rest of the immune system to attack them. Consequently the leukemia cells could grow unchecked. He developed a method to stimulate the cancer cells so they become visible to the immune system. Now, the immune system could target the modified leukemia cells, allowing for development of T cells that specifically destroy both modified and non-modified leukemia cells.

The main purpose of this clinical trial is to determine the safety and maximum tolerated dose of ISF35 in CLL patients. Recruitment will continue for 12 to 18 months, or until 28 patients are enrolled.

Each patient in this study will receive ISF35 via direct injection into one of the enlarged lymph nodes that harbor leukemic cells. Following injection, patients will be monitored for 24 hours at the General Clinical Research Center in UCSD Medical Center and periodic follow-up examinations will continue for 12 months.

In addition to its potential anti-leukemic properties, ISF35 treatment has been well tolerated in clinical trials and has not been associated with significant or unexpected side effects. Mild flu-like symptoms have been reported from use of ISF35, and they typically disappear within 72 hours.

This clinical trial has been partially funded by a research grant to UCSD by the Alliance for Cancer Gene Therapy (ACGT). According to Edward Netter, founder and board president of ACGT, "We are thrilled with the progress of this project, which we feel exemplifies ACGT's mission to identify and support innovative concepts that have enormous potential for new treatments for cancer through gene therapy."

Individuals who have CLL or physicians who treat patients with CLL can learn more about the criteria for entry into this clinical trial by contacting UCSD Clinical Research Nurse Denise Darrah, R.N., 858-822-5375 or email ddarrah@ucsd.edu.

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