

Vaccine increases disease-free survival for follicular lymphoma patients

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A lymphoma vaccine uniquely tailored for each patient extends disease-free survival by 14 months, with signs of an even better response for patients with a specific biological marker, a team led by scientists at The University of Texas MD Anderson Cancer Center reported today in the online version of *Journal of Clinical Oncology*.

"The study continues to show that the vaccine increases the usual time until relapse for follicular lymphoma by about 14 months. That's significant because most [cancer drugs](#) are approved on the basis of extending survival only a few months," said Larry Kwak, M.D., Ph.D., corresponding author of the study. Kwak, who invented the vaccine while at the National Cancer Institute, chairs M. D. Anderson's Department of Lymphoma and Myeloma.

"These results have the potential to usher in a new age of cancer vaccines," he said. "I believe a whole flood of agents will soon begin to show positive results."

The multi-center study is the first successful phase III trial of a lymphoma vaccine and one of the first of a personalized [cancer therapy](#) agent. Initial results were presented in part at the Plenary Session of the American Society of Clinical Oncology (ASCO) Annual Meeting in 2009.

Tumors' proteins used to tune immune system attack

Kwak, who has devoted 20 years to investigating the science of cancer vaccines, specifically a personalized therapy for follicular lymphoma, was named in 2010 as one of Time magazine's 100 most influential people.

"This vaccine is a true example of a homegrown agent we've taken from bench to bedside," he said. "We discovered it in the laboratory, and we've taken it all the way through the clinical trial process. Now its approval as a commercial drug may be imminent."

To make the vaccine, unique proteins from each patient's tumor are isolated and combined with a delivery agent and a growth factor. This mixture then is injected back into the patient. Earlier studies showed this approach induces anti-tumor immune responses with few side effects in most lymphoma patients.

"It's the ultimate in personalized therapy," Kwak said. "Even if two patients have the same type of lymphoma, their tumors will still have different proteins."

According to the National Cancer Institute, non-Hodgkin's lymphoma is one of the most common cancers in the United States. More than 74,000 people were diagnosed with the disease in 2010. Follicular lymphoma accounts for 22 percent of non-Hodgkin lymphomas worldwide.

"Survival of [follicular lymphoma](#) patients has improved with newer types of chemotherapy, but advanced-stage disease still is considered incurable," Kwak said. "Although we usually can get the disease into remission, it comes back in almost all patients without further treatment."

Some patients appear to have even stronger response

The 234 patients in this trial first were treated with a chemotherapy combination known as PACE. Of these patients, 117 went into complete remission or had a complete response for at least six months, and they received either the vaccine or a placebo. During a median follow-up period of 55.6 months, median time to relapse for the 76 vaccinated patients was 44.2 months, compared with 30.6 months for the 41 who received placebo.

However, an unplanned subgroup analysis showed that patients with a certain [biological marker](#) had an even more profound response, extending disease-free survival time from 28.7 months to 52.9 months. While those results need to be confirmed in randomized studies, they suggest the potential for further targeting the vaccine.

"This huge difference points the way toward specific patients who may be likely to respond even more dramatically to the vaccine," Kwak said. "It also helps focus priorities moving forward. For instance, the Food and Drug Administration (FDA) might expedite commercial development of the drug because they know it works so well for certain patients."

What's next?

These findings may be applicable to other types of cancers, as well as a broader range of lymphoma patients. In addition, Kwak said a next-generation lymphoma vaccine his team has been working on should enter clinical testing sometime within the next year.

The National Cancer Institute advanced the vaccine by sponsoring its first randomized phase III clinical trial with the intention of handing the trial off to a corporate partner. BioVest International prevailed in a competitive process to collaborate with the NCI and took over the trial in 2004. BioVest is developing the vaccine under the brand name

BioVaxID™. The company is moving forward to secure FDA approval of the [vaccine](#). This trial was supported by National Cancer Institute and Biovest International, Inc.

Provided by University of Texas M. D. Anderson Cancer Center

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