

Cornell makes cancer vaccine for clinical use

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The Bioproduction Facility at Cornell University has produced the first batch of NY-ESO-1 recombinant protein—a cancer vaccine—that will be used in clinical trials for patients facing either ovarian cancer or melanoma. The facility was developed as a partnership between The Ludwig Institute for Cancer Research and Cornell University.

The melanoma trial is being conducted at New York University Medical Center, while the ovarian [cancer vaccine](#) trial is being conducted at the Roswell Park [Cancer](#) Institute in Buffalo, N.Y. The trials are assessing the safety and the anti-tumor immune response of the NY-ESO-1-specific therapeutic cancer vaccine alone and in combination with other agents, according to the Cancer Research Institute (CRI), an organization that has recently given \$450,000 to Cornell to support vaccine production at the Facility.

The goal of these trials is to maximize the body's immune response to the NY-ESO-1 protein. "Making NY-ESO-1 available for these [clinical trials](#) allows investigators to test ways to develop effective cancer vaccines," says Carl A. Batt, Cornell Liberty Hyde Bailey Professor of Food Science and director of the Bioproduction Facility.

Batt says: "This vaccine is not intended to prevent cancer, but one that will stimulate the body to fight an existing tumor. The challenge is that the vaccine is made from molecules—proteins—that are found in our own bodies and do not normally induce strong immune responses. So part of this trial is to understand how to make the body react to these molecules and attack the cancer."

In 1997, Lloyd J. Old, then-scientific director of the Ludwig Institute for Cancer Research Ltd (LICR), and Yao-Tseng Chen, surgical and molecular pathologist at the Weill Cornell Medical College in New York City, discovered the NY-ESO-1 cancer/testis antigen, which has been found to be expressed by many different cancer types. NY-ESO-1 has been the central focus of the CRI/LICR Cancer Vaccine Collaborative, a global network of laboratory and clinical scientists devoted to the development of cancer vaccines. The immune-boosting effect of NY-ESO-1 vaccines has been studied in more than 40 early phase, single-variable clinical trials. The Cornell NY-ESO-1 protein will be used in other Cancer Vaccine Collaborative clinical trials around the world.

Nasser Altorki, a professor of cardiothoracic surgery and the director of the Division of Thoracic Surgery at New York Presbyterian-Weill Cornell Medical Center, performed some of the earliest NY-ESO-1 vaccine trials.

When the Bioproduction Facility opened in 2002, Old, director of the Ludwig Institute Branch of Human Cancer Immunology at Memorial Sloan-Kettering Cancer Center in New York, and Hunter R. Rawlings III, then-president of Cornell University, challenged the traditional view that making therapeutic cancer products for human testing is the sole territory of pharmaceutical and biotechnology companies. This project has helped show that academic institutions can substantially participate in drug development.

The Ludwig Institute for Cancer Research provided the initial \$2 million to create the Bioproduction Facility, and continues to fund its ongoing operations with recent additional support from The Atlantic Philanthropies. Since then, professional staff and Cornell graduate and undergraduate students have operated the facility. This Good Manufacturing Practice (GMP) facility was created behind the nearly century-old façade of Stocking Hall (in which Cornell students once took

dairy-science classes). It consists of a series of clean rooms, where particulates even smaller than bacteria are filtered. Strict GMP regulations, administered by the U.S. Food and Drug Administration, are used by pharmaceutical, medical device and food manufacturers as they produce and test products.

The effort to bring the laboratory and production unit from idea to reality was led by Batt, Old, and Gerd Ritter, associate director of the LICR New York Branch. Initial discussions to create a facility began between Cornell and LICR in 1998. By the following year, Cornell had signed an agreement with LICR to create it.

Regarding this protein batch now going into clinical trial, Batt says, "We don't expect miracles, but the current array of surgical, radiation and chemotherapy options are not going to eliminate all types of cancers. What these cancer vaccines offer is another tool to help combat cancer, which can be used in conjunction with other existing therapeutic options. Also, bringing together our cancer vaccine development efforts in Ithaca with the clinical research programs of Drs. Nasser Altorki, Yao Chen, and their colleagues at the university's medical school in New York City represents an excellent model for integrating activities at the two campuses."

Source: Cornell University ([news](#) : [web](#))

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