

A Cuban vaccine might some day turn lung cancer into a chronic disease

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The first patients in a clinical trial at Roswell Park Cancer Institute have begun receiving monthly doses of CIMAvax-EGF, a Cuban lung cancer vaccine that U.S. researchers say shows promise in preventing the recurrence of lung cancer - the leading cause of cancer deaths in the

United States.

The Roswell trial, which was authorized by the U.S. Food and Drug Administration last fall, is the first time that a Cuban-made therapy has been tested on U.S. patients. CIMAvax has already undergone extensive [clinical trials](#) in Cuba and around the world and is an approved therapy for treatment of [lung](#) cancer not only on the island but also in Colombia, Peru, Paraguay, and Bosnia and Herzegovina.

The unique partnership between Roswell Park researchers and Havana's Center of Molecular Immunology began in 2011, well before the Obama administration's rapprochement with Cuba, and had its genesis in a cold call from Gisela Gonzalez, a Cuban researcher who was visiting her family in Pittsburgh.

She offered to give a talk about the Havana center's work to researchers at Roswell, an internationally recognized cancer treatment and research center. "It really came out of the blue, and we, like many others, thought Cuba was stuck back in the 'I Love Lucy' days and their technology was probably on par with their 1950s cars," recalled Dr. Kelvin Lee, chairman of Roswell's Department of Immunology.

"She comes up and gives this really great talk," said Lee, who previously worked at the University of Miami Sylvester Comprehensive Cancer Center. "I recognized something really exciting, but I didn't appreciate the magnitude of it until several months later."

Gonzalez invited Roswell researchers to an international immunology convention in Havana. Lee said he came away impressed. "We saw this remarkable amount of innovative scientists and remarkable research they were doing," he said.

When he returned to Roswell, Lee said he told the institute's senior

leadership: "If there's a 20 percent chance that what (Cuban scientists) are seeing in lung cancer patients is actually true, then we need to get in on the ground floor."

What makes the Cuban lung cancer vaccine so exciting to researchers is that instead of attacking cancer cells themselves, as most immunotherapies do, it generates an immune response against EGF, a growth factor circulating in the blood that cancer cells need to grow and thrive.

"By generating that immune response, it neutralizes the circulating (epidermal growth factor or EGF), starves the cancer and the cancer stops growing," Lee said.

Because of the way it appears to work, the vaccine could potentially be effective against other cancers such as colon and head and neck cancers that also rely on EGF to grow. "There's a hint, a hope here that we might be able to develop a vaccine for these other cancers," said Dr. Igor Puzanov, director of the clinical trial program and Roswell's chief of melanoma.

Unlike other cancer therapies, which may cause serious side effects, patients treated with CIMAvax tolerate the vaccine well. "Side effects for Cuban patients on the vaccine have been very minimal," said Dr. Grace Dy, chief of thoracic oncology and the chief investigator in the CIMAvax trial.

The vaccine, which has been administered to more than 5,000 patients worldwide, is also cost-effective.

On the island, where 1,000 Cubans have received the vaccine, the therapy is free. Foreigners who go to Cuba in search of the vaccine can see a doctor and get a year's supply for around \$12,000, Lee said. That

compares to the cost of treatment with Opdivo, an immunotherapy in use in the United States, that costs \$12,000 to \$15,000 per month.

Americans not accepted for the U.S. study who might want to go to Cuba to get the drug need to check U.S. travel regulations. Medical treatment does not fall into 12 categories of Cuba travel that the U.S. government permits without prior approval. Roswell also points out U.S. health insurance is very unlikely to cover CIMAvax acquired in a foreign country.

The Phase I trial is qualifying patients on a rolling basis. The goal is to enroll 60 to 90 patients for the trial, which is expected to be completed in three years. The first group of qualified patients, all of whom have previously been treated for lung cancer, began receiving the vaccine in January. It's being administered in combination with Opdivo, a second-line therapy that's been shown to be comparatively effective in treating lung cancer recurrence.

To be eligible for the clinical trial, patients must have advanced lung cancer that was treated initially with chemotherapy. Newly diagnosed [lung cancer patients](#) who were given Opdivo (also known as nivolumab) as their first line of treatment aren't eligible for the study.

There's plenty of data on the CIMAvax vaccine alone, said Puzanov, but the Roswell trial is the first time the two therapies have been tested in combination. The goal is to assess whether two immunotherapies given together are more effective.

Initially patients enrolled in the study get the combined therapies every two weeks for four courses and then once a month.

Roswell researchers will gradually increase the dosage of CIMAvax and Opdivo, trying to achieve the optimal combination and studying overall

response and survival rates. The most recent trial conducted in Cuba showed that patients treated with CIMAvax had significantly improved quality of life and overall survival rates, according to Roswell researchers.

"We want to tease out the information about why patients respond. It's part of the mosaic of the comprehensive approach of attacking cancer here," said Puzanov. Potentially, the vaccine might even be administered to patients such as chronic smokers who are at high risk of developing lung cancer, according to Roswell researchers.

"This Phase I trial really feels like throwing a stone in a pool to see what type of ripples happen," Lee said. But his hope is that the trial shows the FDA enough that it will fast-track the sale of CIMAvax and other Cuban biologics - medications that rely on biotechnology for their manufacture - in the United States.

While in Cuba recently, Lee met a female lung cancer survivor who had been on the vaccine for 12 years.

"Lung cancer doesn't get the attention it deserves," Dy said. "The No. 1 cause of cancer death in both men and women in the United States is lung cancer. Actual deaths from lung [cancer](#) are more than prostate, breast and colon cancers combined."

Since Roswell and Cuban researchers began collaborating, four Cuban doctorate students have spent six-month stints at Roswell, and Cuban scientists have visited Buffalo to plan the pre-clinical and clinical trials.

"This is a day we have been working toward for many years," Dr. Agustin Lage, director of CIM - the Havana center's Spanish acronym - said last October when New York Gov. Andrew Cuomo announced the FDA authorization of the clinical trial. "Our partnership with Roswell

Park will allow us to learn things about our vaccine faster than what we could achieve working on our own, and we believe it is the best and quickest path for helping a great number of people both in Cuba and the U.S."

Roswell first obtained a license from Treasury's Office of Foreign Assets Control to pursue research, development and potentially manufacture and marketing of biotech products in 2013, and it was renewed in 2015.

The December 2014 rapprochement with Cuba and Cuomo's 2015 trade mission to the island helped fast-track FDA approval, said Lee. "Before, it was just two institutions trying to do something important for our own patients, but we weren't on anybody's front burner," he said. "The state's involvement really pushed us over the finish line."

Asked why a small country with limited resources was on the cutting edge of biotech research, Dy responded: "They were forced to become innovative; they were separated from the rest of the world in a sense. People in Cuba also are very well educated and there are lots of scientists and doctors."

Lee said the emphasis on universal healthcare and trying to come up with very cost-effective treatments also has contributed to Cuban breakthroughs.

"The really exciting thing about CIMAvax is the possibility that it might be used to prevent [lung cancer](#)," said Lee. The Havana center also has a portfolio of other interesting biologics, he said, and "there are about seven we are working on to see if we can move them into clinical trials."

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