

## When could the revolutionary breast cancer vaccine be produced? What the president of the company developing the vaccine says

Denis Grigorescu 29 Jul 2025

(original Romania language story: <u>De când ar putea fi produs vaccinul revoluționar</u> <u>împotriva cancerului la sân. Ce spune președintele companiei care dezvoltă vaccinul</u>)

A new type of vaccine, being tested in the United States, gives hope to millions of women battling one of the most terrible forms of cancer. The first phase of clinical trials on this vaccine was concluded with encouraging results.

## When did the development of the vaccine begin

The vaccine was developed by the company Anixa Biosciences in collaboration with the Cleveland Clinic. It targets the protein alpha-lactalbumin, normally present only during breastfeeding but associated with the most dangerous form of breast cancer, the triplenegative type. It is known for its resistance to treatments and its increased mortality rate.

The first phase of the study included 35 women at increased genetic risk of developing the disease, determined by genetic testing. More than 75% of the participants in this first phase developed a strong immune response, demonstrated by the presence of antibodies in white blood cells. This mechanism could allow the immune system to recognize and destroy cancer cells before the disease develops.

Dr. Amit Kumar, CEO of Anixa Biosciences, the company developing the revolutionary vaccine, explained to Libertatea what the status of this project is.

"The development of the vaccine began more than two decades ago in the laboratory at the Cleveland Clinic. In 2018, my company, Anixa Biosciences, licensed this technology and partnered with the Cleveland Clinic to move the vaccine from the lab stage to clinical testing on humans. After receiving approval from the US FDA, we started testing on humans at the end of 2021," says Dr. Amit Kumar, CEO of Anixa Biosciences. He is also a member of the American Cancer Society.

With a PhD in chemistry from the prestigious Caltech University, a title obtained in 1991, Amit Kumar was later a postdoctoral fellow at Harvard for two years.

## Why the vaccine is effective

Amit Kumar explained how the vaccine developed and still under study manages to target alpha-lactalbumin, a milk protein associated with aggressive triple-negative breast cancer, to help prevent and treat the disease.

"The vaccine is a combination of recombinant alpha-lactalbumin and an adjuvant called Zymosan, in an oil called Montanide. This combination helps the patient's immune system respond to alpha-lactalbumin.

Alpha-lactalbumin has been found in triple-negative breast cancer, as well as other types of breast cancer. Once a patient has been vaccinated and her immune system has been trained to destroy the cells that produce the protein, when cancer cells appear, the immune system recognizes them and destroys them," says Amit Kumar.

The second phase of the study is scheduled for next year and will test a larger group of participants and expand testing to other types of breast cancer: "The final number has not yet been established. It will be decided after we discuss with the FDA (editor's note – Federal Drug Administration, the American agency that validates drugs). But we believe that the total number of patients will be between 80 and 100."

## The price will be affordable

This vaccine could change immuno-oncology. If successful in preventing and treating breast cancer, the same process can be used to prevent many other types of cancer.

"We are already working on tests for ovarian, lung, prostate and colon cancer. We expect many researchers to try to develop vaccines for all types of cancer. We don't have a cost for the vaccine yet, but we expect it to be affordable," says Amit Kumar.

So far, the company has spent several million dollars on the development of the vaccine, and the CEO of Anixa Biosciences estimates that there will be much higher costs to complete the development and testing, but for now it is difficult to estimate how much the total costs will be.

Amit Kumar is optimistic about the year in which the breast cancer vaccine could be available on a global scale and thus lead to the eradication of the terrible disease: "It is possible that the vaccine will be available for treatment in 2030."

The American Cancer Society estimates that during 2025 there will be 316,950 new cases of breast cancer in the United States and that 42,170 women will die from breast cancer.

According to the latest statistics from the World Health Organization, breast cancer caused 670,000 deaths worldwide in 2022, and about half of breast cancer cases occur in women who have no specific risk factors other than gender and age. Also in 2022, there were no less than 2.3 million women diagnosed with breast cancer.