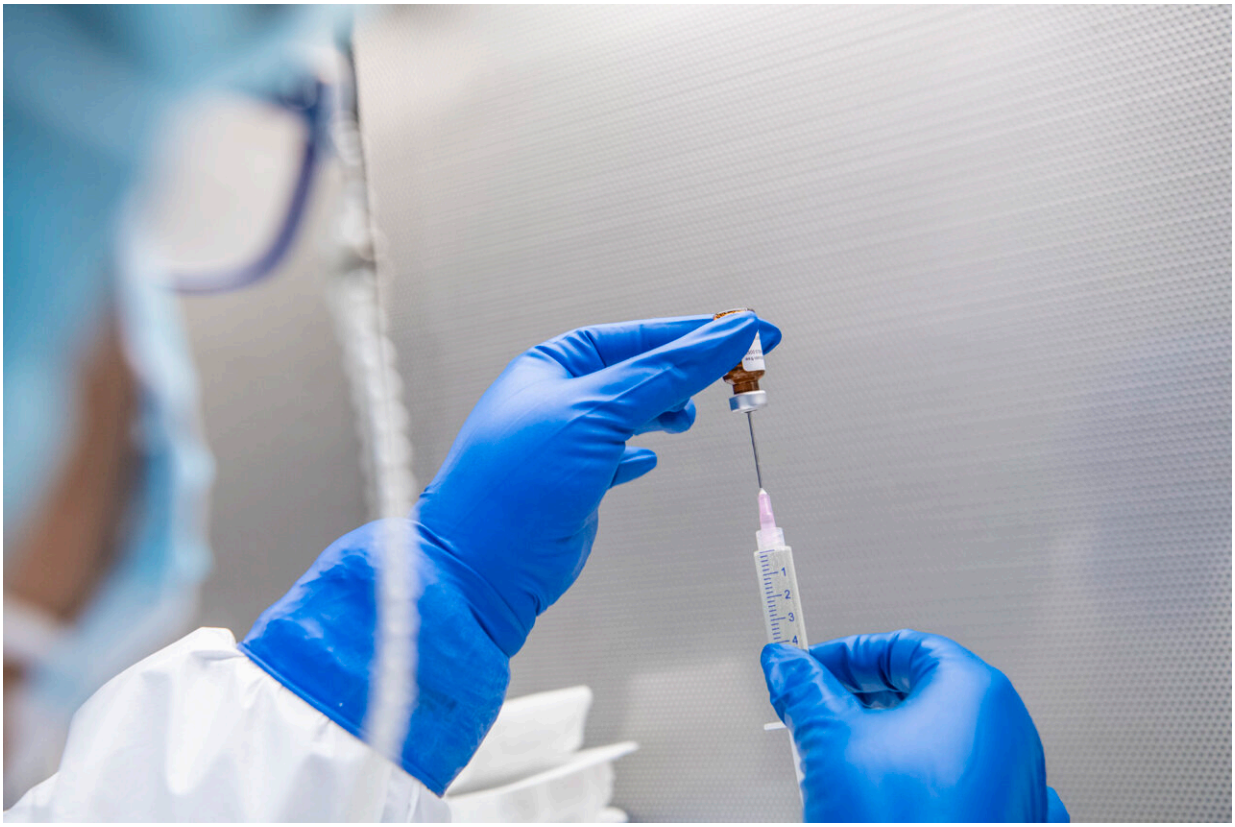
First human vaccine trial to prevent triple negative breast cancer begins

October 26 2021, by Cleveland Clinic



Pharmacy research technican Brenda Flenoy demonstrates a mock preparation of the new breast cancer vaccine in the pharmacy of the basement of the Taussig Cancer Center on Monday, Oct. 25, 2021. Credit: Cleveland Clinic

Cleveland Clinic researchers have opened a novel study for a vaccine

aimed at eventually preventing triple-negative breast cancer, the most aggressive and lethal form of the disease.

This phase I trial is designed to determine the maximum tolerated dose of the vaccine in patients with early-stage triple-negative breast cancer and to characterize and optimize the body's immune response. The U.S. Food and Drug Administration recently approved an investigational new drug application for the vaccine, which permits Cleveland Clinic and partner Anixa Biosciences, Inc. to start the study.

"We are hopeful that this research will lead to more advanced trials to determine the effectiveness of the vaccine against this highly aggressive type of breast cancer," said G. Thomas Budd, M.D., of Cleveland Clinic's Taussig Cancer Institute and principal investigator of the study. "Long term, we are hoping that this can be a true preventive vaccine that would be administered to healthy women to prevent them from developing triple-negative breast cancer, the form of breast cancer for which we have the least effective treatments."

There is a great need for improved treatments for triple-negative breast cancer, which does not have biological characteristics that typically respond to hormonal or targeted therapies. Despite representing only about 12-15% of all breast cancers, triple-negative breast cancer accounts for a disproportionately higher percentage of breast cancer deaths and has a higher rate of recurrence. This form of breast cancer is twice as likely to occur in African-American women, and approximately 70% to 80% of the breast tumors that occur in women with mutations in the BRCA1 genes are triple-negative breast cancer.

"This vaccine approach represents a potential new way to control breast cancer," said Vincent Tuohy, Ph.D., the primary inventor of the vaccine and staff immunologist at Cleveland Clinic's Lerner Research Institute. "The long-term objective of this research is to determine if this vaccine

can prevent breast cancer before it occurs, particularly the more aggressive forms of this disease that predominate in high-risk women." Dr. Tuohy is named as inventor on the technology, which Cleveland Clinic exclusively licensed to Anixa Biosciences, Inc. He will receive a portion of commercialization revenues received by Cleveland Clinic for this technology and also holds personal equity in the company.

The investigational vaccine targets a breast-specific lactation protein, α-lactalbumin, which is no longer found post-lactation in normal, aging tissues but is present in the majority of triple-negative breast cancers. Activating the immune system against this "retired" protein provides pre-emptive immune protection against emerging breast tumors that express α-lactalbumin. The vaccine also contains an adjuvant that activates an innate immune response that allows the immune system to mount a response against emerging tumors to prevent them from growing.

The study is based on pre-clinical research led by Dr. Tuohy that showed that activating the immune system against the α-lactalbumin protein was safe and effective in preventing breast tumors in mice. The research also found that a single vaccination could prevent breast tumors from occurring in mouse models, while also inhibiting the growth of already existing breast tumors. The research, originally published in *Nature Medicine*, was funded in part by philanthropic gifts from more than 20,000 people over the last 12 years.

Funded by the U.S. Department of Defense, the new study at Cleveland Clinic will include 18 to 24 patients who have completed treatment for early-stage triple-negative breast cancer within the past three years and are currently tumor-free but at high risk for recurrence. During the course of the study, participants will receive three vaccinations, each two weeks apart and will be closely monitored for side effects and immune response. The study is estimated to be completed in September 2022.

Researchers anticipate that a subsequent trial will involve healthy, cancer-free women at high risk for developing breast cancer who have decided to undergo voluntary bilateral mastectomy to lower their risk. Typically, those women carry mutations in either the BRCA1 or BRCA2 gene and are therefore at risk of developing triple-negative breast cancer or have high familial risk for any form of breast cancer.

"This vaccine strategy has the potential to be applied to other tumor types," added Dr. Tuohy. "Our translational research program focuses on developing vaccines that prevent diseases we confront with age, like breast, ovarian and endometrial cancers. If successful, these vaccines have the potential to transform the way we control adult-onset cancers and enhance life expectancy in a manner similar to the impact that the childhood vaccination program has had."

More information: Ritika Jaini et al, An autoimmune-mediated strategy for prophylactic breast cancer vaccination, *Nature Medicine* (2010). DOI: 10.1038/nm.2161

Provided by Cleveland Clinic

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