



**NASDAQ:ANIX**

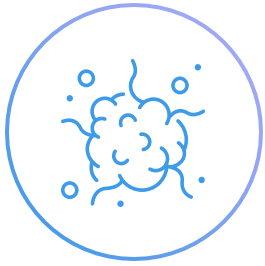
June 2025

## Forward-Looking Statements

Statements that are not historical fact may be considered forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are not statements of historical facts, but rather reflect Anixa Biosciences' current expectations concerning future events and results. We generally use the words "believes," "expects," "intends," "plans," "anticipates," "likely," "will" and similar expressions to identify forward-looking statements. Such forward-looking statements, including those concerning our expectations, involve risks, uncertainties and other factors, some of which are beyond our control, which may cause our actual results, performance or achievements, or industry results, to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. These risks, uncertainties and factors include, but are not limited to, those factors set forth in "Item 1A – Risk Factors" and other sections of our most recent Annual Report on Form 10-K as well as in our Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. You are cautioned not to unduly rely on such forward-looking statements when evaluating the information presented herein.

# Anixa Snapshot

Clinical-stage company developing first-in-class products to treat & prevent cancer



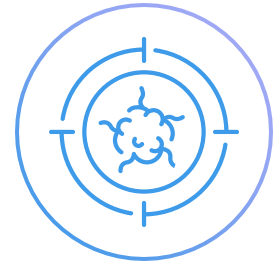
**Robust  
Pipeline**



**Strong Clinical  
Data**



**Key  
Partnerships**



**Significant TAM  
Opportunity**



**Strong Balance  
Sheet**



**Clean Capital  
Table**



**Strong Consistent  
Insider Buying**



**Capital Efficient  
Business Model**

# Capital Efficient Business Model

NASDAQ:ANIX

**\$16M** Cash and short-term investments  
as of April 30, 2025

**~\$5-7M** Approximate annual cash  
burn since 2017

**32M** Common shares outstanding as of  
April 30, 2025



No debt










No warrants, no  
preferred stock

- **Develop programs with partners**
  - ✓ **Leverage existing infrastructure of partner**
  - ✓ **Maintain low overhead and cash burn**
  - ✓ **Allows for multiple orthogonal projects**
- **Out-license or sell programs to pharma for late-stage clinical development and commercialization**

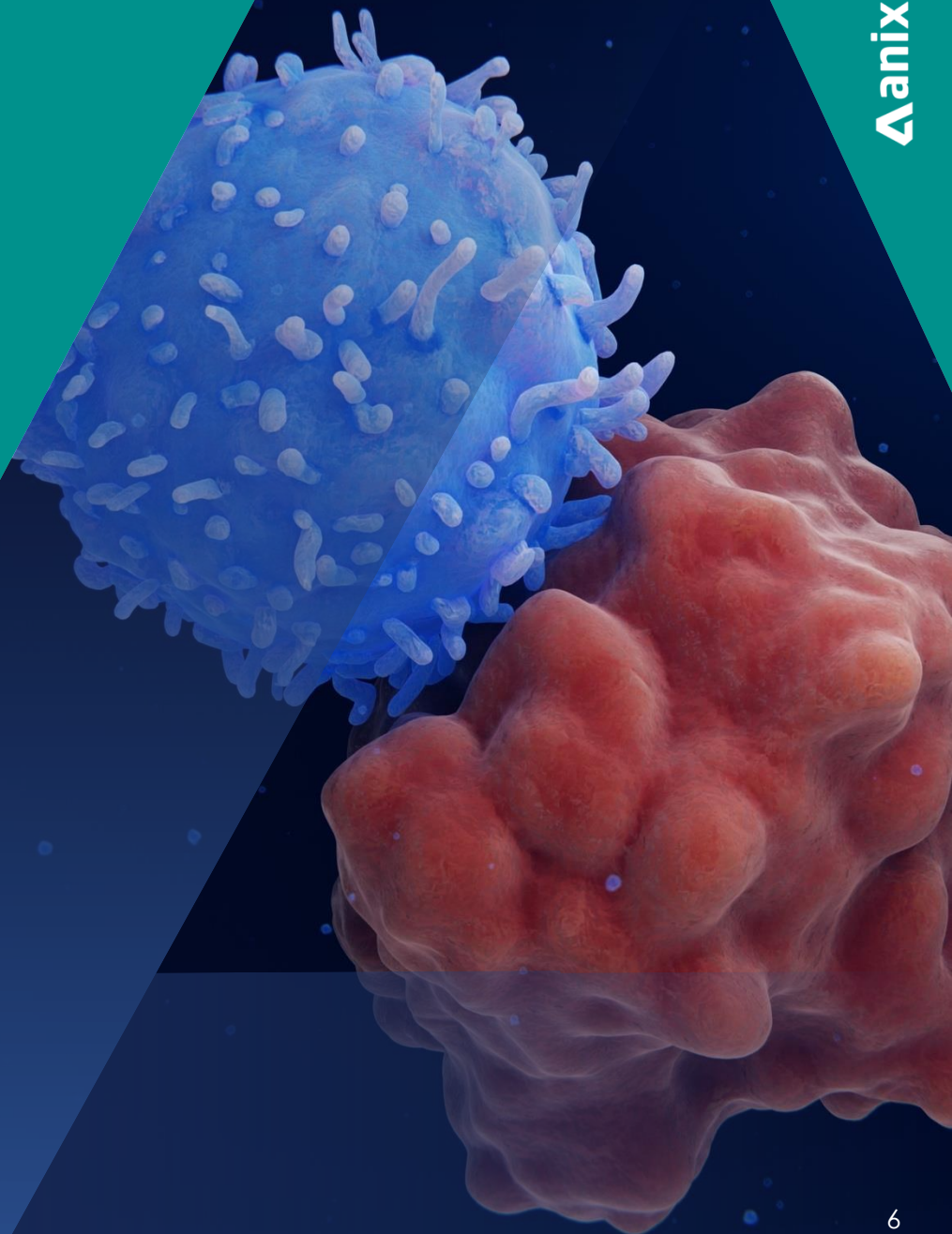
**Total Burn Last Fiscal Year was \$7 Million**

# Clinical Programs & Development Partnerships

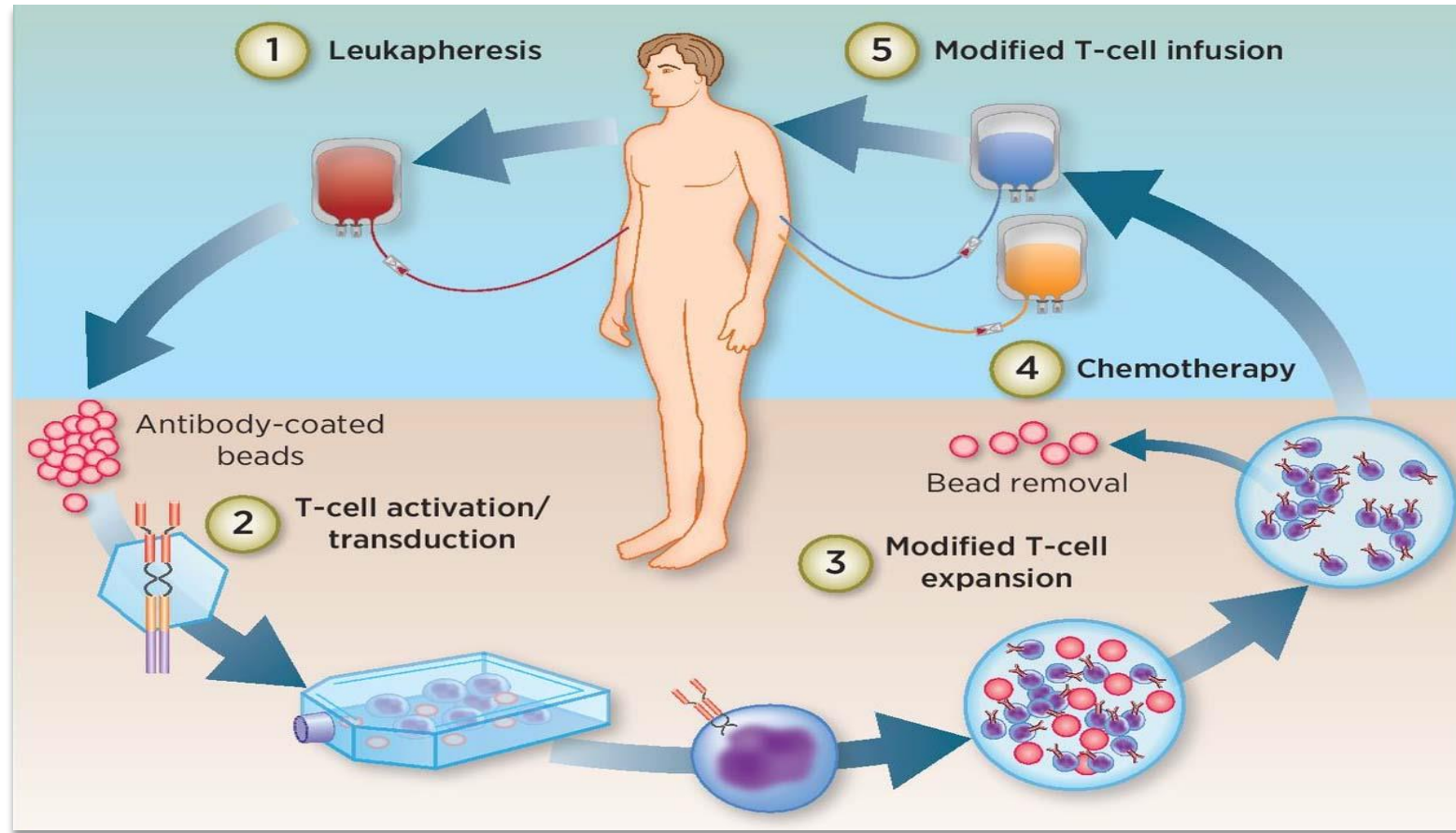
THERAPEUTIC AREA	MECHANISM OF ACTION	INDICATION	GEOGRAPHIC RIGHTS	STAGE	UPCOMING MILESTONES	PARTNERS
Oncology	CAR-T Therapeutic	Ovarian Cancer / Other Solid Tumors	Global	<u>Phase 1</u>	Periodic data releases (enrollment based)	<div>   </div>
Oncology	Vaccine Therapeutic	Breast Cancer	Global	<u>Phase 1</u>	Additional Phase 1a,b,c data releases	<div>   </div>
Oncology	Vaccine	Ovarian Cancer	Global	Pre-clinical	Initiate IND enabling studies	<div>   </div>
Oncology	Vaccine	Lung, Colon, Prostate	Global	R&D	Pre-clinical Data	<div>  </div>

**CAR-T Program**

# Ovarian Cancer Therapy



# CAR-T Procedure- Chimeric Antigen Receptor T cell



In clinical trial, we are treating terminally ill patients who have failed 2-6 approved therapies

# CAR-T Technology

Background & opportunity

## Chimeric Antigen Receptor T cell

### CAR- T has made great inroads in B-Cell cancers

- Durable responses (50-80% of patients)
- Multi-billion-dollar valuations and big pharma deals
  - Novartis - First approved product by FDA
    - Kymriah for Acute Lymphoblastic Leukemia (ALL)
    - Second approval for Diffuse large B-cell Lymphoma (DLBCL)
  - KITE - \$12BB acquisition by GILD
  - JUNO - \$9BB acquisition by CELG

### Our Opportunity

- CAR-T has not worked clinically in solid tumors

### Our Unique Approach

- Anixa's novel tech has three unique attributes:
- Unique target antigen that is primarily found on ovaries in women
- Anti-angiogenesis effect of our T cells
- Intraperitoneal delivery

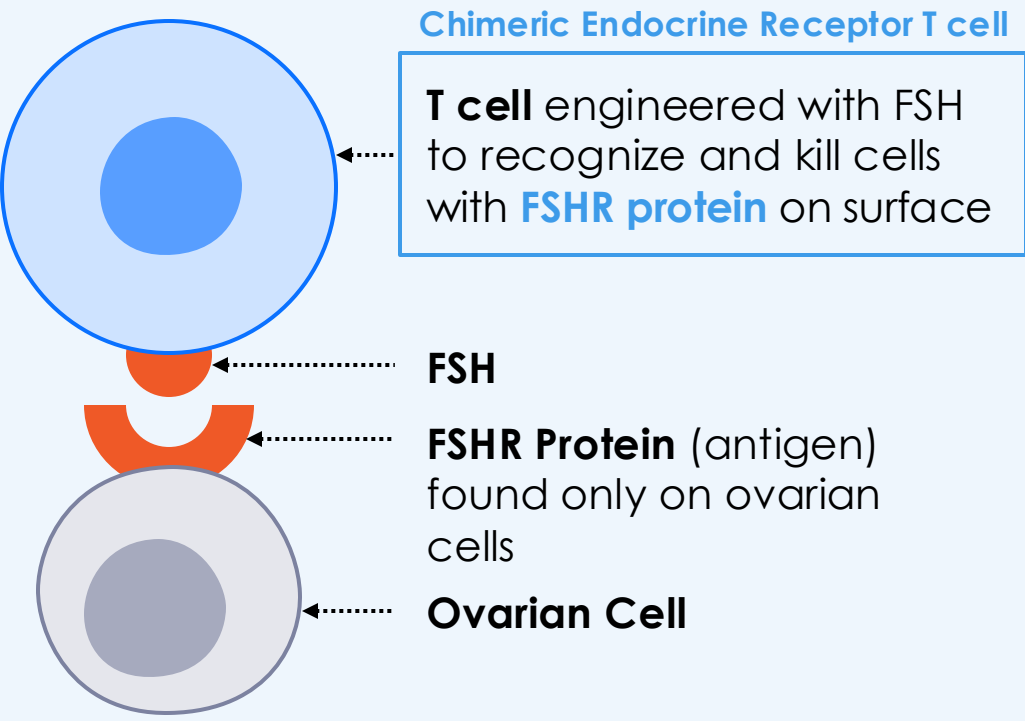


# Anixa's Unique & Targeted CER-T Approach for Solid Tumors

Exclusive worldwide license from The Wistar Institute

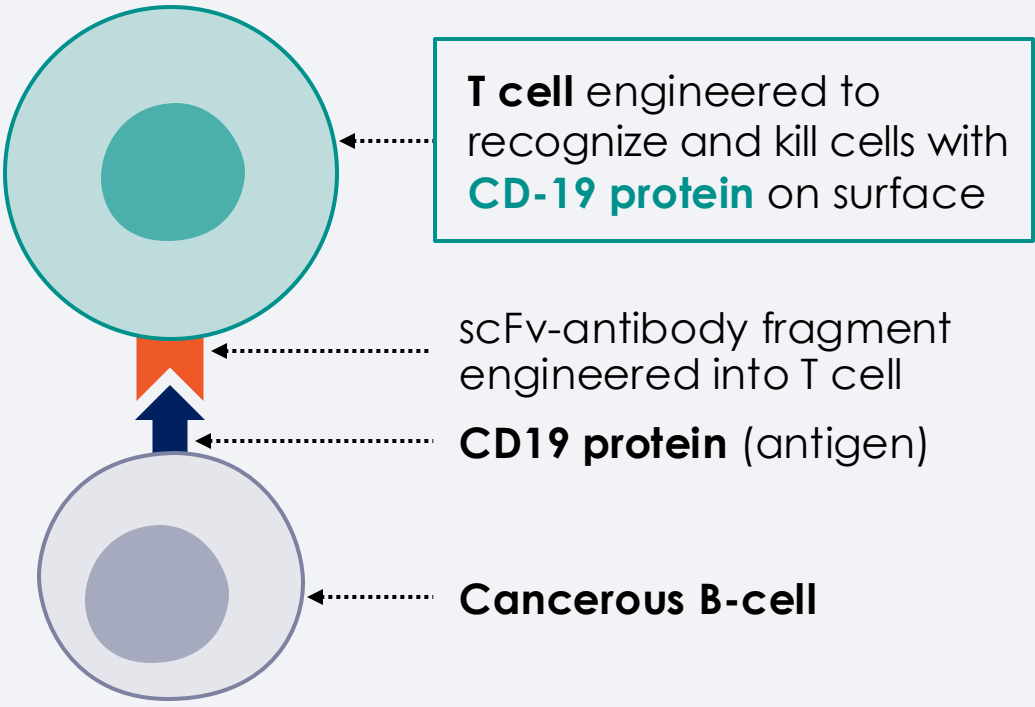
## Anixa's CAR-T Program for Ovarian Cancer

Follicle Stimulating Hormone Receptor ("FSHR")-mediated CAR-T Technology



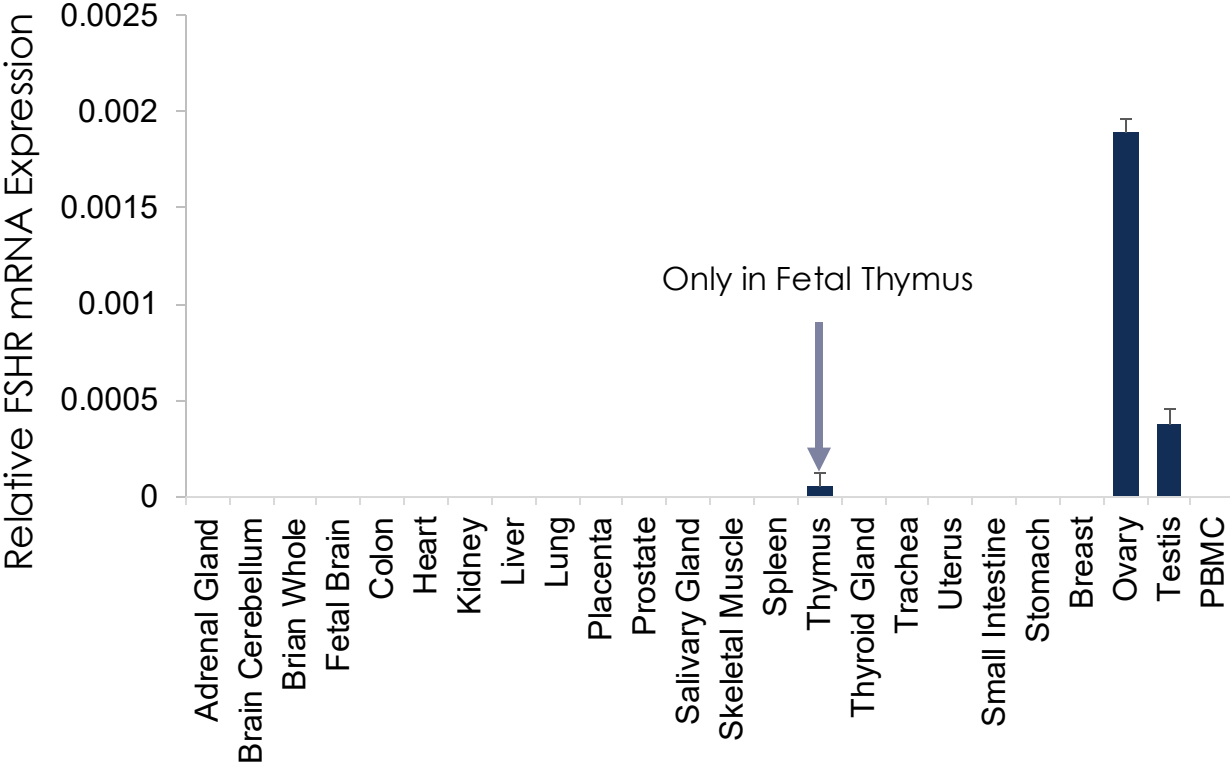
## Other CAR-T Programs

Novartis, JUNO, KITE and others working on B-Cell cancers



# FSHR ONLY Expressed in Ovaries, Testes and Tumor Blood Vessels

\*In Healthy Humans\*



The NEW ENGLAND JOURNAL of MEDICINE

## ORIGINAL ARTICLE

### Expression of Follicle-Stimulating Hormone Receptor in Tumor Blood Vessels

Aurelian Radu, Ph.D., Christophe Pichon, Ph.D., Philippe Camparo, M.D.,  
Martine Antoine, M.D., Yves Allory, M.D., Anne Couvelard, M.D.,  
Gaëlle Fromont, M.D., Mai Thu Vu Hai, Ph.D.,  
and Nicolae Ghinea, Ph.D.

## ABSTRACT

### BACKGROUND

In adult humans, the follicle-stimulating hormone (FSH) receptor is expressed only in the **granulosa cells of the ovary and the Sertoli cells of the testis**. It is minimally expressed by the endothelial cells of gonadal blood vessels.

### METHODS

We used immunohistochemical and immunoblotting techniques involving four separate FSH-receptor-specific monoclonal antibodies that recognize different FSH receptor epitopes and in situ hybridization to detect FSH receptor in tissue samples from patients with a wide range of tumors. Immunoelectron microscopy was used to detect FSH receptor in mouse tumors.

### RESULTS

In all 1336 patients examined, FSH receptor was expressed by endothelial cells in tumors of all grades, including early T1 tumors. The tumors were located in the prostate, breast, colon, pancreas, urinary bladder, kidney, lung, liver, stomach, testis, and ovary. In specimens obtained during surgery performed to remove tumors, the FSH receptor was not expressed in the normal tissues located more than 10 mm from the tumors. The tumor lymphatic vessels did not express FSH receptor. The endothelial cells that expressed FSH receptor were located at the periphery of the tumors in a layer that was approximately 10 mm thick; this layer extended both into and outside of the tumor. Immunoelectron microscopy in mice with xenograft tumors, after perfusion with anti-FSH-receptor antibodies coupled to colloidal gold, showed that the FSH receptor is exposed on the luminal endothelial surface and can bind and internalize circulating ligands.

### CONCLUSIONS

FSH receptor is selectively expressed on the surface of the blood vessels of a wide range of tumors. (Funded by INSERM.)

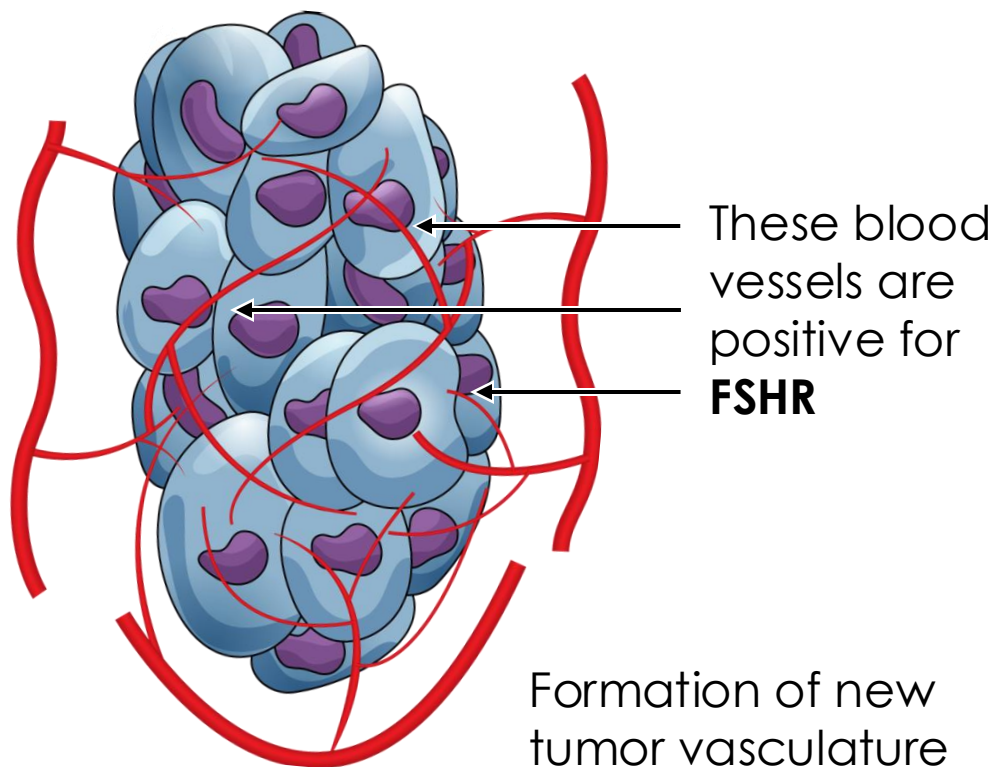
From Mount Sinai School of Medicine, New York (A.R.); and INSERM Unité 753, Villejuif (C.P.), Val-de-Grâce Hospital, Paris (P.C.), Tenon Hospital, Paris (M.A.), INSERM Unité 955-Eq 07, Université Paris-Est, Créteil (Y.A., M.T.V.H., N.G.), Beaujon Hospital, Clichy (A.C.), and Centre Hospitalier Universitaire de Poitiers, Poitiers (G.F.) — all in France. Address reprint requests to Dr. Ghinea at INSERM Unité 955-Eq 07, 8 rue du Général Sarraill, Université Paris-Est, Créteil, France, or at nicolae.ghinea@inserm.fr.

N Engl J Med 2010;363:1621-30.  
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# Our FSHR-Mediated CAR-T Technology- Dual Mechanism of Action

## Angiogenesis

Tumors induce rapid blood vessel growth to nourish themselves



- Many tumors have blood vessels where FSHR is expressed even though healthy tissue does not show such expression
- Anti-angiogenesis drugs are a multi-billion-dollar class of drugs, with Avastin the leader with 2021 sales of \$3 billion
- Enables Dual Mechanism of Action

**Our FSHR targeted CAR-T may destroy tumor vasculature and starve or shrink the tumor, disrupting FSH from both the inside and outside**

**Combination therapy utilizes dual mechanisms of action. Our CAR-T operates a dual mechanism with a single agent**

**Tumors expressing FSHR on vasculature:**

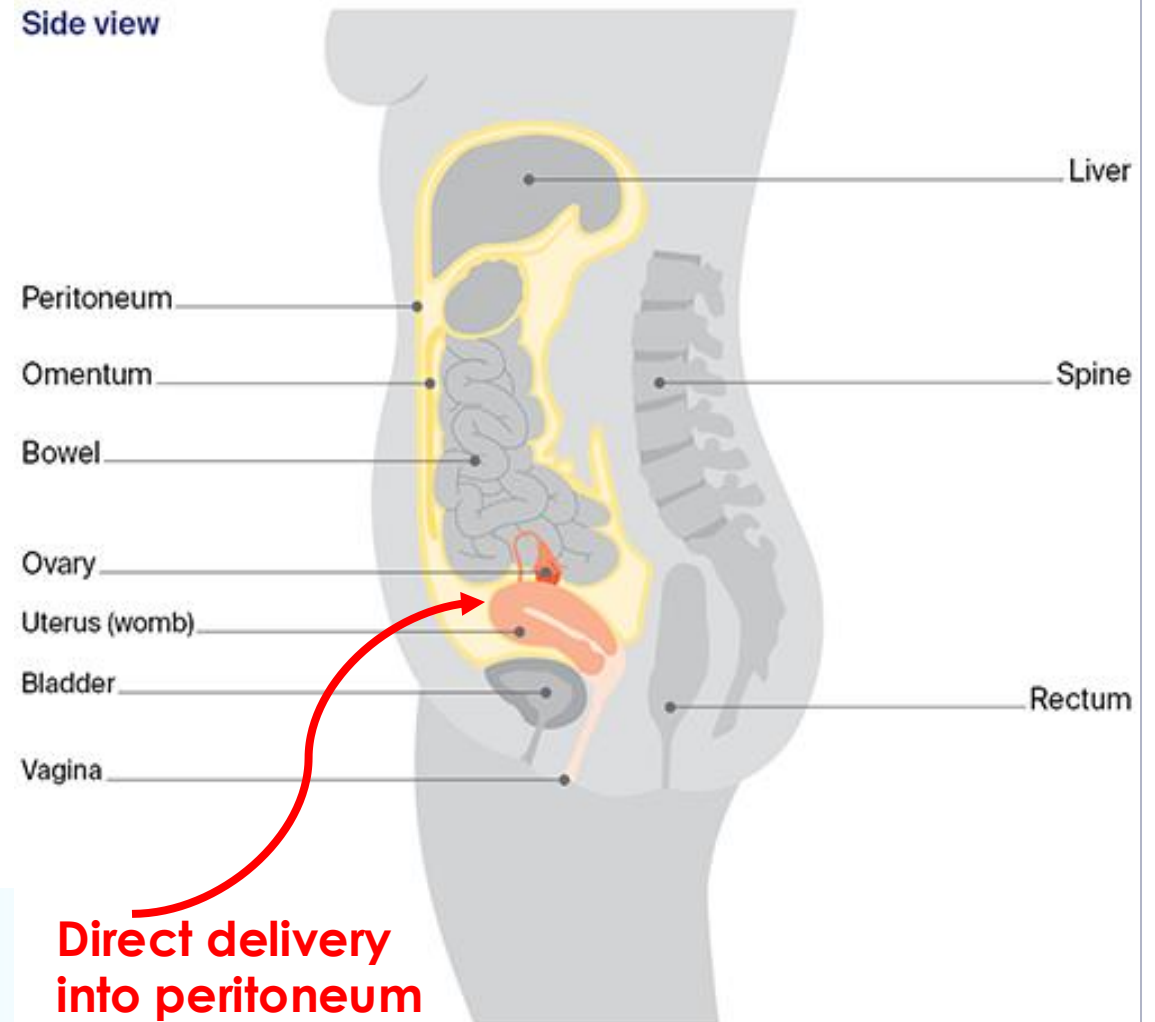
Lung, Breast, Prostate, Colon, Head & Neck, Pancreatic, Liver, Renal, Ovarian and others

# Intraperitoneal Delivery (IP) Is Another Key Advantage

- Most, if not all, ovarian cancer lesions remain within the peritoneal cavity and ascites
- By delivering through an IP catheter, the engineered T cells will largely remain in the peritoneal cavity
- Very few, if any, engineered T cells escape into blood stream
  - Minimizes side effects like CRS
  - Better trafficking to tumor lesions
  - May enable us to go to much higher concentrations than available with IV administration

**We will also test IV delivery, but to date all patients have been treated via IP delivery**

Side view



# Dose-escalation first-in-human clinical trial in recurrent/chemoresistant ovarian Cancer

- PI: R. Wenham, MD
- I.P. vs. I.V.→ Comparative safety and effectiveness

**Table 1. Dose-escalation scheme.**

Cohort	Dose Level	Cyclophosphamide dose	FSHCER T-cell Dose	Number of Patients
1	1	None	$1 \times 10^5$ cells/kg	3-6 patients
2	2	None	$3 \times 10^5$ cells/kg	3-6 patients
3	3	None	$1 \times 10^6$ cells/kg	3-6 patients
4	4	None	$3 \times 10^6$ cells/kg	3-6 patients
6	5	None	$1 \times 10^7$ cells/kg	3-6 patients
5	3	Cyclophosphamide $500 \text{ mg/m}^2$ and fludarabine ( $30 \text{ mg/m}^2$ ) $\times$ 3 days	$1 \times 10^6$ cells/kg	3-6 patients
5b	4	Cyclophosphamide $500 \text{ mg/m}^2$ and fludarabine ( $30 \text{ mg/m}^2$ ) $\times$ 3 days	$3 \times 10^6$ cells/kg	3-6 patients
5c	5	Cyclophosphamide $500 \text{ mg/m}^2$ and fludarabine ( $30 \text{ mg/m}^2$ ) $\times$ 3 days	$1 \times 10^7$ cells/kg	3-6 patients

**Current dosage** ←

# Clinical Results to Date

- **Current Status**
  - 9 patients treated to date, 3 in each cohort with successive dose escalation
  - Excellent safety profile to date
  - Beginning 4<sup>th</sup> dosage cohort
- **Preliminary Results**
  - One patient alive 24+ months since treatment
  - One patient alive 12+ months since treatment
  - Several others survived greater than expected 4 months (median survival), or showing biomarker response
- **FDA has approved a second dose if warranted for patients in trial**
  - One patient has received a second dose and another is being evaluated

The preliminary results on these terminally ill patients is very promising and has exceeded our expectations for the low, subtherapeutic doses

We hope to see even more promising results as we increase dose.

**Vaccine Program**

Breast Cancer



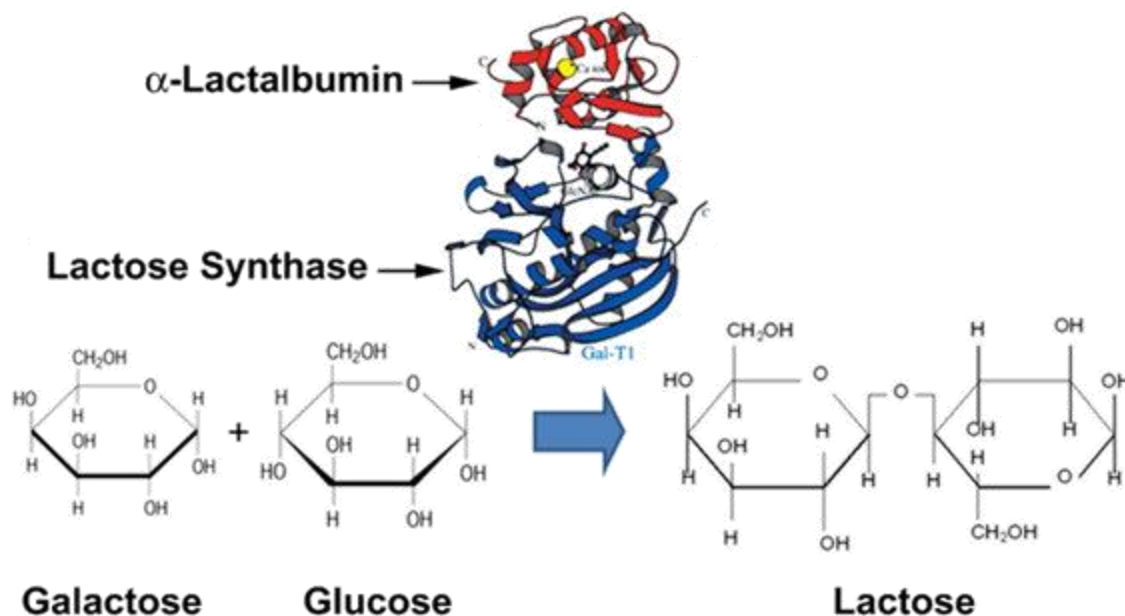


# Breast Cancer Vaccine: Retired Tissue-Specific Protein

Exclusive worldwide license from Cleveland Clinic

## Retired Tissue-Specific Protein

Expressed at periods of life, but no longer expressed as we age



## α-LACTALBUMIN

- Expressed **only** in the breast and **only** during lactation
- Expressed in tumor cells, especially Triple Negative Breast Cancer (**TNBC**)
- Our vaccine targets this retired protein
  - Once vaccinated, the patient's immune system is ready to destroy cells expressing the protein as they arise, disallowing cancer to gain critical mass

## TNBC Overview

- Most aggressive form of breast cancer
- Prevalent cancer in patients with breast cancer gene ("BRCA") mutations



# Proof of Concept\* -Published in 2012

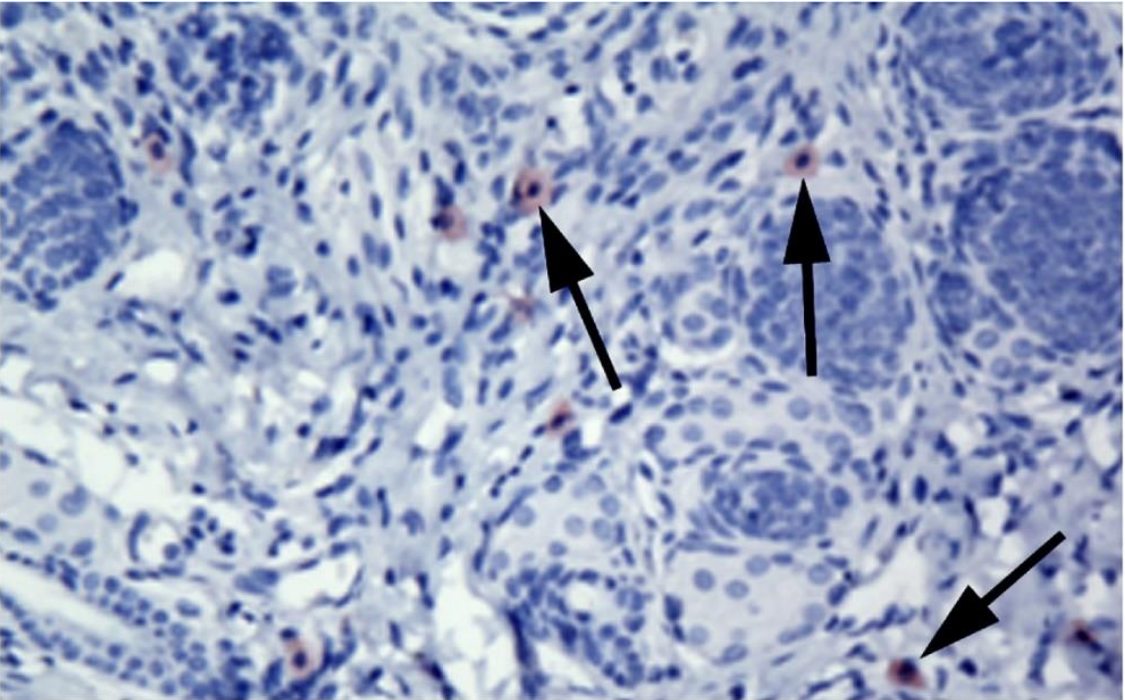


- ✓ After vaccination mice were mated and allowed to have a litter.
- ✓ The pups were perfectly normal at birth.
- ✓ **Mothers were unable to produce milk.**

**This proves that vaccination targeting  $\alpha$ -lactalbumin enables the immune system to destroy all cells producing that protein.**

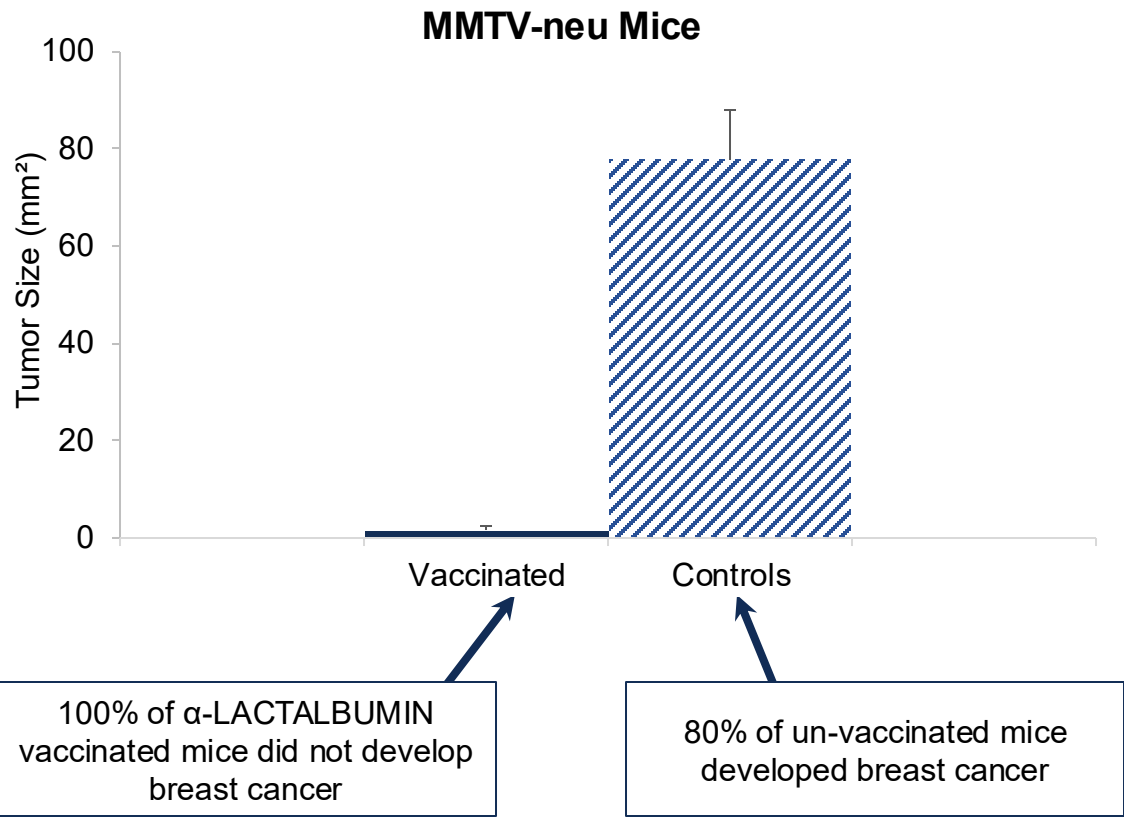
# Pre-Clinical Studies: Vaccination Prevents Breast Cancer

## Well-Tolerated



Vaccinated mice did not exhibit autoimmune damage, while single T-cell infiltrates were seen in non-lactating breast tissue (arrows)

## Robust Pre-Clinical Response



Data published: Cancers, 2016, 8, 56.

# Phase 1 Trial

Conducted by Cleveland Clinic, funded by U.S. Department of Defense (DOD)

## An open-label Phase 1 dose-escalation trial

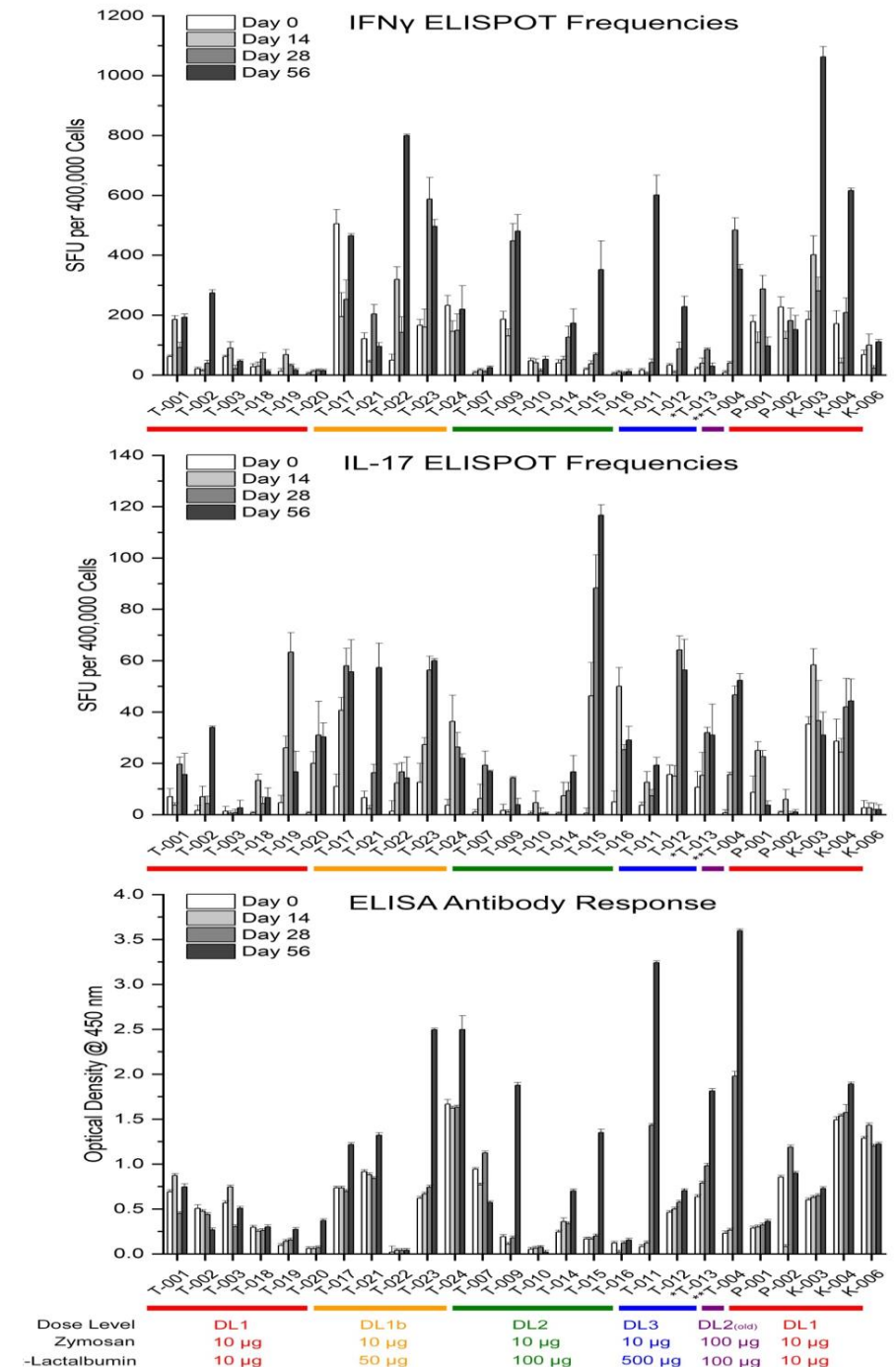
Design	Cohort 1a (Recurrence Group)	Cohort 1b (Prevention Group)	Cohort 1c (Treatment Group)
<p>Participants will receive three vaccinations, each two weeks apart, and will be closely monitored for side effects and immune response</p>	<ul style="list-style-type: none"> <li>24-36 Patients who have been treated for TNBC</li> <li>Safety will be monitored</li> <li>Immune Response will be monitored</li> <li>Maximum Tolerated Dose ("MTD") determined</li> </ul>	<ul style="list-style-type: none"> <li>Healthy women w/mutations</li> <li>Chosen to undergo prophylactic mastectomy</li> <li>Vaccinate before surgery and evaluate immune response and resected tissue</li> <li><b>Unique opportunity to garner supplemental data after studying breast tissue to determine if T cells are surveilling the tissue without any visible cancer tumors</b></li> </ul>	<ul style="list-style-type: none"> <li><b>Additional cohort combining vaccine with Keytruda</b></li> <li>Patients treated for TNBC</li> <li>Combine Keytruda w/ vaccine to evaluate if there is synergy</li> </ul>



# Positive Phase 1 Clinical Results

- 35 patients dosed through June 2025
  - TNBC patients who have undergone standard of care, but are at risk of recurrence (40-80% recur in 5 years)— [cohort 1a](#)
  - Genetic risk patients choosing prophylactic mastectomies— [cohort 1b](#)
  - Patients with residual disease taking Keytruda— [cohort 1c](#)
- Key Findings Presented on November 8, 2024 at Society of Immunotherapy of Cancer (SITC)
  - MTD reached
  - No safety concerns
  - Immune responses observed at all dose levels
  - 70% had protocol specified immune response
  - Intensity of other responses varied
  - Keytruda Plus Vaccine exhibited no additional adverse side effects, enabling combination use
- Phase 1 Status
  - Enrollment complete
  - Final Patient Visits will be in August 2025

## First 26 Patients



# Phase 2 Breast Cancer Vaccine Trial

## Near Term- Therapeutic Approach

### Phase 2 trial in neo-adjuvant setting – before surgery

- Faster evaluation of efficacy
- Multiple types of Breast Cancer
- Faster data, enabling earlier alliance with big Pharma

### Two Arms

- Standard of Care + Vaccine
- Standard of Care only (chemotherapy and/or immunotherapy, such as Keytruda)

# Breast Cancer Vaccine Development Plan and Market Opportunity

**Clinical Trials and Launches will occur in stages**

- **Neo-Adjuvant Therapeutic treatment**
- **Adjuvant-therapeutic treatment**
- **Recurrence Prevention**
- **Prophylactic Vaccination-**
  - **Cancer free individuals for primary prevention**

## **Market Opportunity**

- 2023- \$38.35 billion<sup>1</sup>
- 2030- \$89.67 billion, projected CAGR of 12.9%<sup>1</sup>

## **Market Opportunity**

- Over 3.8 MM breast cancer survivors in the U.S.<sup>2</sup>
  - Tens of millions outside of U.S.
- Millions harbor mutations creating high risk
- More than 80 million women are currently 40 or older in the U.S.
  - 1.4 billion outside the U.S.
  - Millions more age into this group annually

1) Maximize Market Research  
2) National Cancer Institute

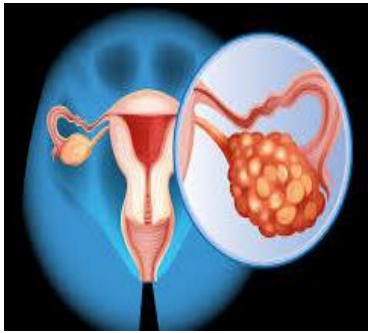


# Pre-Clinical Pipeline Ovarian, Lung, Prostate, Colon

# Collaboration with Cleveland Clinic and the National Cancer Institute

Driven by current promising data from Breast Cancer Vaccine Clinical Trial

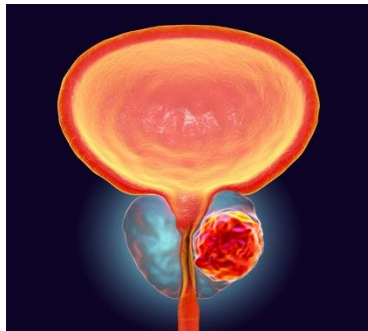
## Maintain our Lead in Prophylactic Cancer Vaccine Development



Ovarian



Lung



Prostate



Colon

### Development of Additional Cancer Vaccines

- Bioinformatic analysis utilizing advanced AI and supercomputing capabilities
- Pre-clinical studies to verify and validate antigen targets
- Animal studies to establish proof of concept
- Clinical Development





# Thank you

## CONTACT INFORMATION:

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