# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**Washington, D.C. 20549**

# FORM 8-K

**CURRENT REPORT**
**Pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): September 28, 2022

# ANIXA BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

| **Delaware** | **001-37492** | **11-2622630** |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

| **3150 Almaden Expressway, Suite 250**<br>**San Jose, CA** | **95118** |
|---|---|
| (Address of principal executive offices) | (Zip Code) |

Registrant's telephone number, including area code: **(408) 708-9808**

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation to the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| Common Stock, par value $0.01 per share | ANIX | The NASDAQ Stock Market LLC |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

**Item 7.01. Regulation FD Disclosure.**

On September 28, 2022, Dr. Jose Conejo-Garcia, Senior Member of the Immunology Department at Moffitt Cancer Center and the inventor of Anixa Biosciences, Inc.'s ("we," "us," "our," or the "Company") chimeric endocrine receptor T-cell technology—a new kind of chimeric antigen receptor T-cell technology (CAR-T)—made a virtual presentation at the Rivkin Center and American Association for Cancer Research (AACR) 14th Biennial Ovarian Cancer Research Symposium. During Dr. Conejo-Garcia's presentation, he discussed the science behind our CAR-T technology and the design of our ongoing clinical trial. We have attached as an exhibit to this Current Report applicable slides from Dr. Conejo-Garcia's presentation. In addition to his slide presentation, Dr. Conejo-Garcia stated the latest results of the trial for which enrollment continues. At the current time, one patient has been treated in the trial and safety signals look favorable, and imaging at one month post-treatment, indicate that the patient's tumor lesions are stable and not growing. The patient appears to be doing fine and will continue to be monitored. While these results are very promising, it is important to note that they are from a single patient at this time. Please see our risk factors included in our Annual Report on Form 10-K as well as our other reports filed with the Securities and Exchange Commission for a discussion of the risks associated with our clinical trial.

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 our 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 clinical trials, 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 in this Current Report.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits

The following exhibits are filed with this Current Report on Form 8-K:

| Exhibit No. | Description |
|---|---|
| 99.1 | Presentation |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: September 29, 2022

ANIXA BIOSCIENCES, INC.

By: */s/ Amit Kumar*
Name: Dr. Amit Kumar
Title: Chief Executive Officer

# Novel approaches for rendering CAR T cells finally effective against gynecologic malignancies

DISCLOSURES

Consultant for: Compass Therapeutics (till 2020), Anixa Biosciences, Alloy Therapeutics, Hibiscus Bioventures.

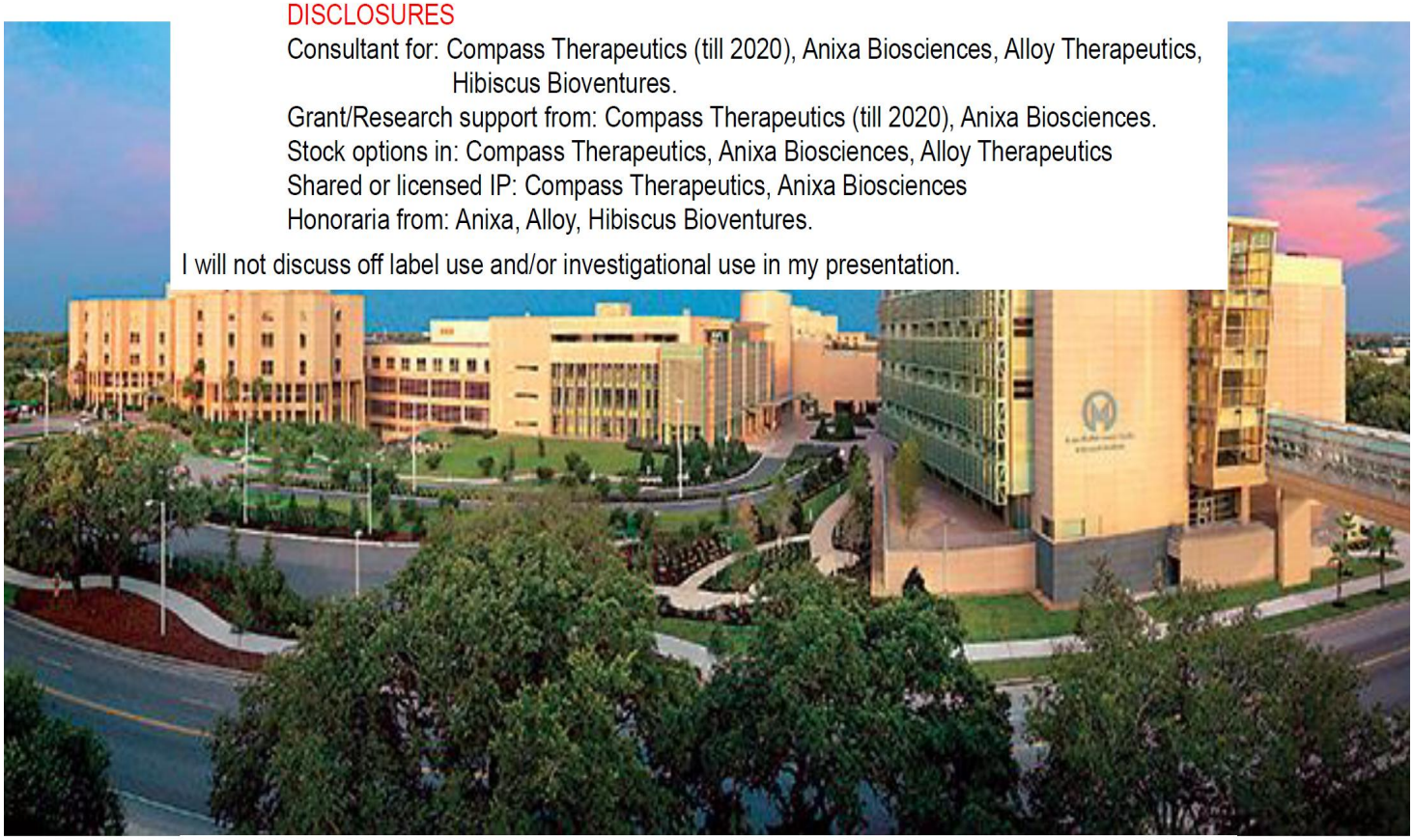
Grant/Research support from: Compass Therapeutics (till 2020), Anixa Biosciences.

Stock options in: Compass Therapeutics, Anixa Biosciences, Alloy Therapeutics

Shared or licensed IP: Compass Therapeutics, Anixa Biosciences

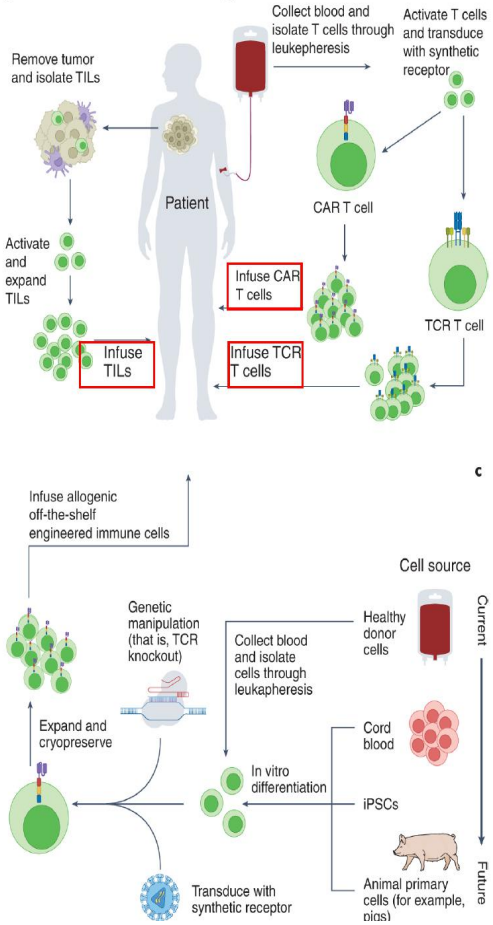
Honoraria from: Anixa, Alloy, Hibiscus Bioventures.

I will not discuss off label use and/or investigational use in my presentation.



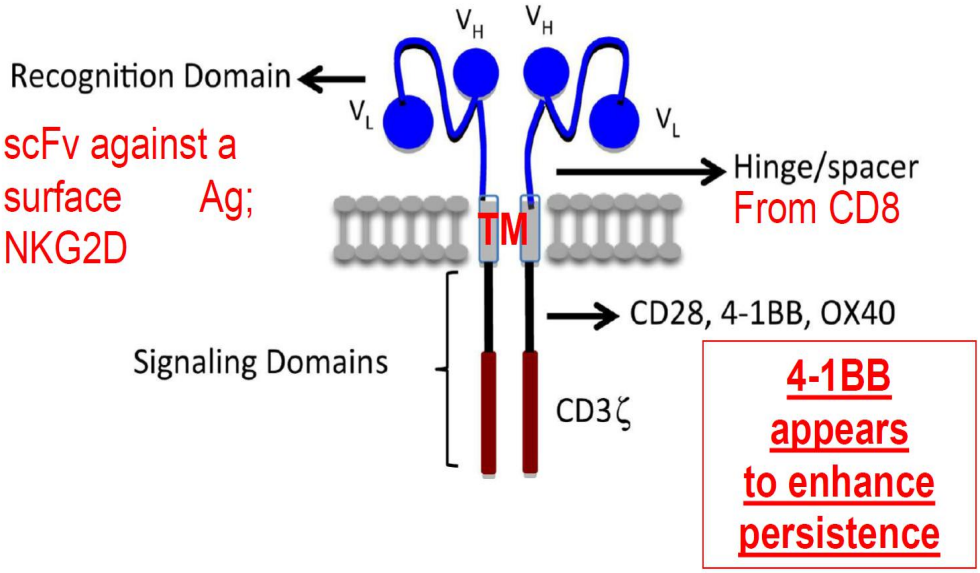
**Jose R Conejo-Garcia, MD, PhD, Rivkin, 2022**

# Engineered T cell adoptive transfer




Carl June et al; Nature Med. 2022.

# Second generation CAR T cells: Basic elements




-Lentiviral/retroviral transduction or RNA electroporation

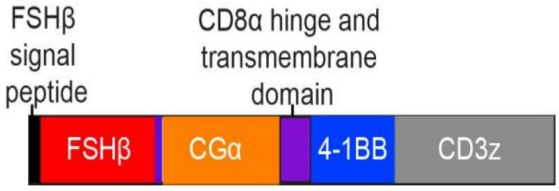
-Third generation in progress: Two co-stimulatory domains (CD28/4-1BB)…too much activity?

# Most current CAR T cell targets in solid tumors are shared with vital healthy tissues

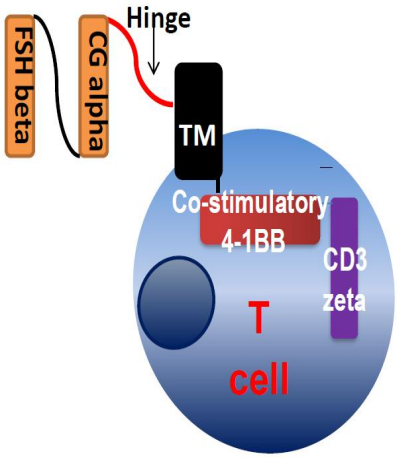
| Target | Disease |
|---|---|
| B7-H3? | Hepatocellular Carcinoma, Non-Small Cell Lung Cancer, Pancreatic Cancer, Germ Cell Tumor, Retinoblastoma, Glioblastoma |
| CAIX | Renal Cell Carcinoma |
| CD70 | Renal Cell Carcinoma, Ovarian Cancer, Cervix Cancer |
| CEA | Colorectal Cancer, Esophageal Cancer, Stomach Cancer, Pancreatic Cancer, Liver Metastases |
| Claudin 18.2 | Gastric / Esophagogastric Junction Adenocarcinoma, Pancreatic Cancer |
| EGFR | Non-Small Cell Lung Cancer, Ependymoma , Bile Duct Cancer, Gastric Cancer, Breast Cancer, Bladder Cancer, Head and Neck Squamous Cell Carcinoma, Cancer of the Salivary Gland, Brain neoplasm, Ependymoma |
| EpCam | Nasopharynx Neoplasm, Breast Cancer |
| **FSHR** | Ovarian cancer |
| GD2 | Osteosarcoma, Neuroblastoma, Malignant Brain Neoplasm, Ependymal tumor |
| GPC3 | Hepatocellular Carcinoma |
| HER-2 | Sarcoma |
| IL13Ralpha2 | Ependymoma, Glioblastoma, Medulloblastoma, Melanoma |
| ICAM-1 | Thyroid cancer |
| KLK2 | Prostate Cancer |
| Mesothelin | Pancreatic Cancer, Ovarian Cancer, Colorectal Cancer, Non-Small Cell Lung Cancer, Mesothelioma |
| MUC1? | Breast Cancer, Ovarian Cancer, Non-Small Cell Lung Cancer, Colorectal Cancer, Pancreatic Cancer, Renal Cell Carcinoma, Nasopharyngeal Cancer, Head and Neck Carcinoma, Gastric Cancer |
| NKG2D ligands | Colorectal cancer |
| PSCA | Prostate cancer, Pancreatic Cancer |
| PSMA | Prostate Cancer |
| ROR1 | Triple Negative Breast Cancer, Non-small Cell Lung Cancer |
| TAG72 | Ovarian Cancer, pancreatic cancer |

**Source: clinicaltrials.gov; June 23, 2022**

# FSHCER T cells targeting FSHR$^{+}$ ovarian cancer (NCT05316129; clinical trial, recruiting)




**PI: R Wenham, MD**
**Moffitt Cancer Center**

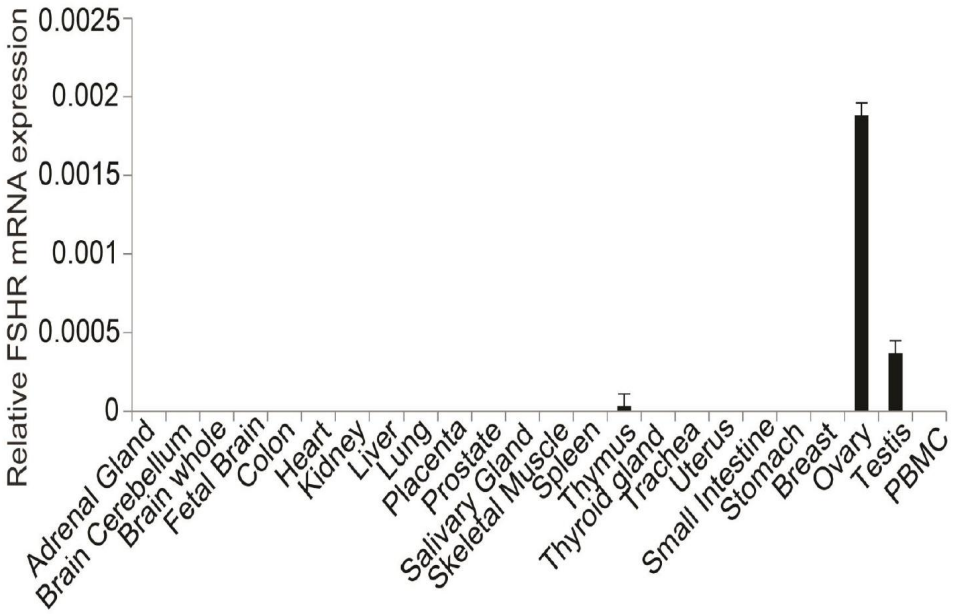



Perales-Puchalt et al; Clin Cancer Res. 2017.

NCT05316129:

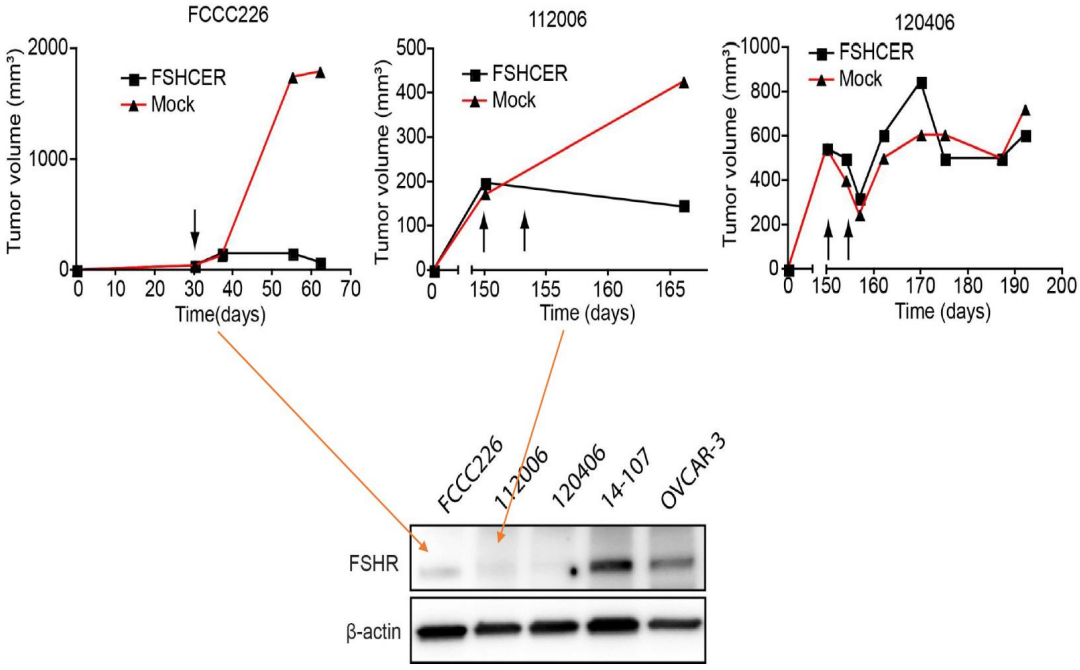
Autologous CD3$^{+}$T cells transduced w/ gamma retroviral vector, pMSGV1, for FSHR-specific 4-1BB/CD3 chimeric endocrine receptor expression, Intraperitoneal (IP)/Intravenous (IV) infusion

# FSHR is NOT expressed in non-ovarian healthy human tissues



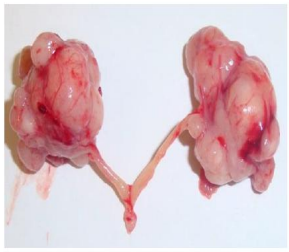

Perales-Puchalt et al; Clin Cancer Res. 2017.

# FSH-re-directed primary human T cells effectively target patient-derived FSHR+ tumors in vivo

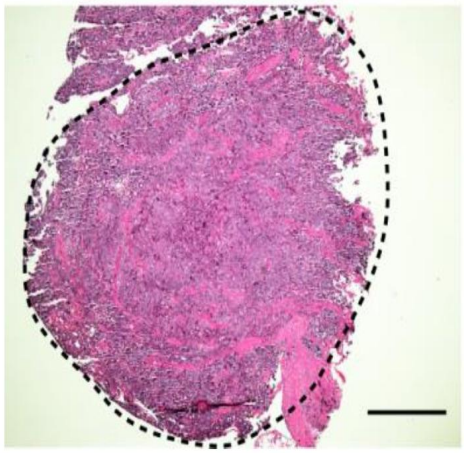



Perales-Puchalt et al; Clin Cancer Res. 2017.

# FSH-re-directed autologous human T cells effectively target orthotopic patient-derived FSHR+ tumors in vivo (II)

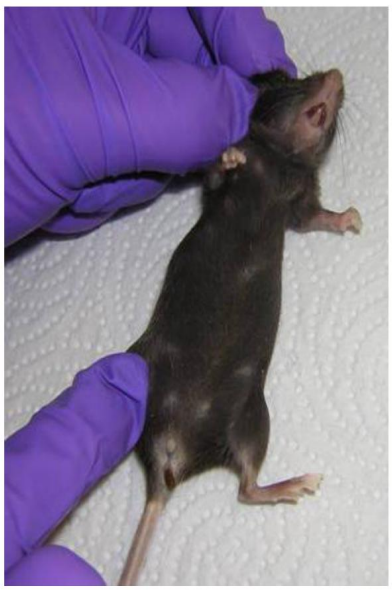


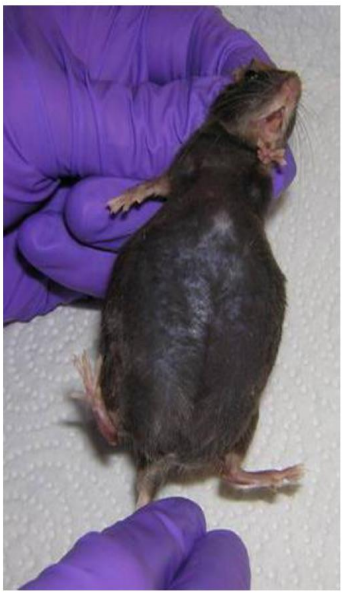
Mock 14-107 FSHCER



Perales-Puchalt et al; Clin Cancer Res. 2017.

**ID8-Defb29-Vegf-a i.p. injected tumor cells cause massive ascites and multiple peritoneal tumor masses in 35-40 days**

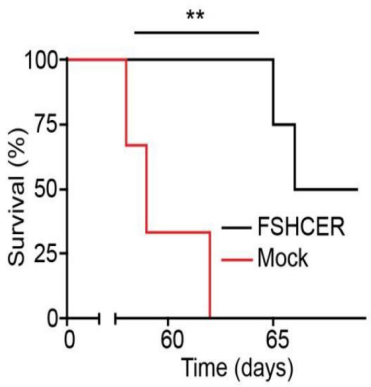




**Day 40 after tumor injection**

# FSH-re-directed mouse T cells effectively target orthotopic FSHR+ tumors in vivo in immunocompetent hosts

N=15 mice/group
3 independent experiments




I.P. Ovarian tumor
10e6 CERT cells
Days 7/14

## NCT05316129: Dose-escalation first-in-human clinical trial in recurrent/chemoresistant ovarian Ca

**-PI: R Wenham, MD** (NCT05316129; all Moffitt ovarian cancer patients; Moffitt CT Facility)

-I.P. *vs.* I.V.→ Comparative safety and effectiveness

-CAR T cell persistence/suppression, features of the infusion product, FSHR level needed

-"Vaccine" effect (boost of pre-existing ani-tumor immunity)

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

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

## TAKE HOME MESSAGE

→Tumor targeting can be achieved without killing vital tissues (FSHR, OR2H1, others?).

→Only by targeting antigens not expressed in vital tissues we will be able to develop effective interventions against solid tumors, through genetic engineering of T cells.

→Low antigen expression cans till provide a strong cytolytic response (>200 copies/cell are sufficient for effective killing).

→Personalized interventions for patients with tumors expressing the right target will be likely required.

**SPECIFICITY, SPECIFICITY, SPECIFICITY**