

Your patient has been diagnosed with an aggressive form of cancer. A personalized vaccine could be the answer. The Jaime Leandro Foundation can help obtain compassionate access.

Traditional vaccines revolutionized the treatment of disease. In recent years, personalized vaccines have shown promise in combating cancer. In addition, technological advances in genetic sequencing, algorithms to identify neoantigens, and peptide manufacturing have vastly improved the personalized vaccine development process.

Of critical importance, the FDA “Expanded Access” rule gives an individual the right to try a medical treatment outside of clinical trials when no comparable alternative options are available.



Turn to JLF

The Jaime Leandro Foundation (JLF) is a private nonprofit organization established to deliver breakthrough cancer treatments based on the latest innovations in research and personalized medicine and leveraging the Expanded Access rule — also known as “Compassionate Use.” We bring the critical components together, partnering with expert academic and commercial institutions to develop and deliver therapeutic vaccines personalized for each patient.

In essence, JLF is the hub, and our partners conduct advanced genetic sequencing, identify and approve the best patient-specific neoantigen targets, and manufacture, assemble, vial, and ship the personalized vaccine, which is administered by the treating physician. Then, JLF partners monitor and report results for the advancement of the field.

Taking the work out of paperwork

We know: preparing and submitting the paperwork necessary for Expanded Access can be a nuisance, taking you away from the many pressing demands on your time. That’s why JLF will assist with preparation of the FDA Expanded Access application. Upon approval, the FDA issues the patient an Investigational New Drug (IND) ID, which facilitates shipment of the vaccine.

LEADERSHIP TEAM

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Jaime Leandro Foundation for Therapeutic Cancer Vaccines

Personalized Neoantigen Vaccines through Expanded Access

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Click to learn more about Jaime.

COLLABORATORS

JLF partners are at the forefront of medicine and science. Each is an industry leader providing cutting-edge expertise and technology at every step. JLF consults with the patient and helps them navigate the entire process.

Ennov1



xCures

ennov1.com

csbio.com

xcures.com


PROCESS

The JLF process involves industry leaders providing cutting-edge technology at every step. JLF consults and contracts with the patient to discuss costs, holds IND and trial liability insurance, and guides the entire process. xCures manages patient protocol startup and consent with the treating physician. Developing a personalized therapeutic vaccine takes about three months.

PHASE 2: VACCINE DESIGN

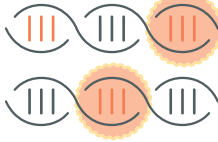
TIMING: 6 WEEKS
COST: \$20,000

2



ennov1 uses pVACseq to predict neoantigens and designs vaccine peptide components

2a




A genomic analyst reviews candidate peptides; immuno-tumor board finalizes and approves peptide list

PHASE 4: VACCINE ADMINISTRATION

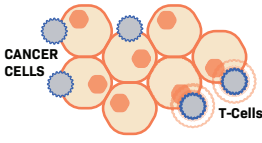
TIMING: UP TO 6 MONTHS
COST: \$12,000 PLUS PHYSICIAN ADMINISTRATION FEES

4



Treating physician administers the vaccine in a series of injections over first 3 months (up to 6 months at physician discretion and availability of additional vaccine)

4a




Immune cells learn to recognize the neoantigens in the cancer cells

PHASE 1: WHOLE EXOME SEQUENCING

TIMING: 4 WEEKS

COST: VARIES BY PROVIDER, JLF CAN HELP WITH CONSULTATION

1

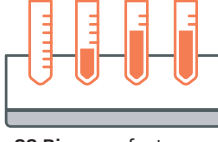


An approved lab conducts whole exome sequencing of tumor sample to identify patient-specific neoantigens

PHASE 3: VACCINE MANUFACTURING


TIMING: 10 WEEKS
COST: \$51,000

3



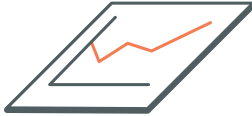
CS Bio manufactures personalized synthetic long GMP peptide vaccine components

3a



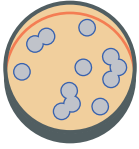
A lab vials and releases final injectable peptides for dosing; vaccine and Poly-ICLC shipped to treating physician pharmacy per xCures instructions

4b



ELISpot monitoring of immune response is performed

4c



xCures through XCELSIOR outcomes registry centrally collects medical records and safety data

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