

DPX-0907 OVERVIEW

Study Title: A Phase I Study of Two Different Doses of the Subcutaneous Administration of an Immunotherapeutic Vaccine, DPX-0907 in Advanced Stage Patients with Ovarian, Breast or Prostate Cancer

The DPX-0907 vaccine is an innovative treatment for breast, ovarian and prostate cancers. DPX-0907 combines seven essential peptide antigens with Immunovaccine's potent DepoVax™ delivery platform. The vaccine is designed to stimulate an immune response to antigens on the surface of tumor cells which are critical to tumor cell processes and kill tumor cells without injury to normal, healthy cells.

1. DPX-0907 VACCINE

Immunovaccine Inc. is developing DPX-0907, a new investigational therapeutic cancer vaccine, to see if it can provide an effective treatment for people with advanced stage patients with breast, ovarian or prostate cancer.

Clinical Tumor Antigens

The seven peptide antigens in DPX-0907 are present on the surface of breast, ovarian and prostate cancer cells. DPX-0907 is a multi-targeted approach that uses the seven novel peptides from proteins in the major cancer pathways.

DPX-0907 is thought to work by stimulating the body's immune system to identify and target cancer cells expressing the above peptide antigens and specifically target and promote tumor killing. The multi-target vaccine approach also avoids tumor escape.

2. STUDY DESCRIPTION

The clinical trial is an open label Phase 1 study designed to evaluate the safety of two dose levels of the immunotherapeutic vaccine DPX-0907. The year long trial will enroll up to 24 patients with advanced breast, ovarian or prostate cancer. Patients will have undergone surgery to remove their tumors, followed by cytotoxic therapy before participating in the study.



DepoVax™ Vaccine Delivery Technology

The patented DepoVax™ delivery platform creates a strong depot effect that makes it unique. The DepoVax™ platform is a vaccine-in-oil delivery system whereby the active vaccine components – the antigens and adjuvant – are presented to the immune system for a prolonged period, significantly enhancing the immune response.

Participants in the Phase I study will receive three doses of the subcutaneous administered vaccine. The study is recruiting patients at several cancer centers in the United States.

3. STUDY OBJECTIVES

The primary goal of the trial is to establish the safety of the vaccine candidate which includes the DepoVax™ delivery platform.

The secondary goals include evaluation of dosing and an assessment of the degree of immune response.

4. PATIENT ELIGIBILITY

| | |
|----------------------------|---|
| Age: | 18 Years and older |
| Sex: | Female or male |
| Performance status: | ECOG 0-1 |
| Life expectancy: | At least 6 months |
| Other: | <ul style="list-style-type: none"> Ability to understand and provide a signed informed consent form approved by the Institutional Review Board. Ability to return to the study site for follow-up, as required by this protocol. HLA A2 haplotype. Adequate blood counts Adequate liver and kidney function If sexually active, patients must agree to use acceptable birth control |

Disease Characteristics and Inclusion Criteria

Ovarian Cancer: Patients with stage III or IV ovarian cancer who have completed a course of platinum-based cytotoxic therapy after debulking surgery with evidence of a complete or partial response by radiological imaging, are eligible. Patients with metastatic ovarian cancer who have stable disease for greater than 3 months after completion of first-line therapy are eligible.

Breast Cancer: Patients with stage IV breast cancer who have received at least one course of hormonal or cytotoxic therapy for metastatic cancer. These patients may have completed their course of cytotoxic therapy and be off therapy with stable disease or better for 3 months or greater duration. Patients may have stable disease and still be on hormonal therapy or have completed a course of hormonal therapy.

Prostate Cancer: Patients with prostate cancer who have failed at least one course of an accepted hormonal therapy. Specifically, prostate cancer patients must have

castrate testosterone levels (< 50 ng/dl) and two PSA values higher than the previously documented baseline at least 3 weeks apart with the absolute PSA being greater than 2 ng/mL and a 25% increase from baseline, or evidence of increases in measurable disease. These patients may have received previous courses of cytotoxic chemotherapy although chemotherapy naïve patients who are deemed not good candidates for, or who have refused, cytotoxic therapy will be eligible. Patients with prostate cancer may remain on anti-androgen therapy during the trial. Prior therapy with Sipuluecel T will be allowed provided there has been 8 weeks from the last Sipuluecel T injection prior to receiving the first injection of DPX-0907 completion of this therapy. Patients with evidence of progressive bone or other metastases are acceptable.

5. STUDY METHODOLOGY

Patients will be screened for eligibility up to 30 days prior to the day of the first injection. Patients will receive three subcutaneous injections of the vaccine three weeks apart. Injections will be administered in the upper thigh. Additional blood samples will also be collected at regular intervals following the last immunization to examine the immune responses generated by the vaccine.

There will be two dose cohorts with up to 12 patients in each cohort. Each patient will receive three immunizations.

| Cohort | Dose level | Study Day 0 | Study Day 21 ± 3 days | Study Day 42 ± 3 days |
|--------|------------|-------------|-----------------------|-----------------------|
| A | 0.25 mL | X | X | X |
| B | 1 mL | X | X | X |

X=Injection

It is estimated that the first patient will be enrolled by March 2010 and it is expected that the last patient will complete the last follow-up visit in approximately 13 months. The enrollment and treatment periods with the vaccine will be approximately 7 months. The follow-up period will be 6 months.

The Safety Review Committee (SRC) will review safety data before proceeding to the next dose or cohort. The SRC will decide on the appropriate action based on pre-defined criteria in the clinical protocol for stopping or not dose progression.

6. PARTICIPATING IN CLINICAL TRIALS

- Participation in a clinical trial is voluntary and you can withdraw from the trial at any time.
- All information regarding your participation is treated as confidential.
- Each trial has its own specific criteria that participants must meet in order to enroll in the trial. These inclusion / exclusion criteria are based on such factors as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions. It is important to note that inclusion and exclusion criteria are not used to reject people personally, but rather to identify appropriate participants and keep them safe.
- Ask questions if you do not understand something.
- Be honest with the investigator regarding all aspects of the trial. Negative information is just as important as positive information.

What is informed consent?

Informed consent is the process in which the clinical trial personnel (physician, nurse, or study coordinator) will explain to the participant the purpose, duration, required procedures, risks, potential benefits of participating in the study as well as who to contact should additional questions/concerns arise. The participant then determines whether or not he/she wishes to participate. The participants' signature on the informed consent document verifies their willingness to take part in the trial. It is important to recognize that informed consent is NOT a contract and can be withdrawn at any time.

What government organization oversees clinical trials?

The Food and Drug Administration (FDA) oversees clinical trials in the United States. The FDA is updated on a regular basis on the progress of the study.

What are the phases of clinical trials?

Clinical trials are conducted in phases. The trials at each phase have a different purpose and help scientists answer different questions.

In **Phase I trials**, researchers test a new drug or treatment in a small group of people for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.

In **Phase II trials**, the study drug or treatment is given to a larger group of people to establish an appropriate dose, see if it is effective and to further evaluate its safety.

In **Phase III trials**, the study drug or treatment is given to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.

What are the benefits and risks of participating in a clinical trial?

Benefits

Clinical trials that are well-designed and well-executed are the best treatment approach for eligible participants to:

- Play an active role in your own health care. Gain access to new research treatments before they are widely available.
- Obtain expert medical care at leading health care facilities during the trial.
- Help others by contributing to medical research.

Risks

There are risks to participating in a clinical trial.

- There may be unpleasant, serious or even life-threatening side effects to treatment.
- The treatment may not be effective for the participant.
- The protocol may require more time and attention than would a non-protocol treatment, including trips to the study site, more treatments, hospital stays or complex dosage requirements.

SAFETY REVIEW COMMITTEE

A Safety Review Committee (SRC) will review safety data during the course of this study and make decisions regarding patient safety. The SRC consists of a Chair, Medical Safety Monitor, and at least two independent medical oncologists. Immunovaccine has assigned an M.D. employed by CATO, as Chair and Medical Safety Monitor.

This study is in accordance with Good Clinical Practice (GCP), the ethical principles that have their origin in the Declaration of Helsinki, Title 21 of the Code of Federal Regulations Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards), and 312 (Investigational New Drug Application), and International Conference on Harmonization E6 (Good Clinical Practice).

For more information on the DPX-0907 study, or to find a participating center and learn more about eligibility criteria, go to www.clinicaltrials.gov.