# VITAL-1 and VITAL-2 Clinical Trials
# FREQUENTLY ASKED QUESTIONS FOR POTENTIAL STUDY PARTICIPANTS

**What is a clinical study?**

A clinical study is a research investigation that evaluates a potential new treatment for a specific disease. The studies are conducted by physicians and their staff. People participating in the study are volunteers. The U.S. Food and Drug Administration (FDA) has approved the use of the investigational drug as part of a research study only; the investigational drug is not available to patients outside the study.

## *Study-Specific Questions*

**What is the objective of this study?**

An investigational immunotherapy drug is being studied for use in men with prostate cancer who have failed hormone therapy. There are currently two studies: VITAL-1 and VITAL-2. VITAL-1, for men without cancer-related pain, compares the duration of survival between men given the investigational immunotherapy versus men given Taxotere and prednisone. VITAL-2, for men with cancer-related pain, compares the duration of survival between men given GVAX® plus Taxotere versus men given Taxotere and prednisone.

**What is the name of the study drug?**

There isn't a brand name yet for this investigational immunotherapy but it is referred to as GVAX® Immunotherapy for Prostate Cancer.

**What are the procedures?**

Details of the procedures will be discussed more thoroughly at your first appointment with the study doctor. Depending on (a) which study you are joining (VITAL-1 or VITAL-2), and (b) which study group you are assigned to, the procedures may be slightly different.

**Who makes the study drug?**

Cell Genesys, Inc.

**Who is the sponsor of this study?**

Cell Genesys, Inc.

**Am I talking to someone at Cell Genesys?**

Not directly. I represent an independent company contracted by Cell Genesys, Inc. to recruit patients for the clinical studies.

**Where is the study being conducted?**

The study is being conducted at sites in the U.S., Canada and several European countries.

**Who can participate in the study/Who qualifies for this study?**

Potentially eligible men include those who have prostate cancer and have taken hormone therapy – such as Lupron, Eulexin, Proscar, Casodex, or Nilandrone – but whose cancer has spread. After evaluating these and other factors, the study doctor will decide whether you are qualified for this trial.

**How long does the study last?**

The study treatment lasts approximately 6 months. After investigational treatments are completed, you will be monitored for the rest of your life to see how you are doing. This is called long-term follow-up.

**Will I receive the investigational immunotherapy drug?**

If you qualify you will be assigned by randomization, a process like tossing a coin, into one of the two arms. In VITAL-1, you will have 50% chance of getting the investigational immunotherapy and 50% chance of getting Taxotere and prednisone. If you qualify for VITAL-2, you will have a 50% chance of getting Taxotere and the investigational immunotherapy and 50% chance of getting Taxotere and prednisone.

**What will I have to do if I am in the study?**

Depending on which group you are randomized to, you will need to go to the study clinic every 2 or 3 weeks for 6 months to receive your investigational treatment. If you are in the group that receives the investigational immunotherapy, there is a possibility of getting the investigational drug for the rest of your life. At each visit, the study doctor will complete a physical exam, take about 4-6 tablespoons of blood from you for laboratory tests, ask questions regarding your pain, and ask about your current pain medications. Then a staff member will administer the investigational treatment.

**When will I know if I qualify for the study?**

The study doctor will make the final decision after examining you and running some tests to check your eligibility for the study.

**What can I expect at the first study clinic visit?**

The study doctor and clinic staff will ask you specific questions, perform a physical examination, and run some tests to determine whether you are eligible for the study. The study will be explained to you in detail, and you will be able to ask questions. You will not receive study medication at the first visit.

**Will I receive the study drug or a placebo?**

There is no possibility of receiving placebo in either study. Depending on which study you join, VITAL-1 or VITAL-2, you will receive either GVAX® immunotherapy or chemotherapy, or both.

**What if I change my mind after I agree to be in the study?**

Participation is completely voluntary in this study, including the long-term follow-up. You may decide to withdraw from the study at any time. If you decide not to participate in the study or if you remove yourself from the study, it will not affect your present or future medical care.

## *Patient's Personal Physician*

**Does my doctor have to give his/her permission?**

No, but we encourage you to inform your personal physician if you decide to participate.

**Should I still see my personal doctor?**

Yes, you are encouraged to continue to see your personal physician for usual care.

**Will my personal doctor be kept informed of my progress and test results?**

We encourage you to talk with the study physician about how your personal doctor will be involved, and about how often the study clinic will inform your personal physician of your progress.

**What information will be furnished to my personal doctor?**

Information on your progress is available to your personal physician at any time with your permission.

## *Reimbursement Issues*

**Will I incur any cost for being in the study?**

There are no additional costs to join either study. When you see the study doctor for the first time, please discuss with him/her any concerns you have about costs.

**I'd like to be in the research study, but I have limited funds for transportation. Can I get reimbursed for other expenses?**

It may be possible to receive modest reimbursement for lodging, food and travel expenses. You will need to talk to the study doctor and staff to see if all or part of your travel expenses can be reimbursed. If you qualify for reimbursement, you will need to give the study staff your receipts in order to be reimbursed. The study doctor or staff will discuss with you what is a reasonable cost.

## *Specific Medical Questions*

If you have specific medical questions, bring them with you when you go to your first screening visit at the study site. Staff there will be happy to answer all your questions and provide more information.