StemVacs Immunotherapy Platform for Prostate Cancer

StemVacs is a platform for antigen-nonspecific immune modulatory treatment that can be utilized as a monotherapy or as a combination with antigen specific modalities such as peptide or protein based vaccines.

StemVacs is therefore a subcutaneously administered vaccine comprised of immune stimulatory peptides resembling cancer stem cell specific proteins.

StemVacs is now available as a treatment option at the Pan American Cancer Treatment Center in Tijuana, Mexico for stages 1-4 breast and prostate cancers.

Immunotherapy as an Alternative to Watchful Waiting

Early Stage Prostate Cancer: Because prostate cancer often grows very slowly, some men (especially those who are older or have other serious health problems) might never need treatment for their prostate cancer. Instead, their doctors usually recommend approaches known as watchful waiting. If you have elevated PSA but slow-growing prostate cancer, does it make sense to play “Russian Roulette” with your health? Currently, the only medical intervention that is available to patients with early-stage prostate cancer who do not want to “wait” is taking finasteride, which although has been shown to decrease the overall incidence, the patients that developed aggressive cancer had higher aggression when taking finasteride as compared to controls [1].

Immunotherapy Instead of Waiting: One promising treatment that we are developing and offering at the Pan Am Cancer Treatment Center, for patients who are “watchfully waiting” is the application of an immunotherapy that specifically trains the immune system to attack cancer.

It has the capacity to activate other immune cells in the body to attack proteins found on prostate-derived cells. Since prostate cancer cells possess prostate proteins, the immune system of patients treated with Provenge begins attacking prostate cancer cells not only in the prostate but all throughout the body [3]. One of the main reasons why Provenge is not utilized in the United States for early-stage prostate cancer is its high costs [4].

This is very unfortunate because in the early stages of prostate cancer the immune system of the patient is still relatively intact, thus offering a much higher chance of success [5, 6].

With the advantage of 10 years of experience in cellular processing and manufacturing, as well as a partnership with Key Opinion Leaders in the area of dendritic cell therapy, the Pan Am Cancer Treatment Center offers a novel way of dealing with early-stage prostate cancer.

Instead of “watchful waiting” or taking drugs that potentially increase the possibility of developing aggressive tumors, we offer a prostate cancer immunotherapeutic based on the same scientific principles as Provenge except for increased efficacy and lower price.

Rationale for Immunotherapy: The immune system is an ever-vigilant defense against bacterial, viral and parasitic infections, as well as against cancer [7]. Early studies demonstrated that some cancer patients whose immune systems are activated as a result of bacterial infections undergo remissions. Importantly, patients who have a chronically low level of immune activity are characterized by staggeringly high incidence of cancer [8].

Further support for an active role of the immune system in protecting the body against cancer comes from recent clinical trials in which a class of immune system stimulatory drugs termed “checkpoint inhibitors” have achieved previously unheard of results in cancers resistant to treatment such as advanced prostate cancer [9].

It is well recognized that various types of cancers possess an incrementally higher level of ability to suppress the immune system the more advanced the cancer is. For example, in prostate cancer patients, those possessing a higher Gleason score suffer from an increased suppression of immune function [10, 11].

Accordingly, augmentation of anticancer responses by introducing immunotherapy earlier in the pathogenesis of cancer progression increases the probability of success.
NanoStilbene: Patented Augmenter of Cancer Immunotherapy

NanoStilbene, a nanoparticle formulation of pterostilbene, is covered for use in cancer immunotherapy under the Company's issued U.S. Patent No.: 9,682,047 and is included as part of the Prostate Cancer Protocol with StemVacs. NanoStilbene is an easily absorbed nanoemulsion of nanoparticle pterostilbene in the range of 75-100nm at a concentration of 30 milligrams per milliliter. The pterostilbene placed in a nanoemulsion droplet is free from air, light, and hard environment; therefore, as a delivery system, nanoemulsion can not only improve the bioavailability of pterostilbene but also protect it from oxidation and hydrolysis, while it possesses an ability of sustained release at the same time.

Therapeutic uses of nanotechnology typically involve the delivery of small-molecule drugs, peptides, proteins, and nucleic acids. Nanoparticles have advanced pharmacological effects compared with the therapeutic entities they contain. Active intracellular delivery and improved pharmacokinetics and pharmacodynamics of drug nanoparticles depend on various factors, including their size and surface properties. Nanoparticle therapeutics is an emerging treatment modality in cancer and other inflammatory disorders. The National Cancer Institute has recognized nanotechnology as an emerging field with the potential to revolutionize modern medicine for detection, treatment, and prevention of cancer.

Conclusion:
At present, the only options available for patients with early-stage prostate cancer is waiting or taking drugs that potentially could increase aggressiveness.

The Pan Am Cancer Treatment Center has generated an economical means of generating the same immunotherapy as the FDA approved Provenge, however specific to targeting early-stage cancer.

The Pan American Cancer Treatment Center is located a few miles south of sunny San Diego, in Tijuana, Mexico. The Pan Am facilities are state of art and offer access to cutting edge cancer immunotherapies outside of clinical trials. After we receive you in San Diego, you will travel by air conditioned transportation to our new and modern treatment center, where you will have access to cellular, small molecule, and protein therapies through accelerated means.

References:
Additional StemVacs Platform Immunotherapeutics

The immune system's natural capacity to detect and destroy abnormal cells may prevent the development of many cancers. However, cancer cells are sometimes able to avoid detection and destruction by the immune system. Cancer cells may:

- reduce the expression of tumor antigens on their surface, making it harder for the immune system to detect them
- express proteins on their surface that induce immune cell inactivation
- induce cells in the surrounding environment (microenvironment) to release substances that suppress immune responses and promote tumor cell proliferation and survival

In the past few years, the rapidly advancing field of cancer immunology has produced several new methods of treating cancer, called immunotherapies, which increase the strength of immune responses against tumors. Immunotherapies either stimulate the activities of specific components of the immune system or counteract signals produced by cancer cells that suppress immune responses.

The overarching approach to cancer on our StemVacs platform is as follows:

- Treat innate immune suppression: Administration of oral apigenin/pterostilbene (Cancer Metabolic DeTox Product) to decrease immune suppressive toxic molecules made by tumor and tumor microenvironment.
- Treat adaptive immune suppression: Administration of MemoryMune to activate dormant memory cells recognizing the tumor. Administration of LymphoBoost to repair deficient IL-12 production.
- Stimulation of immune response to cancer stem cells (StemVacs).
- Consolidation and maintenance of immunity: Cycles of StemVacs, supported by innaMune and LymphoBoost

**Cancer Metabolic DeTox**: This is an orally administered agent that is derived from various herbs termed apigenin. The unique property of apigenin is that it inhibits a cancer associated metabolic pathway that degrades the amino acid tryptophan. Specifically, apigenin inhibits the enzyme indolamine 2,3 deoxygenase (IDO), which is responsible for breaking down tryptophan in the vicinity of the tumor and generating by-products such as kynurenine. It is known that immune activation is dependent on tryptophan being present in the tumor environment. The depletion of tryptophan and generation of kynurenine by tumor cells and tumor associated cells is a major cause of immune suppression in cancer. By administering Cancer Metabolic DeTox, the innate arm of the immune system has a chance to regenerate. This positions the patient for better outcome after administration of specific immune stimulating vaccines.

**innaMune**: Is a biological product derived from a tissue culture of blood cells derived from healthy donors. It is a combination of cytokines that maintain activity of innate immune system cells, as well as having the ability to shift M2 macrophages to M1. In one instance a composition is extracted from polyvalently activated peripheral blood mononuclear cells through dialysis. This immune modulator is useful for the treatment of cancer and alleviation of cancer associated immune depression. As an immunomodulator, innaMune acts as a costimulatory of T cell activation by modulation of cytokine production. In another application the immune modulator is concentrated for miRNA species capable of activating innate immune cells.

**LymphoBoost**: Is a proprietary formulation of Mifepristone, a drug approved for another indication, which we have shown to be capable of stimulating lymphocytes, particularly NK cells and T cells, both critical in maintaining anti-tumor immunity. LymphoBoost is useful for improving a treatment outcome and/or an alteration of immunity in a condition that benefits from immune stimulation. In particular, administration of sufficient doses of mifepristone or a derivative, alone, or in combination with an immunotherapeutic such as, but not limited to, an antibody, a vaccine, a cytokine, or a medicament whose therapeutic activity is associated with immune modulation.

**MemoryMune**: Is a product derived from a two-step culture process of donor blood cells. The product MemoryMune reawakens dormant immune memory cells. It is known that many cancer patients possess memory T cells that enter the tumor, however, once inside the tumor these cells are inactivated. MemoryMune contains a unique combination of growth factors specific for immune system cells called "cytokines".