



NEWS RELEASE

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Autologous Cellular Immunotherapy Provided by Harbin Clinic Cancer Program

FOR IMMEDIATE RELEASE

ROME, GA., December 9, 2010 -- Autologous cellular immunotherapy, which uses a patient's own white blood cells to fight prostate cancer, will be available to patients in the Harbin Clinic Cancer Program, it was announced today by Al Diaz, Medical Director of the Clinic. Harbin will be the first cancer center in Northwest Georgia to offer this treatment.

According to Harbin Clinic Medical Oncologist Thomas Simpson, M.D., "Prostate cancer has the ability to hide from the body's immune system. Prostate cancer cells change the body's immune system so that young antigen-presenting cells fail to recognize and destroy cancer cells."

Autologous cellular immunotherapy takes blood from patients and manipulates the blood in a laboratory so that mature antigen-presenting cells recognize and destroy prostate cancer. The blood is then re-introduced into the patient and the mature antigen cells attack and usually destroy the prostate cancer.

“We are very proud of our cancer program,” Dr. Diaz said. “Like many of our medical specialties, our cancer program leads the way for cancer programs around the world. Autologous cellular immunotherapy is only one example of the cutting-edge technology available to patients in our cancer program and to patients at our new cancer center when it opens in 2011.

Called Provenge, it is the first FDA-approved autologous cellular immunotherapy. The treatment is recommended for patients with asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer. This treatment, Provenge (sipuleucel-T) is an autologous cellular immunotherapy for patients that have been screened by a Urologists and meet the following criteria prior to referral:

- Metastatic castrate resistant prostate cancer
- Asymptomatic or minimally symptomatic defined as:
 - ~ No moderate-to-severe prostate-related pain
 - ~ No use of narcotics for cancer-related pain
- Life expectancy of at least 6 months
- ECOG Performance Status 0 or 1
- No treatment with chemotherapy in at least the previous 3 months
- No visceral (lung, liver, or brain) metastases
- No treatment within 28 days with systemic corticosteroids

According to Dr. Simpson, “Provenge is designed to stimulate the patient’s immune system; therefore, concurrent use of immunosuppressive agents may alter efficacy or safety. Patients should be carefully evaluated to determine whether this

treatment or other prostate cancer treatments in the Harbin Clinic cancer program are most appropriate.”

“The real strength of our prostate cancer treatment program – what makes it special – is the partnership and cooperation among Harbin Clinic specialists,” said Medical Oncologist Melissa Dillmon, Jr., M.D. “Urology, Radiation Oncology and Medical Oncology Departments work together to provide the most appropriate treatment for each patient.”

Harbin Clinic has served North West Georgia for more than 60 years. The clinic currently includes more than 140 physicians in 20 locations. For more information on Harbin Clinic, visit www.Harbinclinic.com.

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Side Bar

Questions and Answers about Prostate Cancer

1. **What is the prostate?**

The prostate is a gland in the male reproductive system. The prostate makes and stores a component of semen and is located in the pelvis, under the bladder and in front of the rectum. The prostate surrounds part of the urethra, the tube that empties urine from the bladder. A healthy prostate is about the size of a walnut. Because of the prostate’s location, the flow of urine can be slowed or stopped if the prostate grows too large.

2. **What is prostate cancer?**

Prostate cancer forms in the tissues of the prostate. Except for skin cancer, cancer of the prostate is the most common cancer in American men. It was estimated that more than 186,000 men in the United States would be diagnosed with prostate cancer in this year. In most men with prostate cancer, the disease grows very slowly. The majority of men with low-grade, early prostate cancer (which means that cancer cells have been found only in the prostate gland) live a long time after their diagnosis. Even without treatment, many of these men will not die of prostate cancer, but rather will live with it until they eventually die of some other, unrelated cause. Nevertheless, it was estimated that nearly 29,000 men would die from prostate cancer this year.

3. Who is at risk for prostate cancer?

An important risk factor is age; more than 70 percent of men diagnosed with this disease are over the age of 65. African American men have a substantially higher risk of prostate cancer than white men, including Hispanic men. In addition, dramatic differences in the incidence of prostate cancer are seen in different populations around the world.

Genetic factors appear to play a role in prostate cancer development, particularly among families in which the diagnosis is made in men under age 60. The risk of prostate cancer rises with the number of close relatives who have the disease.

Some evidence suggests that dietary factors may increase or decrease the risk of prostate cancer.

4. What are the symptoms of prostate cancer?

Most of the time, prostate cancer does not initially cause symptoms. By the time symptoms do occur, the disease may have spread beyond the prostate. Symptoms of prostate cancer may include the following:

- Urinary problems:
 - Not being able to urinate.
 - Having a hard time starting or stopping the flow of urine.
 - Needing to urinate often, especially at night.
 - Weak flow of urine.
 - Urine flow that starts and stops.
 - Pain or burning during urination.
- Difficulty having an erection.
- Blood in the urine or semen.
- Frequent pain in the lower back, hips, or upper thighs.

Although these symptoms can be symptoms of cancer, they are much more likely to be caused by noncancerous conditions. It is important to check with a doctor.

5. What other prostate conditions can cause symptoms like these?

As men get older, their prostate may grow bigger and block the flow of urine or interfere with sexual function. This common condition, called benign prostatic hyperplasia (BPH), is not cancer, but it can cause many of the same symptoms as prostate cancer. Although BPH may not be a threat to life, it may require treatment with medicine or surgery to relieve symptoms. An infection or inflammation of the prostate, called prostatitis, may also cause many of the same symptoms as prostate cancer. Again, it is important to check with a doctor.

6. Can prostate cancer be found before a man has symptoms?

Yes. Prostate cancer screening is looking for the disease before a person has any symptoms. Two screening tests commonly used to detect prostate cancer in the absence of symptoms are the digital rectal exam (DRE), in which a doctor feels the prostate through the rectum to find hard or lumpy areas, and a blood test that detects a substance made by the prostate called prostate-specific antigen (PSA). Together, these tests can detect many “silent” prostate cancers that have not caused symptoms. Due to the widespread use of PSA testing in the United States, approximately 90 percent of all prostate cancers are currently diagnosed at an early stage, and, consequently, men are surviving longer after diagnosis.

7. How reliable are the screening tests for prostate cancer?

Neither of the screening tests for prostate cancer is perfect. Most men with an elevated PSA level do not have prostate cancer (false positives), and some men with prostate cancer have a low PSA level (false negatives). The DRE is also associated with false positives and false negatives. Using the DRE and PSA together will miss fewer cancers (greater sensitivity) but also increases the number of false positives and subsequent biopsies in men without cancer (lower specificity).

The National Cancer Institute’s (NCI) Early Detection Research Network (EDRN) has a Prostate Collaborative Group that is exploring a variety of strategies to find better ways to detect prostate cancer early. In addition, NCI’s prostate cancer Specialized Program of Research Excellence (SPORE) is funding projects to identify new diagnostic and prognostic biological markers, or biomarkers, of prostate cancer besides PSA.

8. How is prostate cancer diagnosed?

A diagnosis of prostate cancer can be confirmed only by biopsy. During a biopsy, a urologist (a doctor who specializes in diseases of urinary and sex organs in men, and urinary organs in women) removes tissue samples, usually with a needle. This is generally done in the doctor’s office with local anesthesia. Then, a pathologist

(a doctor who identifies diseases by studying tissues under a microscope) checks for cancer cells.

Men may have blood tests to see if the cancer has spread. Some men also may need the following imaging tests:

- **Bone scan:** A doctor injects a small amount of a radioactive substance into a blood vessel, and it travels through the bloodstream and collects in the bones. A machine called a scanner detects and measures the radiation. The scanner makes pictures of the bones on a computer screen or on film. The pictures may show cancer that has spread to the bones.
- **Computerized tomography (CT) scan:** An x-ray machine linked to a computer takes a series of detailed pictures of areas inside the body. Doctors often use CT scans to see the pelvis or abdomen.
- **Magnetic resonance imaging (MRI):** A strong magnet linked to a computer is used to make detailed pictures of areas inside the body.

Prostate cancer is described by both grade and stage.

- **Grade** describes how closely the tumor resembles normal glandular tissue of the prostate. Based on the microscopic appearance of the tumor tissue, pathologists may describe it as low-, medium-, or high-grade cancer. One way of grading prostate cancer, called the Gleason system, uses scores of 2 to 10. Another system uses G1 through G4. In both systems, the higher the score, the higher the grade of the tumor. High-grade tumors generally grow more quickly and are more likely to spread than low-grade tumors.
- **Stage** refers to the extent of the cancer. Early prostate cancer, stages I and II, is localized. It has not spread outside the prostate gland. Stage III prostate cancer, often called locally advanced disease, extends outside the gland and may be in the seminal vesicles. Stage IV means the cancer has spread beyond the seminal vesicles to lymph nodes and/or to other tissues or organs.

9. How is localized prostate cancer treated?

Three treatment options are generally accepted for men with localized prostate cancer: Radical prostatectomy, radiation therapy (with or without hormonal therapy), and active surveillance (also called watchful waiting).

- **Prostatectomy** is a surgical procedure to remove the entire prostate gland and nearby tissues. Sometimes lymph nodes in the pelvic area (the lower part of the abdomen, located between the hip bones) are also removed. Radical prostatectomy may be performed using a technique called nerve-sparing

surgery that may prevent damage to the nerves needed for an erection. However, nerve-sparing surgery is not always possible.

- **Radiation therapy** involves the delivery of radiation to the prostate. Radiation therapy is usually administered in an outpatient setting using an external beam of radiation.
- **Brachytherapy** involves implanting radioactive seeds directly into, or very close to the tumor using a needle. Patients with high-risk prostate cancer are candidates for adding hormonal therapy to standard radiation therapy.
- **Active Surveillance (watchful waiting)** may be an option recommended for patients with early-stage prostate cancer, particularly those who have low-grade tumors with only a small amount of cancer seen in the biopsy specimen.
- **Autologous cellular immunotherapy** uses a patient's own white blood cells to fight prostate cancer.
- **All of the treatment options are available through the Harbin Clinic Prostate Cancer Program.**

10. How does a patient decide what the best treatment option is for localized prostate cancer?

Choosing a treatment option involves the patient, his family, and one or more doctors. They will need to consider the grade and stage of the cancer, the man's age and health, and his values and feelings about the potential benefits and harms of each treatment option.