

Researchers Put Advanced Prostate Cancer On Trial ㊦

(NAPSA)—Can high-dose vitamin D, a naturally occurring hormone, improve an advanced prostate cancer patient's treatment with chemotherapy? That is what researchers in the United States, Canada and Europe are trying to determine.

For 20 years, scientists have explored the role of vitamin D in the prevention, treatment and reduction of cancer and other autoimmune diseases. However, they all encountered the same problem—they could not administer enough vitamin D to fight the disease without causing severe toxicity.

The promise of vitamin D to treat cancer was almost shelved until researchers at Oregon Health & Science University and Novacea, a biopharmaceutical company, were able to develop a highly concentrated form of calcitriol, a derivative of vitamin D, that had the potential to be administered safely to patients.

Now, a clinical study is under way investigating Asentar in the treatment of advanced prostate cancer. Patients take Asentar, which comes in a small capsule, the day before their next Taxotere® (docetaxel) chemotherapy treatment. Researchers will monitor patients to see if Asentar may help patients to live longer while reducing some of the side effects caused by chemotherapy, such as blood clots and fractures.

"This is a new and interesting approach to treat prostate cancer patients whose disease has progressed and who currently have limited treatment options," said Luke T. Nordquist, M.D. of Nebraska Methodist Hospital, Omaha, Neb. "The previous Phase 2 results showed that Asentar appeared to improve survival while reducing some of the serious side effects of chemotherapy, an important finding that surprised many researchers and called for further clinical evaluations."

All patients in the study will receive chemotherapy treatment with docetaxel. In addition to docetaxel, half of the patients will receive prednisone (part of the FDA-approved docetaxel regimen) and the other half will receive the investigational agent, Asentar.

According to the American Cancer Society:

- Prostate cancer is the third-leading cause of cancer death in men, after lung cancer and colorectal cancer, and

- This year, more than 234,460 men will be diagnosed with, and an estimated 27,350 men will die from, prostate cancer in the United States.

Prostate cancer occurs when cells within the prostate grow uncontrollably, producing multiple small tumors. At this stage, the disease is often curable with standard treatments such as surgery or radiation that aim to remove or kill all cancerous cells in the prostate. Unfortunately, at this stage, the cancer produces few or no symptoms and can be difficult to detect.

If untreated and allowed to grow, the cancerous cells from the tumors can spread in a process called metastasis. In this process, prostate cancer cells are transported through the lymphatic system and the bloodstream to other parts of the body, where they can reside and grow as secondary tumors. Once cancerous cells begin to spread beyond the prostate, the prostate cancer is considered to be recurrent.

Recurrent prostate cancer that progresses while a patient is taking hormonal therapy is called androgen-independent prostate cancer (AIPC). At this stage in the disease, the cancer has generally metastasized (spread) to a patient's bones and/or lymph nodes. For AIPC patients, a combination of docetaxel and prednisone, approved by the FDA for treatment of AIPC with a two-month survival benefit, has shown to prolong the lives of these patients. Some of the other chemotherapy drugs used to treat prostate cancer include doxorubicin, etoposide, vinblastine, paclitaxel and carboplatin.

Researchers at approximately 200 medical centers in the United States, Canada and Europe are seeking to evaluate the potential survival and safety benefits of Asentar in combination with docetaxel in a 900-patient Phase 3 clinical trial, known as ASCENT-2. Asentar is an investigational new drug currently in clinical trials and has not been approved by the U.S. Food and Drug Administration.

The ASCENT-2 study is for men over the age of 18 who have been diagnosed with AIPC. Study medication will be provided to all qualified study participants at no cost. To learn more about the study, individuals are encouraged to visit www.ASCENT-2.com.