

## **A Phase III Randomized, Open-Label Study of CG1940 and CG8711 Versus Docetaxel and Estramustine in Patients with Metastatic Hormone-Refractory Prostate Cancer who are Chemotherapy-Naïve**

### **Nontechnical Abstract**

Prostate cancer is a common form of cancer in adult males in the US. In 1997, 32,891 men died from prostate cancer in the United States. Surgical removal of the prostate or radiation treatment may cure early prostate cancer if the tumor has not spread outside the prostate gland. However, in 70% of patients, the cancer will spread, mostly to the bone. At this point, the cancer cannot be cured. Hormone therapy can control advanced cancer temporarily in most patients, but the advanced cancer progresses in nearly all patients. Once a patient's cancer no longer responds to hormone therapy, chemotherapy may relieve pain or other symptoms and is being tested in patients to see if life can be prolonged.

CG1940 and CG8711 is a vaccine made from cells taken from the tumors of two patients with advanced prostate cancer. To make the vaccine, the cells are altered by inserting a gene for GM-CSF, (granulocyte-macrophage colony-stimulating factor), a substance made by the body that helps the immune system recognize a tumor and destroy it. The gene for GM-CSF is inserted into the prostate cancer cells using an artificial virus containing parts of a natural virus called "Adeno-associated Virus." The cells are then grown in a laboratory to produce the vaccine. The vaccine cells are treated with radiation so they cannot grow or divide after injection. The cells themselves do not contain virus and are **not** radioactive. The cells are frozen to preserve them until they are administered to the patient.

This is a Phase III clinical trial. Patients will be randomly assigned to receive either a series 13 treatments with GC1940 and CG8711 or 9 cycles of a chemotherapy regimen consisting of docetaxel, and prednisone. This chemotherapy treatment is commonly given to prostate cancer patients who have failed hormonal therapy and have prostate cancer that is spreading in the body. The objectives of this trial are to compare between the two treatment regimens (1) the duration of survival, (2) the effect of the prostate cancer on the bone (spinal cord compression, bone surgery, local radiation to the bone, or skeletal fracture), (3) the number of patients with progression of bone metastases, and (4) the time to onset of bone pain.

Patients in this study must have cancer of the prostate that has spread to the bone or tissues and have failed hormonal therapy. They must be active and able to walk and take care of themselves independently. They must not have a history of moderate or severe bone pain, requiring use of medications for treatment of the bone pain. Patients who have received prior gene therapy or chemotherapy are not eligible for enrollment in this trial. Patients cannot receive other therapy for their prostate cancer while they are on this trial.

Patients randomly assigned to receive vaccinations will receive 13 doses of CG1940 and CG8711, injected into the skin. Each dose will be given about every 14 days. Patients assigned to chemotherapy (docetaxel, and prednisone) will receive a treatment of

docetaxol given into a vein and prednisone every day (composing a 21-day cycle); patients will complete nine 21-day cycles of chemotherapy.

Patients will be followed closely in the clinic for one year after they start receiving treatment and will be evaluated by blood tests, x-rays and scans of the bone. Patients will be assessed for adverse events, any new cancer, and any new diagnoses of autoimmune disease. Thereafter, patients will be followed for the rest of their life for survival and long-term assessments.