PRESS RELEASE

UNM Cancer Center Participating in National Clinical Trial

New and different approach bridges gene therapy and immunotherapy to address intermediate and high risk prostate cancer

FOR IMMEDIATE RELEASE:

May 6, 2013 — Albuquerque, NM (UNM Cancer Center) —The University of New Mexico Cancer Center is among a few select institutions nationwide participating in a Phase 3 clinical trial studying a novel treatment for men with newly diagnosed, localized prostate cancer.

In most cases, prostate cancer is detected early and eradicated. However, even with early detection, the cancer returns in up to 30% of patients. The trial will study whether combining this innovative treatment with standard radiation therapy will produce an immune response that will kill cancerous cells throughout the body and decrease the likelihood of the tumor ever coming back.

In this study, men receive three injections of an engineered virus directly into the prostate followed by 14 days of oral doses of a medication called valacyclovir. The injection is a viral vehicle, a virus that can't make more of itself, that delivers a specific gene into the cancer cell. Once inside, the gene converts the valacyclovir into an active form causing death of the tumor cell. This process also generates a vaccine response against the cancer that can detect and kill microscopic cancer cells wherever they lurk, helping to prevent the cancer from returning.

Thomas Schroeder, MD, is Medical Director of Radiation Oncology and the institutional principal investigator for the ProstAtak clinical trial at the UNM Cancer Center. He says, "The protocol for this trial is very interesting because it is a new and different approach." Dr. Schroeder is referring to combining this treatment with the standard of care, so that men's bodies have a stimulated immune system more able to detect and kill cancerous cells.

This clinical trial is designed for men with intermediate-risk localized prostate cancer—cancer that has not spread beyond the prostate—or for men with some forms of high risk cancer. "This treatment will hopefully help men who have just been diagnosed with cancer and are trying to decide on a treatment approach," says Dr. Schroeder. For men with low risk cancer, therapies such as surgery, radiation, and watchful waiting, are still the best choices.

But this novel treatment may help men with more aggressive prostate cancer who need to consider the possibility of the cancer coming back. This treatment may help them decrease the odds of the cancer returning at a later time in their lives.

Gene therapy provided researchers with the background for this clinical trial. The injection of the engineered virus combined with valacyclovir and standard of care radiation therapy causes complex interactions within the body resulting in essentially a tumor-specific vaccine. These interactions kill cancer cells and build up antibodies.

The injected vaccine is an engineered cold-virus that carries the genetic material into the prostate needed to kill and stimulate an immune response against the cancer cells. Dr. Schroeder calls the engineered virus a delivery device. “The idea is to stimulate an immune response to the cancer. By using the body’s immune response to viruses we incidentally create an immune response to the cancer.” Valacyclovir only works on the cells that are infected with the virus, which was injected directly into the prostate. So, this treatment involves two steps: introducing genetic material into the cancerous cells, which kills the cells; and ramping up the immune system so it can detect future cancerous cells in other parts of the body.

Dr. Schroeder says that the treatment is not likely to increase or worsen the degree of any side effects. Men may experience typical side effects from radiation, or hormone therapy, but the treatment itself has minimal side effects. The men may get fevers and chills for twelve to twenty-four hours following the injection. The use of hormone therapy is not required on the study, but can be used at the treating physician’s discretion.

Researchers have already tested and completed phases one and two of the study. The results indicated a decrease in the recurrence of cancer. The ongoing phase three trial, a randomized, fully blinded, placebo controlled study, is to definitively evaluate this approach and seek FDA approval. If successful, this treatment may add to current therapies as a more effective approach for men with intermediate- to high-risk prostate cancer who undergo radiation.

About the UNM Cancer Center

The UNM Cancer Center is the Official Cancer Center of New Mexico and the only National Cancer Institute-designated cancer center in the state. One of just 67 NCI-designated cancer centers nationwide, the UNM Cancer Center is recognized for its scientific excellence, contributions to cancer research and delivery of medical advances to patients and their families. Annual federal and private funding of over $65 million supports the UNM Cancer Center’s research programs. The UNM Cancer Center treats more than 65 percent of the adults and virtually all of the children in New Mexico affected by cancer, from every county in the state. It is home to New Mexico’s largest team of board-certified oncology physicians and research scientists, representing every cancer specialty and hailing from prestigious institutions such as MD Anderson, Johns Hopkins and the Mayo Clinic. Through its partnership with Memorial Medical Center in Las Cruces, the UNM Cancer Center brings world-class cancer care to the southern part of the state; its collaborative clinical programs in Santa Fe and Farmington serve northern New Mexico. The UNM Cancer Center also supports several community

outreach programs to make cancer screening, diagnosis and treatment available to every New Mexican. Learn more at www.cancer.unm.edu.

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