

EARLY CLINICAL TRIALS SHOW THAT NOVEL EXPERIMENTAL DRUG SHRINKS TUMORS IN PATIENTS WITH VARIOUS TYPES OF CANCER

CHICAGO, IL – June 1, 2003 – As more is learned about how cancer develops, scientists have begun designing new drugs that directly target cancer cells, leaving healthy ones intact. Having fewer side effects, some of these drugs work by blocking growth signaling processes within cancer cells, while others enlist the body's immune system to recognize and mount an attack against the cancer cell. But regardless of how they work, most of these drugs are designed to treat a specific cancer and cannot be used to treat other tumor types.

Now, an early clinical trial at the Cedars-Sinai Medical Center has shown that an experimental drug called 2C4 (trade name is Omnitarg) was effective to shrink tumors in patients with several different types of cancer. The findings, presented at the 39th annual meeting of the American Society of Clinical Oncology in Chicago, may lead to a new way to treat various types of cancer.

“What’s interesting is that this drug effectively shrank tumors in several completely different types of cancer in early stage clinical trials,” said David Agus, M.D., Research Director at the Cedars-Sinai Prostate Cancer Center and first author of the study. “This tells us that the drug targets a growth signaling pathway in cancer cells that is common in many solid tumors.”

The drug, called 2C4 and developed by Genentech, Inc., is a monoclonal antibody, or protein that enlists the body's immune system to attack foreign invaders, such as viruses or bacteria. It works by targeting HER-2/*neu*, a member of the HER kinase family of proteins. The protein sits on the surface of cancer cells and receives signals from growth factor molecules within the HER family, which in turn stimulate tumors to grow.

But earlier research in Dr. Agus' laboratory indicated that 2C4 was not limited to targeting HER-2/*neu* alone and blocked signaling activity among the entire HER network of proteins in both breast and prostate cancer tumors grown in mice. These findings led the investigators to begin the first clinical trial to test the safety and effectiveness of the drug in patients with other types of solid-tumor cancers.

In the study, 21 patients with advanced cancers including breast, prostate, lung, ovarian, colon, pancreas and sarcoma received 2C4 by infusion every three weeks at a dose level ranging between 0.5 and 15 milligrams per kilogram of body weight. Among these patients, 19 completed at least two cycles or six weeks of treatment with 2C4, while two died at the outset of treatment due to complications of their

disease. The investigators found that eight or 42 percent of the 19 patients treated with 2C4, responded to treatment either because their tumors shrank over 50 percent, or because their tumors stopped growing for a given time period before their disease progressed. (Cedars-Sinai IRB No. 3691)

Of the 19 patients who received 2C4, three achieved partial remission as measured by shrinkage of their tumors by over 50 percent. These included one patient with ovarian cancer, who received 5 mg/kg of 2C4; one with prostate cancer, who received 15 mg/kg of 2C4; and one patient with a pancreatic neuroendocrine cancer who received 15 mg/kg of 2C4. Two of these patients (ovarian and pancreatic cancer) remain in remission and have been receiving 2C4 for over a year since beginning therapy.

“To see results that show activity in a Phase I safety trial is remarkable, especially since these patients were in the advanced stages of their disease and had no other treatment options available to them,” said Dr. Agus. “This is especially exciting as there was little drug related toxicity or side effects associated with this treatment.”

In addition, the investigators report that five additional patients’ disease stabilized for at least three months after just two treatment cycles with 2C4. These patients included three with cancers of the prostate, one with non-small cell lung cancer and one with ovarian cancer.

“Targeting a pathway, rather than a tumor type, is an exciting new area in the treatment of cancer, and 2C4 is one of several experimental drugs that show how this treatment strategy can benefit patients,” commented Dr. Agus.

A Phase II clinical trial with 2C4 started in May, 2003 at Cedars-Sinai Medical Center to evaluate the effectiveness of the drug in patients with advanced cancers of the prostate, (Cedars-Sinai IRB No. 4100-01) and is scheduled to be open for ovarian cancer patients in June.

Cedars-Sinai Medical Center is one of the largest non-profit academic medical centers in the Western United States. For the fifth straight two-year period, Cedars-Sinai has been named Southern California’s gold standard in health care in an independent survey. Cedars-Sinai is internationally renowned for its diagnostic and treatment capabilities and its broad spectrum of programs and services, as well as breakthroughs in biomedical research and superlative medical education. Named one of the 100 “Most Wired” hospitals in health care in 2001, the Medical Center ranks among the top 10 non-university hospitals in the nation for its research activities.

###

If you have received this news release in error and do not wish to receive future advisories, or if they should be directed to someone else in your organization, please call 1-800-396-1002, so we can update our records. Alternatively, you may fax your updated information or your request for removal from our list to 808-263-3364 or e-mail it to sandy@vancommunications.com.