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**NEW CLASS OF TARGETED CANCER DRUGS SHOWS PROMISE IN SLOWING THE PROGRESSION OF RECURRENT PROSTATE CANCER, SAY CEDARS-SINAI RESEARCHERS**

***New drug suggests possibility of prolonged median survival time for men with advanced prostate cancer***

**LOS ANGELES (February 20, 2007)** -- A new class of targeted anti-cancer drugs that blocks the human epidermal growth factor (HER) receptor family shows promise in prolonging the lives of patients with recurrent prostate cancer, a new Cedars-Sinai study shows. The drug, a molecular targeted compound called pertuzumab, works by binding to and inhibiting the function of HER2 receptors, interrupting a key pathway that leads to cancer growth.

The study, published in the February 20 issue of the *Journal of Clinical Oncology*, involved 41 patients with treatment-resistant prostate cancer who had experienced progression of their disease after prior chemotherapy. Patients received the drug every three weeks until disease progression. MRI and CAT scans were used to evaluate the tumors during the period of drug therapy. While no shrinkage of tumors was reported, retrospective analysis showed that survival rate was prolonged to 16.4 months with the drug as compared to a median average of 10.7 months in a historical control group with similar baseline prognostic features.

“Advanced prostate cancer is difficult to treat – and the drug therapies currently available to these patients have not been very effective, especially in patients whose disease has progressed after chemotherapy treatment,” said David B. Agus, M.D., principal investigator of the study and research director of Cedars-Sinai’s Louis Warschaw Prostate Cancer Center at the Samuel Oschin Comprehensive Cancer Institute. “Pertuzumab may offer a new treatment approach for these patients when it is evaluated as a tool to slow – not stop or shrink -- tumor growth.”

“The theory is that by significantly slowing progression of the cancer, patients will experience a good quality of life for a longer period of time,” said Agus. “Ultimately, we hope drugs like pertuzumab will help us reach the point where cancer can be viewed as a lifetime disease to be managed much like AIDS is looked at now. This would be major shift from the current paradigm for cancer treatment, and is a promising area of research. This study must be viewed cautiously, however, as we are comparing statistics from historical control groups.”

(more)

Pertuzumab is a single-agent antibody designed to bind to the HER2 receptor and inhibit the ability of HER2 to pair with other HER family members (HER1, HER2, HER3 and HER4). If the pairing process (called dimerization) is not interrupted, the binding of these growth factors activates an intracellular signaling pathway that leads to tumor proliferation.

While other drugs such as docetaxel have shown to benefit men with advanced prostate cancer, no other second-line therapy (a treatment given when an initial treatment (first-line therapy) does not work or stops working) to date has shown to prolong survival.

Previous research published by cancer researchers at Cedars-Sinai and other institutions has shown that pertuzumab affects the growth of several other types of cancers, including breast, ovarian and lung cancer, and that the drug may also prolong survival for patients with advanced ovarian cancer.

In the current study, the pertuzumab was well-tolerated but no objective tumor shrinkages were observed. No decline in PSA (prostate-specific antigen; a tumor marker) levels was detected in patients during the study. According to the researchers, this study raises a question long debated in prostate cancer literature: what should clinical outcome standards or end point be for studies involving patients with advanced, intractable prostate cancer who have limited treatment options.

The next step for researchers is to test the pertuzumab on a larger group of patients in a randomized fashion, and to analyze data that is not retrospective.

Prostate cancer is the most common type of cancer found in American men, other than skin cancer and is the second leading cause of cancer death in men. The American Cancer Society estimates that there will be about 218,890 new cases of prostate cancer in the United States in 2007 and that approximately 27,050 men will die of this disease.

Other institutions that participated in the study included Arizona Cancer Center, the Cleveland Clinic Foundation, Indiana University, Memorial Sloan-Kettering Cancer Center and the University of Wisconsin, Madison.

The research was supported by Genentech, Inc. and the National Cancer Institute Specialized Program of Research Excellence (SPORE) program.

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