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### **TARGETED CANCER DRUG COMBINED WITH A PILL FORM OF LOW-DOSE CHEMOTHERAPY FOUND TO SHRINK TUMORS AND SLOW PROGRESSION OF RECURRENT OVARIAN CANCER**

ORLANDO, FLA. (May 15, 2005, 11:15 a.m., EDT) – A targeted cancer drug given with low-dose chemotherapy shrank ovarian tumors and slowed progression of ovarian cancer in patients with recurrent disease, according to research findings presented by Agustin Garcia, M.D., principal investigator of the study and Director of Breast Cancer Research at the Women’s Cancer Research Institute at the Samuel Oschin Comprehensive Cancer Institute at Cedars-Sinai Medical Center. The targeted drug, bevacizumab (Avastin™), is one of a new class of “anti-angiogenesis” drugs that prevents the growth of blood vessels that feed cancer tumors.

The study, presented at the 41<sup>st</sup> annual meeting of the American Society of Clinical Oncology (ASCO) in Orlando, Florida, evaluated 29 patients with recurrent ovarian cancer after having undergone up to three rounds of treatment with standard chemotherapy. All patients received a low dose of chemotherapy daily (taken in pill form) and bevacizumab by intravenous infusion. The investigators found that nearly half of the patients had no progression of their ovarian cancer six months after receiving treatment with bevacizumab and low-dose oral chemotherapy. In addition, tumors shrank in over 20 percent of patients.

“Our early results suggest that this targeted drug worked effectively with a pill form of low-dose chemotherapy to shrink or stop the growth of ovarian cancer in patients whose disease had recurred after prior treatment with standard chemotherapy,” Garcia said.

Bevacizumab is the common name for Avastin™, a monoclonal antibody that targets and stalls the function of a substance made by cells called the vascular endothelial growth factor (VEGF), which stimulates the growth of blood vessels that nourish cancer tumors and cause them to grow – a process called angiogenesis. Currently, bevacizumab has been approved by the Food and Drug Administration as a first-line treatment in combination with 5-FU-based chemotherapy for patients with colon cancer that has spread to other parts of the body.

Cyclophosphamide is a standard chemotherapy drug given intravenously or as a pill that is used to treat several types of cancer often in combination with other drugs. But laboratory researchers have found that when the drug is given at a lower dose over a prolonged period, the dosage is too low to kill cancer cells, but can stop blood vessel growth that feeds the tumor.

“Our theory was that if we could combine a known anti-angiogenesis agent with a lower dose of chemotherapy on a prolonged basis, the two would work synergistically to cut off the blood supply feeding the ovarian cancer tumor and stop the cancer from growing,” Garcia said.

To find out whether bevacizumab and cyclophosphamide would shrink tumors and increase the survival of patients with recurrent ovarian cancer, the investigators evaluated 29 patients whose disease had recurred after at least one and up to three prior rounds of treatment with standard chemotherapy. Patients received 50 milligrams of a cyclophosphamide pill daily and 10 milligrams per kilogram of bevacizumab intravenously once weekly for the first three weeks of the study and every two weeks thereafter.

The investigators found that 47 percent of patients' had no progression of their disease at six months of treatment with both bevacizumab and cyclophosphamide. Further, ovarian cancer tumors shrank in 21 percent of the patients, while 59 percent achieved stable disease – or ovarian cancer that did not progress or diminish for at least two months of treatment. Side effects were similar to those reported in other studies of bevacizumab, including high blood pressure, fatigue, and blood clots.

“Our study suggests that an anti-angiogenesis cancer drug used in combination with a low dose of chemotherapy – which was conveniently taken in pill-form – shrank tumors and may delay progression of the disease in a significant number of patients with recurrent ovarian cancer,” Garcia said. “These early results may lead to a new use of this monoclonal antibody in the treatment of ovarian cancer.”

Ovarian cancer is the seventh most common cancer among women and ranks fourth as the cause of cancer death in women. The American Cancer Society estimates that about 22,220 women in the United States will develop ovarian cancer this year and that about 16,210 women will die from the disease. Typically, ovarian cancer is treated with surgery, chemotherapy and radiation, depending on how far the cancer has spread. To date, no standardized screening test is available to detect ovarian cancer.

This study was sponsored by the National Cancer Institute under its Cooperative Research and Development Agreement with Genentech for the development of bevacizumab. It was performed as part of the California Cancer Consortium, a collaborative National Cancer Institute (NCI) funded group consisting of Cedars-Sinai Medical Center; Princess Margaret Hospital; University of Chicago; University of California, Davis; City of Hope; and University of Southern California Norris Cancer Center.

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