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For Immediate Release

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**ABBOTT LABORATORIES ANNOUNCES INTENT TO SUBMIT  
NEW DRUG APPLICATION FOR XINLAY™ (ATRASENTAN) IN  
THE U.S.**

ABBOTT PARK, Ill., July 8, 2004 - Abbott Laboratories today announced its intent to submit a New Drug Application (NDA) for Xinlay™ (pronounced zin-lay) by the end of 2004 with the U.S. Food and Drug Administration (FDA). Abbott is seeking approval of Xinlay for men with metastatic, hormone-refractory prostate cancer and has been granted fast-track designation from the FDA. Prostate cancer is the most common solid tumor, non-skin cancer in American men. An estimated 230,000 men will be diagnosed with prostate cancer and 29,000 will die from the disease this year in the United States.

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"We are very excited about the possibility to bring the first of several Abbott-discovered oncology drugs to patients," said John Leonard, M.D., vice president for global pharmaceutical development at Abbott Laboratories. "We are looking at novel approaches to treat prostate cancer with the hope of providing additional treatment options to patients sooner."

Abbott intends to submit an NDA based on a meta-analysis that examined pooled data from two large, randomized, well-controlled clinical trials (M96-594 & M00-211) of Xinlay with a total patient population of 1,097. The intent to treat analysis showed a delay in time to disease progression ( $p=0.013$ ) in men with metastatic, hormone-refractory prostate cancer who took the drug versus those who took placebo.

The meta-analysis was presented at the American Society of Clinical Oncology in June. Analyzed separately, the two studies showed trends in favor of Xinlay, but did not show statistical significance.

The two individual studies pooled for the meta-analysis tested the same patient population with similar baseline demographics, used the same primary endpoint of time to disease progression (radiographic progression was more explicitly defined in the M00-211 protocol) and were placebo-controlled, double blind, multinational studies. In the larger M00-211 study, patients were randomized to 10mg of Xinlay or placebo. In the M96-594 study, patients were randomized to 10mg or 2.5mg of Xinlay, or placebo. Abbott has conducted statistical tests for heterogeneity of the studies and on the overall treatment effect to support the rigor of the meta-analysis.

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Xinlay was generally well tolerated in both studies among all patients. The most common associated adverse events for Xinlay vs. placebo were, headache (20 percent vs. 13 percent), peripheral edema (38 percent vs. 13 percent) and rhinitis (32 percent vs. 14 percent), respectively.

**About Xinlay**

Xinlay, an oral, once-daily, non-hormonal, non-chemotherapy, anti-cancer agent, belongs to a class of compounds known as selective endothelin-A receptor antagonists (SERAs™). SERAs antagonize the effect of endothelin (ET-1), one of the proteins thought to be involved in the stimulation of the spread of cancer cells. Xinlay is the result of Abbott's discovery effort in oncology.

Xinlay has been studied in Phase II and Phase III clinical trials in patients with metastatic, hormone-refractory prostate cancer. It is currently in its second Phase III pivotal trial involving men with hormone-refractory prostate cancer that has not spread (non-metastatic). It is also being evaluated in a Phase II trial in hormone-naïve men with rising prostate-specific antigen (PSA) following prostate cancer surgery. Additionally, Abbott continues to explore Xinlay in other cancers, including kidney, ovarian, brain and non-small-cell lung cancers.

**About Abbott Laboratories**

Abbott Laboratories is committed to the discovery and development of innovative treatments to help patients in the fight against cancer. Abbott's oncology research is focused on developing targeted, less toxic therapies. The company has several different classes of compounds in various stages of clinical development. These approaches address multiple phases of cancer progression, including angiogenesis (new blood vessel formation), signal transduction and programmed cell death (apoptosis).

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Abbott's Oncology Franchise extends beyond pharmaceutical research to supportive care products and diagnostics. Abbott currently manufactures products for pain management, including patient-controlled analgesia pumps, and markets tests for detection of cancer, including a PSA test. Abbott's innovative genomic tests include Vysis® UroVysion™, for monitoring the recurrence of bladder cancer, and PathVysion®, for detecting the HER-2 gene, which predicts potential treatment benefit in women with breast cancer. Abbott also markets nutritional products designed to meet the unique dietary needs of cancer patients.

Abbott Laboratories is a global, broad-based health care company devoted to the discovery, development, manufacture and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. The company employs more than 55,000 people and markets its products in more than 130 countries.

Abbott's news releases and other information are available on the company's Web site at [www.abbott.com](http://www.abbott.com).

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