



NovaRx Initiates Pivotal Phase III Clinical Trial in Lung Cancer Patients

For Immediate Release

SAN DIEGO, CA – August 21, 2008

– NovaRx Corporation announced today that the company initiated its pivotal Phase III clinical trial of Lucanix[®] (belagenpumatucel-L) in the treatment of advanced non-small cell lung cancer (NSCLC). The first patient enrolled in the study was treated by Dr. Lyudmila Bazhenova the trial's principal investigator at the University of California, San Diego School of Medicine.

The study is designated as the STOP trial because of its expected endpoints: Survival; Tumor-free, Overall; and Progression-free. It is an international, multicenter, randomized, double-blind study involving up to 700 individuals with advanced stage NSCLC, and will be conducted at approximately 90 clinical sites in the U.S., Canada, India, and Europe.

In a Phase II clinical trial, two-year survival among patients with stages IIIB and IV disease who received Lucanix[®] was significantly longer than that of individuals being treated with the current standard of care. A second, investigator-initiated phase II study supported these results.

In contrast to conventional cancer therapies, where systemic chemotherapeutic drugs nonspecifically kill normal cells as well as tumor cells, the therapeutic vaccine developed by NovaRx induces the patient's immune system to specifically target the cancer. In phase II clinical studies to date, the side effects of this treatment have included redness or soreness at the injection site.

“In medical research, you see something like this once in a lifetime,” said John Nemunaitis, M.D., executive director at



the Mary Crowley Medical Research Center in Dallas, TX and principal investigator of both the Phase II Lucanix[®] study and the investigator-initiated Phase II trial.

“This is a very promising approach to cancer treatment, and results reported so far are beyond anyone's expectations. I am very excited to be a part of this confirmatory effort, and to be able to offer this unique treatment option to my patients,” said Dr. Lyudmila Bazhenova, principal investigator of the STOP trial at the Rebecca and John Moore's Cancer Center of UCSD. “Traditional chemotherapy for stage IV NSCLC still yields disappointing results, and my hope is that this trial will improve the natural history of the disease.”

The FDA granted NovaRx Fast-Track

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approval for the Lucanix[®] trial in March of 2007, and Special Protocol Assessment approval in January of 2008.

According to the American Cancer Society, in 2008 there will be an estimated 215,000 new cases of lung cancer diagnosed, and 162,000 deaths caused by this disease in the United States alone. Lung cancer is the number one cause of cancer death throughout the world. “The statistics for global lung cancer deaths are staggering. I am confident that this Phase III trial will establish Lucanix[®] as a viable treatment option for patients with this dreaded disease,” said Dr. Habib Fakhrai, president and co-founder of NovaRx.

In Phase II testing, 50 percent of patients entering the trial with stable disease who received Lucanix[®] following one frontline regimen of chemotherapy lived more than 44 months, compared to less than 10-12 months for such patients under the current standard of care. In addition, patients with advanced disease who received Lucanix[®] after zero to five prior chemotherapy treatments demonstrated a one-year survival of 61 percent and a two-year survival of 41 percent. Such late-stage patients typically demonstrate one-year survival of less than 30 percent. Lucanix[®] was shown to produce only insignificant side effects.

“In addition to significantly increased survival,” Fakhrai continued, “we saw virtually no side effects in the patients treated in phase II trials. Based on our previous trial results, we think Lucanix[®] may lead to a significant advancement in patient care. We look forward to continuing to enroll patients in this very important clinical study.”

“We are delighted to have been selected as one of the major centers to test this highly promising immunotherapeutic approach to treating individuals with NSCLC,” said Dr. Julian Molina, principal investigator of the STOP Trial at Mayo Clinic in Rochester, Minnesota.

Lucanix[®] consists of four non-small cell lung cancer cell lines that have been genetically engineered to shut off their immune suppressive properties. These cell lines are then modified to block a molecule called transforming growth factor-beta (TGF-beta), which is commonly produced by cancer cells as a cloak against the body’s natural immune system. When TGF-beta is blocked, the immune system can mount an anti-tumor response. The results of Phase II testing were published in the October 10, 2006 edition of the *Journal of Clinical Oncology*.

Studies to test the therapeutic vaccine in other types of cancer are also in progress. “NovaRx remains committed to developing whole cell-based therapeutic vaccines for any form of cancer in which this approach may significantly improve patient outcomes by either curing their disease entirely, or by stabilizing it over the course of their lives,” said Justin Murdock, CEO and chairman of the board of NovaRx.

Founded in 1997, NovaRx Corp. is a clinical-stage biopharmaceutical company dedicated to the discovery, development, and commercialization of novel cell-based therapeutic vaccines for the treatment of cancer. The company’s 24,000 square foot headquarters in San Diego, CA, house corporate offices and manufacturing operations. The proprietary core technology upon which Lucanix[®] is based has been exclusively licensed to NovaRx on a worldwide basis. Lucanix[®] is a trademark of NovaRx Corp.

For more information on the NovaRx Lucanix[®] Phase III STOP Trial in NSCLC please visit NovaRx.com.

Patients interested in learning more about the STOP trial or how to enroll should call 1-866-949-5864 (949-LUNG).

**Media please call:
1-866-950-5864 (950-Lung).**

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