

## FOR IMMEDIATE RELEASE

### Media Contacts

#### *At Heat Biologics:*

Liz Roop, NPC Creative Services  
(813) 960-5092 ext. 302  
[liz@npccs.com](mailto:liz@npccs.com)

#### *At University of Miami Miller School of Medicine:*

Lisa Worley  
Office of Medical Communications  
305-243-5184 / 305-458-9654  
[Lworley2@med.miami.edu](mailto:Lworley2@med.miami.edu)

### **Heat Biologics, University of Miami Announce IRB Approval to Accelerate Enrollment in Phase I Clinical Trial of Vaccine to Treat NSCLC Lung Cancer**

MIAMI – (May 4, 2009) – The University of Miami Miller School of Medicine and Heat Biologics, Inc. ([www.heatbio.com](http://www.heatbio.com)) announced today that the University's Institutional Review Board (IRB) has approved an expansion and acceleration of the Phase I clinical trial of a novel vaccine to treat non-small cell lung cancer (NSCLC) underway at the University's Sylvester Comprehensive Cancer Center. Heat Biologics holds the exclusive license to develop and commercialize the GP96-Ig cell-based vaccine technology.

As part of an academic study, the University had been enrolling patients in the clinical trial on a limited basis to satisfy the IRB of its safety. The IRB's approval means enrollment can now be expanded to accommodate simultaneous administration of the vaccine on three dosage schedules: twice a week, weekly and bi-weekly. Twelve patients will be enrolled in each group at a rate of three patients every four weeks.

If successful, GP96-Ig is expected to fill a substantial need in the treatment of NSCLC, which accounts for 85 percent of all lung cancers and has a five-year survival rate of just 15 percent. For NSCLC patients, treatment options are often limited.

"There are more than 200,000 new lung cancers patients in America every year, and close to 160,000 will die every year due to a lack of effective therapy for this lethal disease," said lead investigator Luis E. Raez, M.D., associate professor of medicine and co-leader of the Lung Cancer Site Disease Group at Sylvester. "Chemotherapy is largely palliative and new therapy approaches are urgently needed for this disease."

Unlike conventional vaccines, which are used to prevent infectious diseases, the GP96-Ig vaccine stimulates the immune system to fight the disease once it is diagnosed. The treatment was developed

by Eckhard Podack, M.D., Ph.D., Sylvester Distinguished Professor of Medicine and chairman of the UM Department of Microbiology and Immunology, who genetically engineered the gp-96 heat shock protein to be secreted by NSCLC cells, triggering an attack response from the body's immune system.

"The heat shock vaccine technology has achieved extraordinary cytotoxic immune responses in large animal models, contributing to our confidence in this vaccine approach for cancer," said Dr. Podack. "While the current clinical trial is focused on testing the therapeutic effects of the GP96-Ig vaccine on lung cancer, if successful the underlying technology can be used for many different applications."

Adds Jeffrey Wolf, CEO, Heat Biologics: "The impact the GP96-Ig vaccine will have on the lives of NSCLC patients is significant, but it is just the beginning. The potential this vaccine holds as a technology platform across which treatments for other cancers, as well as viral and other inflammatory and infectious diseases, can be delivered is staggering."

Heat Biologics also holds the exclusive license to a second treatment developed by Dr. Podack, tumor necrosis factor receptor 25 (TNFR25) agonists and antagonists. TNFR25 agonists have the ability to block the production of regulatory T cells, allowing the immune system to work uninhibited. By applying this therapy in conjunction with GP96-Ig, anti-tumor treatment can be much more effective. TNFR25 antagonists work as anti-inflammatory agents, easing the symptoms of asthma and several other auto-immune diseases.

"It is gratifying to see this important technology advance. We are hopeful that the results continue to be favorable. Dr. Podack's discovery has the potential to help a large number of patients. He is a first rate scientist who has pursued an erudite line of scientific investigation. I am cheering for his success and the success of the technology," said Bart Chernow, M.D., Professor of Medicine and Vice Provost for Technology Advancement at the University of Miami.

For information on enrolling in the GP96-Ig Phase 1 clinical trial underway at UM Sylvester Comprehensive Cancer Center, contact 305-243-4180.

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#### *About Heat Biologics*

Heat Biologics ([www.heatbio.com](http://www.heatbio.com)) is a clinical-stage company focused on the development and commercialization of three complementary technology platforms that can work alone or together to treat a variety of cancers, viral and autoimmune diseases. The Company's HeatShock (GP96-Ig) technology offers a novel approach to treating cancer and other diseases by using live, modified cell lines to activate the immune system against specific defined targets. Heat's Medicare (anti-TNFR25 Mab) and Inhibicor (anti-TL1-A Mab) technologies use proprietary antibodies to stimulate or down-regulate the immune system to treat asthma, viral and autoimmune disorders. Together, these technologies provide a powerful platform to treat a wide variety of disorders.

#### *About Sylvester*

Sylvester Comprehensive Cancer Center at the University of Miami Miller School of Medicine opened in 1992 to provide comprehensive cancer services and today serves as the hub for cancer-related research, diagnosis, and treatment at UHealth—University of Miami Health System. Sylvester handles 1,500 inpatient admissions annually, performs 2,400 surgical procedures, and treats more than 3,900 new cancer patients. All Sylvester cancer specialists are on the faculty of the Miller School of Medicine,

South Florida's only academic medical center. In addition, Sylvester physicians and scientists are engaged in 200 clinical trials and receive more than \$33 million annually in research grants. Sylvester at Deerfield Beach opened in 2003 to better meet the needs of residents of Broward and Palm Beach counties, and now offers appointments with 30 physicians from 14 of Sylvester's 15 Site Disease Groups, complementary therapies from the Courtelis Center, and education and outreach events. Sylvester (<http://www.sylvester.org>) recently opened a satellite facility in Kendall as well.