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Media Contacts:

At Heat Biologics:

Liz Roop
NPC Creative Services
(813) 960-5092 ext. 302
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

NIH Awards Grant to Advance Testing of Heat Biologics' Immunotherapy Vaccine to Treat HIV

MIAMI – (July 6, 2010) – The National Institutes of Health (NIH) has awarded the University of Miami Miller School of Medicine a \$1.5 million grant to advance preclinical trials testing the prophylactic and therapeutic efficacy of Heat Biologics' anti-viral vaccine to treat HIV. The grant enables Heat to expand what is already the largest preclinical trial of its kind ever funded by the NIH.

Heat Biologics is a clinical-stage immunotherapy company focused on developing off-the-shelf drugs to combat a wide range of diseases. The company's HS-HIV1 vaccine for HIV is based upon Heat's proprietary HS-System, which was developed at the UM Miller School of Medicine. The vaccine is designed to stimulate the body's immune system to activate a cytotoxic T cell response that is specific for a number of HIV proteins. As a result, HS-HIV1 is able to generate multiple simultaneous HIV-specific immune responses, accomplishing a reaction that would normally require multiple drugs to achieve.

The study is being conducted in collaboration with the University of Miami and the Experimental Immunology Branch at the NIH under the guidance of HS-System innovator, Eckhard Podack, M.D., Ph.D., chair of the Miller School of Medicine's Department of Microbiology and Immunology. Results are expected by the end of 2010.

"Our earlier studies resulted in unprecedented preclinical data that demonstrated HS-HIV1's potential to induce the highest level immune response of any previously tested vaccine therapy," said Podack. "Most importantly, we were able to demonstrate a multi-specific immune response, which is critical for HIV therapy because of the need for any effective treatment to impact the immune system's response to multiple viral proteins."

Adds Heat President Taffy Williams, Ph.D.: “This grant enables us to move into the next phase and focus on demonstrating our vaccine’s efficacy in reducing or eliminating viral titers in infected test subjects, as well as in preventing infection when subjects are virally challenged. We are confident the data recorded during these preclinical trials will allow us to transition quickly into a Phase I clinical trial.”

While HIV can be controlled with an intensive drug regimen known as highly active anti-retroviral therapy (HAART), it is toxic to many patients, too expensive to be made available in parts of the world where HIV is most pervasive, and only rarely leads to clearance of the HIV virus.

“Finding a vaccine that can prevent HIV infections and eliminate the financial obstacles to worldwide distribution has been an international priority. With the support of the NIH, the work being done by Dr. Podack and Heat Biologics holds great potential for achieving those goals and sparing millions from the tragic outcomes of this devastating disease,” said Bart Chernow, M.D., professor of medicine and vice provost for technology advancement at the UM Miller School of Medicine.

About Heat Biologics

Heat Biologics (www.heatbio.com) is a clinical-stage immunotherapy company focused on developing novel, off-the-shelf drugs that modulate the immune system to combat a wide range of cancers and viral infections, including HIV, Hepatitis C and influenza. Less invasive than personalized (autologous) immunotherapies, which require treatment of the patient’s own cancer or blood, Heat’s proprietary off-the-shelf (allogeneic) HS-System exploits the natural ability of diseased cells to activate the immune system and amplifies the body’s natural defenses. The company is currently in Phase I/II clinical trials with its first product, a drug to treat Non Small Cell Lung Cancer (NSCLC), and has a robust pipeline of products in various stages of preclinical testing.