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Media Contact:
Liz Roop
NPC Creative Services
(813) 960-5092 ext. 302
liz@npccs.com

Heat Biologics to File Commercial IND Application with FDA and Initiate Phase II Clinical Trials of Lung Cancer Therapeutic Vaccine

MIAMI – (Feb. 18, 2011) – Heat Biologics announced today that it plans to file an Investigational New Drug (IND) application with the Food and Drug Administration (FDA), which would enable it to proceed with a Phase II clinical trial of its HS-110 therapeutic non-small cell lung cancer (NSCLC) vaccine under a commercial IND. This represents the next important step in the clinical-stage company's commercial development program.

Heat (www.heatbio.com) is focused on developing novel off-the-shelf "ImPACT" therapeutic vaccines to combat a wide range of cancers and infectious diseases. Its announcement came following a pre-application meeting with the FDA, during which the parties agreed on next steps and certain areas relating to the development program.

"The company is very encouraged by the results we've seen thus far, and we have elected to proceed to Phase II trials under a commercial IND. The input provided by the FDA will be extremely valuable as we pursue this critical step in our development process, one that will ultimately pave the way for commercial availability of HS-110," said Heat President Taffy Williams, Ph.D. "Having reached this milestone is particularly gratifying because it demonstrates progress toward a viable treatment for patients with advanced-stage NSCLC, a disease that kills more than 70% of the 215,000 people diagnosed with it each year."

HS-110 is a vaccine therapy built on Heat's ImPACT technology, which reprograms tumor cells to release an important immuno-protein called gp96-Ig that robustly generates a potent immune response to cancer cells by mobilizing and activating killer T cells against multiple tumor antigens. This stimulates the patient's own immune system to fight specific stealth targets, such as, in the case of HS-110, abnormal proteins that are expressed by lung cancer cells.

Heat plans to initiate its multicenter Phase II clinical trials in the second quarter of 2011.

About Heat Biologics
Heat Biologics (www.heatbio.com) is a clinical-stage company focused on developing its novel off-the-shelf "ImPACT" therapeutic vaccines to combat a wide range of cancers and infectious diseases. ImPACT therapy exploits the natural ability of antigens to activate the immune system by utilizing live, off-the-shelf, genetically modified cells injected into a patient to elicit a powerful immune response against the disease target. Heat's cutting-edge ImPACT Therapy is based upon heat shock protein gp-96, a chaperone protein found in all human cells and normally tethered to our cells with a leash called the KDEL sequence. ImPACT Therapy removes this KDEL leash, thus transforming

allogeneic living cells into powerful machines that continually pump out gp96 and their chaperoned antigens to activate the immune system against the full spectrum of antigens expressed by a patient's disease.

Heat is currently generating very positive toxicity, efficacy and immune response results in its NIH-sponsored Phase I human clinical trials against non-small cell lung cancer and plans to enter Phase IIA trials for this indication in the second quarter of 2011. Positive prophylactic and therapeutic data against SIV (the primate equivalent of HIV) is also been generated in a large 48-primate NIH-sponsored study, the first of ImPACT's ability to combat viral diseases. Heat plans to initiate additional clinical trials against bladder and ovarian cancer later in the year.