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Heat Biologics Meets Efficacy Endpoint in its Phase 1b Lung Cancer Trial to Progress to Phase 2

Encouraging results evaluating HS-110 in combination with Bristol-Myers Squibb's anti-PD-1 checkpoint inhibitor, nivolumab (Opdivo®)

Signs of synergistic efficacy with nivolumab enables expansion to a Phase 2 trial

DURHAM, N.C., March 13, 2017 (GLOBE NEWSWIRE) -- Heat Biologics, Inc. ("Heat") (Nasdaq:HTBX), a leader in the development of immunotherapies designed to activate a patient's immune system against cancer, announced that the company achieved the efficacy endpoint for its Phase 1b trial evaluating HS-110 in combination with Bristol-Myers Squibb's anti-PD-1 checkpoint inhibitor, nivolumab (Opdivo®), for the treatment of non-small cell lung cancer (NSCLC) and that the trial met the expansion criteria to advance into a Phase 2. In reviewing the Phase 1b data, the Data Monitoring Committee (DMC) determined that the Phase 1b safety endpoint was met and that there do not appear to be additional toxicities seen in the HS-110/nivolumab combination compared to existing data on nivolumab alone. Furthermore, 5 out of 15 patients treated with the HS-110/nivolumab combination had 20% or greater tumor reduction. The DMC concluded that the positive safety profile, mechanistic evidence and encouraging signs of synergistic efficacy warranted expansion to a Phase 2 trial.

"We are encouraged by the results from this Phase 1b trial evaluating the therapeutic vaccine, HS-110, combined with the checkpoint inhibitor, nivolumab, in patients with advanced non-small cell lung cancer," said Daniel Morgensztern, M.D., Associate Professor of Medicine and Director of Thoracic Oncology, Washington University School of Medicine. "We continue to see that the combination appears to be generally well-tolerated, and the encouraging signs of efficacy warrant a larger sample size. We've seen some patients with increased tumor infiltrating lymphocytes (TIL) after treatment, and anticipate that we can confirm this trend in the Phase 2."

"We are pleased with the DMC's decision to expand the trial to a Phase 2 given the positive clinical responses seen to-date. We saw that those patients with increased levels of TIL at 10 weeks had a durable benefit, with six out of eight of these patients (75%) alive at the one-year follow-up point," said Jeff Hutchins, Ph.D., Heat's Chief Scientific Officer and Senior Vice President of Preclinical Development. "We designed this trial with the Bristol-Myers Squibb Checkmate 057 nivolumab trial in mind, which reported a 19% response rate in a similar patient population. Although this is a small sample size and a non-randomized trial, we believe that this is an encouraging sign that the combination may be more effective than checkpoint therapy alone and could provide therapeutic benefit to a majority of lung cancer patients who do not respond well to checkpoint monotherapy. We remain focused on

enrolling new patients to better characterize the objective response rate, durability of the response and associated immune activity."

About Heat Biologics, Inc.

Heat Biologics, Inc. (Nasdaq:HTBX) is an immuno-oncology company developing novel therapies that are designed to activate a patient's immune system against cancer utilizing an engineered form of gp96, a protein that activates the immune system when cells die. Heat's highly specific T cell-stimulating therapeutic vaccine platform technologies, *ImPACT* and *ComPACT*, in combination with other therapies, such as checkpoint inhibitors, are designed to address three distinct but synergistic mechanisms of action: robust activation of CD8+ "killer" T cells (one of the human immune system's most potent weapons against cancer); reversal of tumor-induced immune suppression; and T cell co-stimulation to further enhance patients' immune response. Currently, Heat is conducting a Phase 1b trial with HS-110 (viagenpumatucel-L) in combination with an anti-PD-1 checkpoint inhibitor to treat patients with non-small cell lung cancer (NSCLC) and a Phase 2 trial with HS-410 (vesigenurtacel-L) in patients with non-muscle invasive bladder cancer (NMIBC).

Heat's wholly-owned subsidiary, Zolovax, Inc., is developing therapeutic and preventative vaccines to treat infectious diseases based on Heat's gp96 vaccine technology, with a current focus on the development of a Zika vaccine in conjunction with the University of Miami.

For more information, please visit www.heatbio.com.

Forward Looking Statements

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 on our current expectations and projections about future events. In some cases, forward-looking statements can be identified by terminology such as "may," "should," "potential," "continue," "expects," "anticipates," "intends," "plans," "believes," "estimates," and similar expressions. These statements are based upon current beliefs, expectations and assumptions and include statements regarding the encouraging signs of efficacy warrant a larger sample size, potentially confirming this trend in the Phase 2, the belief that the combination may be more effective than checkpoint therapy alone and could provide therapeutic benefit to a majority of lung cancer patients who do not respond well to checkpoint monotherapy and the potential of Heat's *ImPACT* and *ComPACT* therapies. These statements are based on management's expectations and assumptions as of the date of this press release and are subject to a number of risks and uncertainties, many of which are difficult to predict that could cause actual results to differ materially from current expectations and assumptions from those set forth or implied by any forward-looking statements, including the ability of Heat to develop its product candidates and prove them safe and efficacious, as well as results that are consistent with prior results, the ability to enroll patients and complete the clinical trials on time and achieve desired results and benefits, the company's ability to obtain regulatory approvals for commercialization of product candidates or to comply with ongoing regulatory requirements, regulatory limitations relating to the company's ability to promote or commercialize its product candidates for specific indications, acceptance of its product candidates in the marketplace and the successful development, marketing or sale of products, the company's ability to maintain its license agreements, the continued maintenance and growth of its patent estate, its ability to establish and maintain collaborations, its ability to obtain or maintain the capital or grants

necessary to fund its research and development activities, and its ability to retain its key scientists or management personnel and the other factors described in the company's annual report on Form 10-K for the year ended December 31, 2015 and other filings with the SEC. The information in this release is provided only as of the date of this release and the company undertakes no obligation to update any forward-looking statements contained in this release based on new information, future events, or otherwise, except as required by law.

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