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FDA Lifts Heat Biologics Partial Clinical Hold

Heat to Resume Patient Enrollment in Its Phase 2 HS-410 Monotherapy Arm

DURHAM, N.C., Feb. 10, 2016 (GLOBE NEWSWIRE) -- Heat Biologics, Inc. ("Heat") (Nasdaq:HTBX), an immuno-oncology company developing novel therapies that activate a patient's immune system against cancer, announced that the U.S. Food and Drug Administration (FDA) has lifted the partial clinical hold on the company's Phase 2 clinical trial evaluating HS-410 either alone or in combination with standard of care Bacillus Calmette-Guérin (BCG), for the treatment of non-muscle invasive bladder cancer (NMIBC). Heat will resume patient enrollment.

"We appreciate the FDA's expedited review and resolution of this matter as we resume enrollment in our Phase 2 monotherapy trial arm. We are encouraged by the positive results reported to-date and believe HS-410 represents a potential treatment option for patients suffering with non-muscle invasive bladder cancer," said Jeff Wolf, Heat's Founder and Chief Executive Officer. "Our clinical timelines remain materially unchanged with topline data expected in the fourth quarter of 2016 for the Phase 2 randomized trial arms evaluating HS-410 in combination with BCG. We are grateful for the ongoing support of the patients and their physicians participating in our clinical trial."

About HS-410 (vesigenurtacel-L)

HS-410 is an investigational product candidate for NMIBC based on Heat's proprietary *ImPACT* immunotherapy platform, designed to generate CD8+ "killer" T cells that attack cancer cells. HS-410 is currently being evaluated in a Phase 2, placebo-controlled, 100-patient NMIBC trial at multiple centers and has been granted U.S. FDA Fast Track Designation for the treatment of NMIBC.

About Heat Biologics, Inc.

Heat Biologics, Inc. (Nasdaq:HTBX) is an immuno-oncology company developing novel therapies that activate a patient's immune system against cancer. Heat's highly specific T cell-stimulating platform technologies, *ImPACT* and *ComPACT*, form the basis of its product candidates. These platforms, 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 2 trial with its HS-410 (vesigenurtacel-L) in patients with non-muscle invasive bladder cancer (NMIBC) and a Phase 1b trial with its HS-110 (viagenpumatucel-L) in combination with an anti-PD-1 checkpoint inhibitor to treat patients with non-small cell lung cancer

(NSCLC). For more information, please visit www.heatbio.com.

Forward Looking Statements

This press release includes forward-looking statements 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 such as the belief that HS-410 represents a potential treatment option for patients suffering with non-muscle invasive bladder cancer; the expected topline data in the fourth quarter of 2016 for the Phase 2 trial's randomized arms evaluating HS-410 in combination with BCG; and the potential of Heat's *ImPACT* and *ComPACT* therapies. These statements are subject to a number of risks and uncertainties, many of which are difficult to predict, including the ability of Heat's *ImPACT* and *ComPACT* therapies to perform as designed, the ability to enroll patients and complete the clinical trials on time, and the other factors described in our annual report on Form 10-K for the year ended December 31, 2014 and Heat's other filings with the SEC. The information in this release is provided only as of the date of this release, and we undertake 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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