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Heat Biologics Presents Immune Data on its HS-410 Phase 2 Bladder Cancer Trial at the Genitourinary Cancers Symposium

DURHAM, N.C., Feb. 17, 2017 (GLOBE NEWSWIRE) -- Heat Biologics, Inc. ("Heat") (Nasdaq:HTBX), announced that it presented a poster of its immunological data from its 94-patient Phase 2 trial evaluating vesigenurtacel-L (HS-410) either alone or in combination with BCG in patients with non-muscle invasive bladder cancer (NMIBC) at the 2017 Genitourinary (GU) Cancers Symposium. Researchers reported that HS-410, in combination with BCG, continues to be generally well-tolerated, that HS-410 activates CD8+ T cells and that these immune responders appear to have a lower recurrence rate than non-immune responders. Taken together, these data strengthen support for the vaccine mechanism of action and clinical proof-of-concept of immune activation.

Patients were also evaluated based on their levels of tumor infiltrating lymphocytes (TIL) at the start of treatment. In the placebo arm, patients with low TIL levels at baseline had a higher incidence of disease recurrence than patients with high TIL levels at baseline. However, in the vaccine-treated group, recurrence levels were essentially the same between the high and low TIL subgroups, at 25% and 29%, respectively. The fact that these two groups of patients saw clinical outcomes that were roughly identical may warrant further evaluation.

"These data continue to support our hypothesized vaccine mechanism of action," said Jeff Hutchins, Ph.D., Heat's Chief Scientific Officer and Senior Vice President of Preclinical Development. "Furthermore, we believe this vaccine treatment strategy could be evaluated in more advanced bladder patient populations, where immunotherapy has been shown to be effective, but where not all patients respond to therapy, likely due to insufficient T cell activation and proliferation."

As previously reported, vaccine arms did not show a statistical improvement over the placebo arm in the primary endpoint (1-year recurrence free survival). However, in keeping with clinical trial guidance, Heat continues to monitor all patients enrolled in the study for a 2-year duration.

The poster will be uploaded to thepublications section of Heat's corporate website in line with the conference's embargo policy.

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, 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 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 data continuing to support Heat’s hypothesized vaccine mechanism of action, Heat’s belief that the vaccine treatment strategy could be evaluated in more advanced bladder patient populations, where immunotherapy has been shown to be effective, but where not all patients respond to therapy, likely due to insufficient T cell activation and proliferation 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's *ImPACT* and *ComPACT* therapies to perform as designed, to demonstrate safety and efficacy, 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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