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Heat Biologics CSO to Present Interim Results From the Monotherapy Arm in Its Ongoing HS-410 Phase 2 Bladder Cancer Trial at the Phacilitate Immunotherapy World Conference

- *Early results support mechanism of action*
- *Six out of seven patients who have reached the 3-month timepoint remain recurrence free*

DURHAM, N.C., Jan. 26, 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 Taylor Schreiber, M.D. Ph.D., Heat's Chief Scientific Officer, will discuss three-month interim data from the unblinded, monotherapy cohort of the company's ongoing Phase 2 trial of [HS-410](#) (vesigenurtacel-L) for the treatment of high risk, non-muscle invasive bladder cancer (NMIBC) at the [Phacilitate Immunotherapy World Conference](#) in Washington, D.C. on January 25-27, 2016. In the monotherapy arm of Heat's Phase 2 trial, a series of weekly intradermal injections of HS-410 is being dosed as an alternative to intravesical standard of care, Bacillus Calmette-Guérin (BCG).

Dr. Schreiber will report that to-date HS-410 has been well-tolerated, with no serious adverse events. Six out of seven patients in the 25-patient arm, who have reached the 3-month timepoint after treatment with HS-410 alone, remain recurrence free. One of those patients had *carcinoma in situ* (CIS) – the patient population believed to be least responsive to BCG - and that patient experienced complete response. Images of the bladder taken from treated patients showed changes that resemble lymphoid (T cell rich) structures that we have observed in biopsy samples, indicating that HS-410 is generating an immune response as expected.

"These interim data are consistent with previous results from our Phase 1 trial, demonstrating that intradermal injections of HS-410 lead to a localized immune response within the urinary bladder," said Dr. Schreiber. "The fact that these localized immune responses are now being seen in the absence of standard of care, BCG, indicates that the response is due to HS-410. If the monotherapy arm of the trial demonstrates a trend toward low recurrence rates in the absence of BCG, that may extend options for subsequent pivotal study designs, and may potentially provide bladder cancer patients with an alternative to repeated BCG catheterization procedures. We look forward to presenting additional data from this trial in the future."

Heat continues to enroll the anticipated 25 patients who will receive HS-410 monotherapy and expects to complete enrollment in the first half of 2016. The three other blinded, randomized, placebo-controlled arms in the Phase 2 trial evaluating HS-410 in combination with BCG are fully enrolled with a total of 75 patients. Heat anticipates reporting topline efficacy, immune-response and safety data from those arms in the fourth quarter of 2016.

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 an ongoing 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 Bladder Cancer

According to the American Cancer Society, bladder cancer is the fifth most common cancer in the U.S., with approximately 75,000 new cases and 16,000 deaths in 2015. About 75% of the newly diagnosed patients have NMIBC. A key issue for bladder cancer is the high rate of recurrence, for which limited treatment options are available beyond complete bladder removal.

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 (viagenpumatucl-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 regarding HS-410's potential to extend options for subsequent pivotal study designs, and provide bladder cancer patients with an alternative to repeated BCG catheterization procedures, the continued enrollment in the monotherapy arm of the Phase 2 clinical trial, the expected completion of enrollment in the first half of 2016, topline Phase 2 data expected in the fourth quarter of 2016, the market size 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, 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.

CONTACT:
Heat Biologics, Inc.
Jennifer Almond
Investor and Media Relations
919-240-7133
investorrelations@heatbio.com



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