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Heat Biologics Resumes Enrollment in its Non-Small Cell Lung Cancer Trial Evaluating HS-110 in Combination with Anti-PD-1 Checkpoint Inhibitor

Data will Enable Further Evaluation of the Potential of HS-110 to Convert “Cold” to “Hot Tumors” in NSCLC Patients

DURHAM, N.C., Sept. 14, 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 company has resumed enrollment in its Phase 1b trial evaluating HS-110 in combination with nivolumab (Opdivo®), a Bristol-Myers Squibb anti-PD-1 checkpoint inhibitor, for the treatment of non-small cell lung cancer (NSCLC). The decision to resume trial enrollment was based on the positive data reported in June, including two clinical responses in “cold tumor” patients, and enabled by additional company funding through the exercise of warrants, [as reported in the latest company financial and corporate update](#).

“We are pleased to resume enrollment in this trial, especially following [the three case studies we reported earlier this year in June](#), where two out of the three patients showed an increase in CD8+ T cells in biopsy samples after treatment with HS-110 plus nivolumab,” stated Taylor Schreiber, M.D., Ph.D., Heat’s Chief Scientific Officer. “These early data suggest that HS-110 in combination with nivolumab may improve response rates for patients with ‘cold tumors’ who typically have lower response rates to checkpoint inhibitor monotherapy.”

The anti-PD-1 combination trial is designed to evaluate whether HS-110 expands the proportion of NSCLC patients responsive to PD-1 blockade, particularly in the estimated 50% of patients lacking an anti-tumor immune response. There are currently eight patients enrolled and the company expects to report topline 6-month data for these patients in the fourth quarter of this year. Heat intends to complete enrollment of each of the two 9-patient cohorts consistent with the original design of the trial, with the potential to expand each cohort up to 30 patients. The topline data for additional patients enrolled in the trial are anticipated within the next twelve months.

“It is important to note that the trial is structured as a Phase 1b/Phase 2 with pre-specified thresholds in place to expand the trial to a full Phase 2. We believe that we are close to fulfilling these thresholds given the positive clinical responses we have already reported,” added Dr. Schreiber.

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 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 potential of HS-110 to convert "cold" to "hot tumors" in NSCLC patients, the suggestion that HS-110 in combination with nivolumab may improve response rates for patients with "cold tumors," the intent to complete enrollment of each of the two 9-patient cohorts consistent with the original design of the trial, with the potential to expand each cohort up to 30 patients, the expected reporting of topline 6-month data in the fourth quarter of 2016, the anticipated topline data for additional patients enrolled in the trial within the next twelve months, the belief that the company is close to fulfilling pre-specified thresholds to expand the trial to a full Phase 2 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 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, 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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