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Heat Biologics Presents a Poster on its HS-110/Nivolumab Combination Phase 1b Non-Small Cell Lung Cancer Trial at ASCO Annual Meeting

- *Poster reviews trial design and endpoints*
- *Additional data illustrates clinical and immune response correlation*

DURHAM, N.C., June 06, 2016 (GLOBE NEWSWIRE) -- [Heat Biologics, Inc.](#) (Nasdaq:HTBX), an immuno-oncology company developing novel therapies that activate a patient's immune system against cancer, announced that it presented a poster entitled "Broadening response rates to PD-1 therapy in advanced lung adenocarcinoma: Viagenpumatucel-L (HS-110) in combination with nivolumab in the ongoing DURGA trial" (Abstract #TPS9102) at the American Society of Clinical Oncology (ASCO) Annual Meeting.

The poster was accepted within the Trials in Progress category and as such, reviewed the design and endpoints for the ongoing Phase 1b study of HS-110 in combination with anti-PD-1 checkpoint inhibitor, nivolumab, for the treatment of non-small cell lung cancer (NSCLC). Eight patients are currently enrolled.

Recent study findings, not presented at ASCO, suggest that the addition of HS-110 to nivolumab does not significantly alter the nivolumab safety profile to-date. In addition, case studies of three trial patients (one non-responder and two responders) have been characterized. While all three patients showed a decrease in immune cell PD-1 expression, which is consistent with nivolumab's mechanism of action, both responders also showed a decrease in immunosuppressor cells, as well as increases in activated effector T cells in the peripheral blood. Furthermore, the two responders showed an increase in CD8+ T cells in biopsy samples after treatment with the HS-110/nivolumab combination. ELISPOT analysis of patient blood samples demonstrated induction of antigen-specific immune responses to both total vaccine antigen and individual shared tumor antigens in both responding patients, but not the clinical non-responder. Finally, these responding patients also had low-grade injection site reactions in addition to rash, which the non-responder did not, suggesting their clinical and immune responses may be attributed to the HS-110 vaccine.

These data are included in the updated corporate presentation which is available on Heat's corporate website at www.heatbio.com. As previously announced, full topline data on all eight patients is expected to be presented in the fourth quarter, including all primary and secondary endpoints.

“In these early data, we observed a correlation between patients’ clinical outcomes and their immunological responses, which we believe indicates that tumor response may be a result of increased immunological activity,” said Melissa Price, Ph.D., Heat’s VP of Product Development. “Additionally, the two responders qualitatively converted from low to high tumor infiltrating lymphocytes (TILs), which is consistent with data previously reported from our bladder cancer study. This finding supports our hypothesis that patients with low levels of TILs, who typically do not respond well to single-agent checkpoint inhibitors, may respond to a combination with our *ImPACT* vaccine.”

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 (viagenpumacel-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 about Heat’s 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 suggestion that the addition of HS-110 to nivolumab does not significantly alter the nivolumab safety profile to-date, the suggestion that the patients’ clinical and immune responses may possibly be attributed to the HS-110 vaccine, timing of presentation of full topline data on all eight patients in the fourth quarter, the correlation between patients’ clinical outcomes and their immunological responses, indicating that tumor response may be a result of increased immunological activity, the findings supporting the hypothesis that patients with low levels of TILs, who typically do not respond well to single-agent checkpoint inhibitors, may respond to a combination with Heat’s *ImPACT* vaccine 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, 2015 and our other filings with the SEC, including subsequent periodic reports on Forms 10-Q and 8-K. 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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