December 6, 2016

Heat Biologics Presents Topline HS-110/Nivolumab Combination Lung Cancer Results

Reports Positive Data on Primary Endpoint with Positive Safety Data

Overall Survival Compares Favorably with Single-Agent Nivolumab

Management to host a call on Thursday, December 8th, at 8:30 a.m. ET

DURHAM, N.C., Dec. 06, 2016 (GLOBE NEWSWIRE) -- Heat Biologics, Inc. (Nasdaq:HTBX), a leader in the development of gp96-based immunotherapies designed to activate a patient's immune system to fight cancer, reported topline response and survival results in the ongoing Phase 1b study evaluating HS-110, in combination with Bristol-Myers Squibb's anti-PD-1 checkpoint inhibitor, nivolumab (Opdivo®), for the treatment of non-small cell lung cancer (NSCLC), at the International Association for the Study of Lung Cancer Annual Meeting in Vienna, Austria.

In an oral presentation, principal investigator, Daniel Morgensztern, MD, Associate Professor of Medicine and Director of Thoracic Oncology, Washington University School of Medicine, reported that one-year results from the first eight trial patients showed that the HS-110/nivolumab combination was well-tolerated, with a safety profile consistent with single agent nivolumab. There were no additional toxicities seen in HS-110/nivolumab combination compared to existing data on single agent nivolumab alone. HS-110 generated a robust antigen-specific immune response in several patients, consistent with the mechanism of action seen in other HS-110 trials. Additionally, the patients who responded best to the combination therapy (immune responders) had longer overall survival and better objective response rate (ORR) than the non-immune responders, even though they had the same baseline immune function.

Immune responders in the study saw a 50% ORR, while non-immune responders saw a 0% ORR. This is important, as checkpoint inhibitors have been shown, independently, to be much more effective in tumors with pre-existing, high tumor-infiltrating lymphocytes (TIL). As such, there now exists an acute need to address the large proportion of non-responders with low-TIL tumors.

Moreover, the immune responders had a better median overall survival (OS) than non-immune responders. The one-year OS is currently 50% for the responders, and 25% for the non-responders. Finally, immune responders also saw a better median OS at 12.7 months, than non-immune responders, who saw a median OS of 7.1 months. Researchers concluded that immune response may correlate with clinical efficacy and that HS-110 may have synergistic activity with immune checkpoint inhibitors.

“We are encouraged by the data generated in the trial,” said Dr. Morgensztern. “We were impressed by the ability of HS-110 to activate a CD8+ T cell immune response. The HS-110/nivolumab combination is worth continued exploration in the treatment of lung cancer, as the HS-110 mechanism of action is potentially synergistic with anti-PD-1 checkpoint inhibitors.”

“We’ve continued to see ELISPOT analysis correlate with clinical efficacy with HS-110 in NSCLC, an encouraging trend also observed in other trials with HS-110,” said Taylor Schreiber, MD, PhD, Heat’s Chief Scientific Officer. “We are seeing trends between TIL status and TIL increases after treatment among these patients, which may speak to the ability of HS-110 to convert “cold” tumors to “hot” tumors to increase the effectiveness of PD-1 checkpoint therapy in lung cancer.”

“These new data are further confirmation of the ability of our*ImPACT* platform, which has been administered to over 200 patients in 4 clinical studies, to generate a robust antigen-specific immune response, an important component of immunotherapy,” said Jeff Wolf, Heat’s CEO. “The future of immuno-oncology lies in combining synergistic modalities to create more effective treatments. At Heat, we are actively pursuing opportunities to combine our *ImPACT* and *ComPACT* platforms with checkpoint inhibitors, and other promising immunotherapies to improve patient outcomes.”

Heat plans to hold an investor call on December 8th at 8:30 a.m. ET to discuss its overall clinical strategy moving forward. The call will be available on the company’s website at www.heatbio.com, or by calling 866-320-0174 for U.S. callers, or +1 785-424-1631 for international callers. A webcast will also be archived on the company’s website and a telephone replay of the call will be available approximately one hour following the call, through midnight December 15, 2016, and can be accessed by calling: 877-481-4010 (U.S. callers) or +1 919-882-2331 (international callers) and entering conference ID: 10169.

The oral presentation will be uploaded to Heat’s website athttp://www.heatbio.com/our-science/publications 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).

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. The Zolovax patent portfolio also includes gp96 vaccines targeting West Nile virus, Dengue and yellow fever among others.

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 the conclusion that immune response may correlate with clinical efficacy and that HS-110 may have synergistic activity with immune checkpoint inhibitors, the belief that the HS-110/nivolumab combination is worth continued exploration with a mechanism of action synergistic with anti-PD-1 checkpoint inhibitors to improve treatment in lung cancer, the ability of HS-110 to convert “cold” tumors to “hot” tumors to increase the effectiveness of PD-1 checkpoint therapy in lung cancer and the other 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 ability to achieve similar results in a larger patient population and 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. 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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Source: Heat Biologics