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Heat Biologics Announces Positive Interim Data from its Phase 2 Clinical Trial of HS-110 and Nivolumab in Non-Small Cell Lung Cancer (NSCLC)

- Tumor Shrinkage and Disease Control Demonstrated in a Majority of Evaluable Patients
- HS-110 + Nivolumab Combination Showed Durable Responses in Difficult-to-treat Low TIL Patients and Low PD-L1 Patients, Who Respond Poorly to Checkpoint Inhibitors
- Data Consistent with HS-110 Mechanism of Action
- Live Webcast at 8am Eastern Time Today

DURHAM, NC / ACCESSWIRE / February 28, 2018 /Heat Biologics, Inc. (NASDAQ: HTBX), a biopharmaceutical company developing drugs designed to activate a patient's immune system against cancer, today announced interim results from its Phase 2 study investigating HS-110 in combination with Bristol-Myers Squibb's

anti-PD-1 checkpoint inhibitor, nivolumab (Opdivo®), in patients with advanced non-small cell lung cancer (NSCLC) whose cancers have progressed after treatment with one or more lines of therapy.

Among the 35 patients in the Intent-to-Treat ("ITT") population, 6 patients (17%) achieved a partial response and 14 patients (40%) achieved disease control. Evaluable ITT patients (those who underwent at least one follow-up scan regardless of treatment duration) demonstrated overall response and disease control rates of 26% and 67%, respectively. Overall responses appeared durable and long lasting. The survival data are still maturing, and median overall survival has not yet been reached. The combination of HS-110 and nivolumab was well tolerated, with no additional toxicities compared to what has been observed with single agent checkpoint inhibitors.

As predefined in the clinical protocol, patient subgroups were evaluated for levels of tumor infiltrating lymphocytes ("TIL") and for PD-L1 checkpoint protein expression on tumor cells. Four of 9 "cold tumor" patients with low TIL levels (<10%) at baseline had partial responses. HS-110 also showed a durable effect in patients with low levels of PD-L1, with 3 of 9 patients responding. Both of these patient populations respond poorly to checkpoint inhibitors.

George Peoples, M.D., Chief Medical Officer, stated, "The results from this combination trial with HS-110 and nivolumab are very promising, demonstrating durable responses in those patients with low levels of TIL and PD-L1. These patients represent the most difficult-to-treat patient groups and comprise the majority of the NSCLC population."

"We look forward to continuing patient enrollment to better define the optimal NSCLC population and inform the design of a pivotal trial," commented Jeff Wolf, Chairman and CEO. "These data are consistent with the mechanism of action of our T-cell Activation Platform that promotes a robust T-cell immune response, an important component of an effective immunotherapy combination against cancer."

DURGA Trial Design

The ongoing DURGA trial is a single arm multicenter trial that was designed to evaluate the combination of HS-110 and nivolumab in patients with NSCLC. Patients with advanced and previously treated NSCLC were treated with weekly HS-110 for 18 weeks and nivolumab 3 mg/kg every 2 weeks until disease progression or death. The primary endpoints are 1) safety and tolerability, and 2) objective response rate as defined by RECIST 1.1 criteria. Secondary endpoints include disease control rate, duration of response, peripheral blood immune response, progression-free survival and overall survival.

Live Webcast with Slides

The interim data from the DURGA trial will be presented at an analyst event, taking place at 8am Eastern Time, today, Wednesday February 28th. To register and watch a live webcast of the event, visit http://lifesci.rampard.com/20180228.

About Heat Biologics, Inc.

Heat Biologics is a biopharmaceutical company developing immunotherapies designed to activate a patient's immune system against cancer by inducing CD8+ "Killer" T-cells. Our T-cell Activation Platform (TCAP) produces therapies designed to turn "cold" tumors "hot," and be administered in combination with checkpoint inhibitor therapies and other immuno-modulators to increase their effectiveness. We are currently enrolling patients in our Phase 2 clinical trial for non-small cell lung cancer, in combination with Bristol-Myers Squibb's nivolumab (Opdivo®). Pelican Therapeutics, a subsidiary of Heat, is focused on the development of co-stimulatory monoclonal antibody and fusion protein-based therapies designed to activate the immune system. We also have numerous pre-clinical programs at various stages of development. 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 our continued enrollment of patients in this trial, the future pivotal trial and the potential benefits of our products. 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* therapy to perform as designed, to demonstrate safety and efficacy, as well as results that are consistent with results from the

interim data and prior results, the ability to enroll patients and complete the clinical trials on time and achieve desired results and benefits, Heat's ability to obtain regulatory approvals for commercialization of product candidates or to comply with ongoing regulatory requirements, regulatory limitations relating to Heat'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, Heat'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, its ability to successfully integrate Pelican, and the other factors described in Heat's most recent annual report on Form 10-K 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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