November 11, 2019

Heat Biologics Presents Additional Phase 2 Interim Data in Advanced NSCLC Patients at the SITC 34th Annual Meeting

Promising results in patients whose disease has progressed after checkpoint inhibitor therapy

DURHAM, NC / ACCESSWIRE / November 11, 2019 /Heat Biologics, Inc. (NASDAQ:HTBX), a biopharmaceutical company developing immunotherapies designed to activate a patient's immune system against cancer, today announced that the Company presented additional positive Phase 2 interim top line data from Cohort B of the Company's Phase 2 trial of its T-cell activating cell-based therapy, HS-110, in combination with Opdivo® (nivolumab) in advanced non-small cell lung cancer (NSCLC). The data was presented at a poster session at the Society for Immunotherapy of Cancer's (SITC) 34th Annual Meeting on November 8th.

Cohort B enrolled patients who had previously received a minimum of 4 months of checkpoint inhibitor (CPI) therapy and whose disease had subsequently progressed, a patient population with a significant unmet medical need. 61% of patients achieved disease stabilization per iRECIST. Median progression-free survival was 3.2 months and median overall survival was 11.8 months. Moreover, patients experiencing dermal injection site reactions (ISR) had statistically significant improvement in PFS and OS compared to those without ISR (Hazard Ratio = 0.40, p=0.0068 and Hazard Ratio = 0.16, p=0.0005, respectively).

George Peoples, M.D., FACS, Heat Biologics' Chief Medical Advisor, commented, "This data is extremely promising, as the combination of HS-110 and nivolumab may provide patients with treatment options other than salvage cytotoxic chemotherapy. Consistent with our previously reported data, the benefit of HS-110 in combination with nivolumab is independent of PD-L1 expression and we are seeing positive data in low PD-L1 patients (<1%) that typically do not respond well to checkpoint inhibitor monotherapy."

Dr. Peoples continued, "This data suggests re-challenging the immune system with nivolumab and HS-110 after checkpoint inhibitor treatment failure may restore responsiveness and clinical benefit. Further supporting the mechanism of action of HS-110, patients experiencing dermal injection site reactions (ISR) had statistically significant improvement in PFS and OS compared to those without ISR."

This combination of HS-110 and nivolumab is well-tolerated and when compared to CPI monotherapy, no increase in the incidence of immune-related adverse events has been observed.

Jeff Wolf, Heat Biologics' CEO, commented, "This data is very encouraging as the

combination of HS-110 with nivolumab may address an important unmet need among patients whose disease has progressed following checkpoint inhibitor therapy. These patients currently have limited treatment options. We look forward to advancing our clinical trials and exploring potential partnership and other strategic options to move this program forward."

About Heat Biologics, Inc.

Heat Biologics is a biopharmaceutical company developing immunotherapies designed to activate a patient's immune system against cancer using CD8+ "Killer" T-cells. HS-110 is the Company's first biologic product candidate in a series of proprietary immunotherapies designed to stimulate a patient's own T-cells to attack cancer. Heat has completed enrollment in its Phase 2 clinical trial for advanced non-small cell lung cancer, in combination with Bristol-Myers Squibb's nivolumab (Opdivo®) or with Merck's pembrolizumab (Keytruda®). 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. Heat also has 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 such as: the combination of HS-110 and nivolumab may provide patients with treatment options other than salvage cytotoxic chemotherapy, the data suggests that re-challenging the immune system with nivolumab and HS-110 after checkpoint inhibitor treatment failure may restore responsiveness and clinical benefit and these latest results suggests that HS-110 in combination with nivolumab may address a key unmet medical need among patients whose disease has progressed following checkpoint inhibitor therapy. 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 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, 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, its ability to retain its key scientists or management personnel, and the other factors described in Heat's Annual Report on Form 10-K and 10-K/A for the year ended

December 31, 2018 and other subsequent 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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SOURCE: Heat Biologics, Inc.

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