June 4, 2021

# Heat Biologics to Showcase Favorable Survival Data of HS-110 in Previously Treated Non-Small Cell Lung Cancer Patients at 2021 American Society of Clinical Oncology Annual Meeting

## Survival benefit observed in two treatment settings of previously treated non-small lung cancer patients

DURHAM, N.C., June 04, 2021 (GLOBE NEWSWIRE) -- Heat Biologics, Inc. (Nasdaq: HTBX), a clinical-stage biopharmaceutical company focused on developing first-in-class therapies to modulate the immune system, today announced that Dr. Roger B. Cohen, MD, Professor of Medicine at the University of Pennsylvania Perelman School of Medicine, presented an overview of the latest HS-110 data at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting which is being held from June 4-8, 2021. This poster presentation can be viewed on Heat Biologics' website at: https://www.heatbio.com/product-pipeline/scientific-publications. The ASCO Annual Meeting is the world's largest oncology conference showcasing the latest advancements in cancer research.

HS-110, in combination with a checkpoint inhibitor (CPI), is a potentially transformational agent to improve survival benefit for patients with non-small cell lung cancer (NSCLC). This is a first-in-class, allogeneic, off-the shelf cell-based therapy developed by Heat leveraging its proprietary gp96 platform. At this year's ASCO meeting, the Company is pleased to report the latest data of HS-110 in combination with OPDIVO® (nivolumab) in two distinct treatment settings in a total of 115 previously treated patients with NSCLC:

- Median overall survival (mOS) of 24.6 months was observed in previously treated, CPI naïve patients with advanced NSCLC (Cohort A, n=47). This data compares favorably with published data of Checkmate 057, which reported a mOS of 12.2 months in patients who received nivolumab as single agent in a similar treatment setting.
- mOS of 11.9 months was reported in NSCLC patients who were previously treated with CPI and whose disease had subsequently progressed (Cohort B, n=68). Published data from other studies stated median OS of 6.8 to 9.0 months for NSCLC patients treated with chemotherapies after CPI progression.
- Multiple subset analyses including injection-site reaction (ISR) and tumor PD-L1 expression were performed.
    - Significantly longer mOS was observed in patients with ISR compared with those without such a reaction for both Cohorts A and B.
    - Extended survival benefit was observed in PD-L1 positive patients in Cohort A.

- A trend of improved overall survival was observed in patients with low blood tumor mutation burden in Cohort B.

Dr. Roger B. Cohen, Professor of Medicine at the University of Pennsylvania Perelman School of Medicine, commented, “HS-110 is a promising agent for treatment of incurable NSCLC. The latest data presented support further clinical evaluation in combination with first line regimens that include a CPI as well as addressing high unmet medical needs for CPI progressors.”

Jeff Wolf, Chief Executive Officer of Heat, commented, “This data further reinforces the potential utility of HS-110 in combination with a CPI for multiple treatment settings of NSCLC. The growing body of clinical data demonstrates that HS-110 in combination with a CPI is well tolerated and has the potential to enhance survival benefit when given with a CPI. Our latest results, consistent with previously reported data, provide a strong foundation for the Company to discuss possible Phase 3 registration trial designs with the FDA and potential partners.”

**About HS-110**
HS-110 is a first-in-class, off-the-shelf, allogeneic cell therapy designed to utilize gp96 for immune activation against multiple tumor testis antigens. Phase 2 trial of HS-110 in combination with Bristol Myers Squibb's OPDIVO® (nivolumab) has completed enrollment in patients with incurable or metastatic NSCLC. OPDIVO® is a programmed death-1 immune checkpoint inhibitor. HS-110 has broad potential for providing multiple treatment options to NSCLC patients in combination with a PD-1 inhibitor. Positive interim survival data has been demonstrated in two distinct treatment settings in previously treated NSCLC patients who have not been treated with CPI as well as patients who have progressed during or after previous treatment with a CPI. Combination of HS-110 and PD-(L)1 therapies may confer additional survival benefit.

**About Heat Biologics, Inc.**
Heat Biologics is a biopharmaceutical company focused on developing first-in-class therapies to modulate the immune system. Heat’s gp96 platform is designed to activate immune responses against cancer or infectious diseases. The Company has multiple product candidates in development leveraging the gp96 platform, including HS-110, which has completed enrollment in its Phase 2 trial, and a COVID-19 vaccine program in preclinical development. In addition, Heat Biologics is also developing a pipeline of proprietary immunomodulatory antibodies and cell-based therapies, including PTX-35 and HS-130 in Phase 1 clinical trials.

**Forward Looking Statement**
*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, expectation, and assumptions and include statements such as the HS-110, in combination with a checkpoint inhibitor (CPI), being a potentially transformational agent to improve survival benefit for patients with non-small cell lung cancer (NSCLC), HS-110 being a promising agent for treatment of incurable NSCLC, potential utility of HS-110 in*

*combination with a CPI for multiple treatment settings of NSCLC, HS-110 in combination with a CPI having the potential to enhance survival benefit when given with a CPI and HS-110 being administered in combination with first line regimens that include a CPI as well as addressing high unmet medical needs for CPI progressors. These statements are subject to a number of risks and uncertainties, many of which are difficult to predict, 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 of HS-110, in combination with a CPI to be utilized in multiple treatment settings of NSCLC and to improve survival benefit for patients with non-small cell lung cancer (NSCLC), the ability HS-110 to be administered in combination with first line regimens that include a CPI as well as addressing high unmet medical needs for CPI progressors, Heat's vaccine platform to provide protection against COVID-19, the ability to enroll patients and complete the clinical trials on time and achieve desired results and benefits, especially in light of COVID-19, 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 continue to maintain its listing on the Nasdaq Capital Market and its ability to retain its key scientists or management personnel, and the other factors described in Heat's most recent annual report on Form 10-K filed with the SEC, and other subsequent filings with the SEC. The information in this release is provided only as of the date of this release, and Heat 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.*

**Media and Investor Relations Contact**
David Waldman
+1 919 289 4017
investorrelations@heatbio.com

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