November 5, 2019

Heat Biologics Reports Positive Phase 2 Interim Data in NSCLC Patients Who Previously Failed Checkpoint Inhibitor Treatment

Announces Abstract Summarizing Favorable Interim Phase 2 Data of HS-110 Plus Nivolumab

Additional Data to be Reported in Poster Presentation at the SITC 34th Annual Meeting on November 8, 2019

DURHAM, NC / ACCESSWIRE / November 5, 2019 /Heat Biologics, Inc. (NASDAQ:HTBX), a biopharmaceutical company developing immunotherapies designed to activate a patient's immune system against cancer, today announced that an abstract has been posted on The Society for Immunotherapy of Cancer's (SITC) website in connection with the Company's planned poster presentation at SITC's 34th Annual Meeting on November 8, 2019.

The abstract summarizes the latest interim top line data from Cohort B of the Company's Phase 2 trial of the Company's "off-the-shelf" cell-based therapy, HS-110, in combination with Opdivo® (Nivolumab) in advanced non-small cell lung cancer (NSCLC), which completed enrollment in July 2019. This cohort enrolled patients who had previously received a checkpoint inhibitor (CPI) and whose disease had subsequently progressed. 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. Additionally, the combination of HS-110 and nivolumab is well-tolerated, and no increase in the incidence of immune-related adverse events was observed to date, as compared to CPI monotherapy. The full abstract is available at: https://www.heatbio.com/technology/scientific-publications

Jeff Wolf, Heat Biologics' CEO, commented, "NSCLC patients who progressed after checkpoint inhibitor treatment have limited therapeutic options. The latest results are encouraging and suggest that HS-110 in combination with nivolumab may address this key unmet medical need. As of this data cut, the median overall survival (OS) is estimated to be 11.8 months, with 70% of the patients still alive. I am unaware of any published checkpoint combination studies that offered superior OS in patients that had experienced previous checkpoint inhibitor treatment failure in NSCLC. This data also compares favorably to reported studies using chemotherapy following checkpoint inhibitor progression [1, 2] ".

Signals of clinical efficacy were observed in the reported objective response rate (ORR), disease control rate (DCR) and progression free survival (PFS). Importantly, 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). Additional data will be presented at SITC on November 8 ,2019.

Details of Heat Biologics' poster presentation:

Abstract Title: Treating advanced non-small lung cancer (NSCLC) patients after checkpoint inhibitor treatment failure with a novel combination of Viagenpumatucel-L (HS-110) plus nivolumab

Poster #: P411
Date: Friday, November 8, 2019, 7am - 8pm (Eastern Time)
Location: Gaylord National Hotel & Convention Center, Washington DC

References:

[1] Costantini A, Corny J, Fallet V et al. Efficacy of next treatment received after nivolumab progression in patients with advanced nonsmall cell lung cancer. ERJ Open Res. 2018 Apr 20;4(2).

[2] Schvartsman G, Peng SA, Bis G, et al. Response rates to single-agent chemotherapy after exposure to immune checkpoint inhibitors in advanced non-small cell lung cancer. Lung Cancer. 2017 Oct;112:90-95.

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 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 for NSCLC patients . 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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https://www.accesswire.com/565311/Heat-Biologics-Reports-Positive-Phase-2-Interim-Data-in-NSCLC-Patients-Who-Previously-Failed-Checkpoint-Inhibitor-Treatment