August 26, 2020

Heat Biologics Announces Publication of Preclinical COVID-19 Vaccine Results

- ***Data supports a differentiated gp96-based COVID-19 vaccine that induces systemic and tissue-specific (lung) memory CD8+ T cells***
- ***Gp96-based vaccine generates tissue-resident memory CD8+ T cells that may be instrumental in eradicating SARS-CoV-2 infected cells***
- ***Tissue specific memory CD8+ T cells potentially important for compromised patient populations***

DURHAM, NC / ACCESSWIRE / August 26, 2020 /Heat Biologics, Inc. ("Heat") (NASDAQ:HTBX), a clinical-stage biopharmaceutical company focused on developing first-in-class therapies to modulate the immune system, including multiple oncology product candidates and a novel COVID-19 vaccine, today announced publication of positive preclinical COVID-19 results in bioRxiv, which is available at: https://www.biorxiv.org/content/10.1101/2020.08.24.265090v1.

Publication highlights for Heat's gp96 based COVID-19 vaccine (gp96-Ig-S):

- Significantly increases the frequency of systemic and tissue-specific CD8+ T-cells by conferring cellular immunity that is essential against any viral infection, including SARS-CoV-2
- Primes potent effector memory CD8+ T cell responses and tissue resident memory CD8+ T cells localized in lung which are essential in protection against respiratory virus infection
- Elicits a robust immune response directed against the Spike protein of SARS-CoV-2, generating both helper CD4+ T-cells that aide in antibody production, as well as virus killing cytotoxic CD8+ T cells
- Induces the secretion of cytokines (IFN-gamma, IL-2, TNF-alpha) from CD8+ and CD4+ T cells in both the spleen and lungs
- Induces high frequencies of S-protein specific (against S1 and S2 epitopes) CD8+ T cells in the respiratory airways, the predominant site of viral infection

Studies in COVID-19 patients with moderate or asymptomatic infection indicate that the expansion of memory CD8+ T cells directed at immunodominant epitopes on S protein may be important, including tissue resident CD8+ T cells that localize in high numbers in the lung tissue to protect against infection (1,2,3). The preclinical data demonstrates that Heat's vaccine achieves this objective with tissue resident memory CD8+ T cells that localize in lung tissue. The generation of a durable cellular immune response driven by memory CD8+ T cells may protect against re-infection. Heat's vaccine is designed to prophylactically "train" the immune system to induce this response in patients and should be especially effective in those individuals most prone to severe infection, such as the elderly, individuals with relevant comorbidities or other patients who are immuno-suppressed.

Natasa Strbo, MD, DSc, Assistant Professor of Microbiology and Immunology at the University of Miami Miller School of Medicine and co-developer of Heat's gp96 platform, commented, "Vaccines that can induce SARS-CoV-2 specific CD8+ T cells that home in to the airway epithelium are needed to effectively mount an immune response against SARS-CoV-2. Our latest publication demonstrates the importance of tissue resident memory CD8+ T cells triggered by our vaccine in protecting against infection."

Jeff Wolf, Chief Executive Officer of Heat, commented, "We believe that these results are a powerful reinforcement that this platform represents a unique and relevant paradigm for novel vaccine development, capable of inducing cellular immune responses in epithelial tissues such as the lungs. This publication demonstrates the potential utility and versatility of our vaccine platform to address SARS-CoV-2, relevant mutations and other pathogens of interest."

1. Peng Y, Mentzer AJ, Liu G, Yao X, Yin Z, Dong D, et al. Broad and strong memory CD4 (+) and CD8 (+) T cells induced by SARS-CoV-2 in UK convalescent COVID-19 patients. bioRxiv. 2020. Epub 2020/06/25. doi: 10.1101/2020.06.05.134551. PubMed PMID: 32577665; PubMed Central PMCID: PMCPMC7302222.

2. Sekine T, Perez-Potti A, Rivera-Ballesteros O, Strålin K, Gorin J-B, Olsson A, et al. Robust T cell immunity in convalescent individuals with asymptomatic or mild COVID-19. bioRxiv. 2020.

3. Liao M, Liu Y, Yuan J, Wen Y, Xu G, Zhao J, et al. Single-cell landscape of bronchoalveolar immune cells in patients with COVID-19. Nat Med. 2020;26(6):842-4. doi: 10.1038/s41591-020-0901-9. PubMed PMID: 32398875.

About Heat Biologics, Inc.

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

For more information, please visit: www.heatbio.com, and also follow us on Twitter.

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 Heat's vaccine prophylactically "training" the immune system to induce this response in patients and being especially effective in those individuals most prone to severe infection, such as the elderly,

individuals with relevant comorbidities or other patients who are immuno-suppressed, the results being a powerful reinforcement that this platform represents a unique and relevant paradigm for novel vaccine development, capable of inducing cellular immune responses in epithelial tissues such as the lungs and the potential utility and versatility of Heat's vaccine platform to address SARS-CoV-2, relevant mutations and other pathogens of interest. These statements are subject to a number of risks and uncertainties, many of which are difficult to predict, including the ability of Heat's vaccine platform to provide protection against COVID-19, 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, 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.

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