

December 16, 2020



Heat Biologics Announces Completion of ZVX-60 Vaccine Cell Line for COVID-19

Preparations for manufacturing underway

DURHAM, NC / ACCESSWIRE / December 16, 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 announces it has completed its gp96-based COVID-19 vaccine cell line ("ZVX-60"), which is being developed for use as either a standalone vaccine, or in combination with other vaccines to enhance prophylactic protection. Data, generated at the University of Miami Miller School of Medicine, has confirmed expression of gp96, OX40L and Spike protein. The Company also reports it has begun preparations for manufacturing, as the next-step towards first-in-human Phase 1 clinical trials.

Jeff Wolf, Chief Executive Officer of Heat, commented, "We are encouraged by the recent Phase 3 data reported by other vaccine developers, and commend the FDA for their fast action to accelerate approval. Importantly, we believe ZVX-60 holds promise as an adjunct therapy to enhance protection provided by other vaccine approaches. Our preclinical data thus far suggests that our cell line generates a robust T-cell mediated immune response directed against the Spike protein of SARS-CoV-2. Notably, the cell line induced expansion of both "killer" CD8+ T-cells that destroy virus infected cells, as well as "helper" CD4 T-cells that assist in producing anti-viral antibodies."

"We are also excited to report that preparations for manufacturing the vaccine are well underway. Given the utility and versatility of our vaccine platform, we look forward to advancing ZVX-60 into clinical development."

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 regarding ZVX-60 holding promise as an adjunct therapy to enhance protection provided by other vaccine approaches, the cell line generating a robust T-cell mediated immune response directed against the Spike protein of SARS-CoV-2 and advancing ZVX-60 into clinical development. 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 enhance protection provided by other vaccine approaches and 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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