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Heat Biologics Announces First Patient Dosed in the First Phase 1 Trial of HS-130

First allogeneic, off-the-shelf cell therapy approach that enhances T-cell activation through localized OX40-mediated co-stimulation of dormant immune signals

DURHAM, NC / ACCESSWIRE / December 16, 2019 / Heat Biologics, Inc. (NASDAQ:HTBX), a clinical-stage biopharmaceutical company specialized in the development of therapeutics designed to activate patients' immune systems against cancer, today announced that the Company has dosed the first patient in the first Phase 1 clinical trial of HS-130, in combination with HS-110, for patients with advanced solid tumors refractory to standard of care.

HS-130 is Heat's allogeneic cell line engineered to locally secrete the extracellular domain of OX40 ligand fusion protein (OX40L-Fc), a key costimulator of T cells, designed to augment antigen-specific CD8+ T cell response. HS-130 was manufactured by utilizing the Company's proprietary process to reprogram a live, genetically modified cancer cell line. In multiple preclinical models, these responses have demonstrated improved efficacy and safety using OX40L-Fc via cell-based delivery compared to systemic delivery of an OX40 agonist antibody in combination with HS-110.

The first-in-human study is expected to enroll up to 30 patients under the supervision of lead investigator Dr. Rachel Sanborn, Director of the Phase 1 Clinical Trials Program at the Earle A. Chiles Research Institute, a division of Providence Cancer Institute in Portland, Oregon. In this study, patients will receive escalating doses of HS-130 in combination with HS-110. The objectives of the study are to evaluate patient safety and to determine the optimal dose for a subsequent Phase 2 trial.

Jeff Wolf, Heat's CEO, commented, "We are pleased to announce the initiation of this combination study, which marks a key milestone for Heat as we advance our latest asset into clinical development. We look forward to sharing clinical proof of concept data to enable the development of a new generation of allogeneic therapy drug candidates in 2020."

About HS-110

HS-110 is designed by engineering gp96-Fc to deliver more than 70 cancer testis antigens to stimulate the patients' immune system and activate a robust cytotoxic T cell response. HS-110 has completed enrollment in a 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®) (NCT 02439450).

About HS-130

HS-130 is designed with the same parent cell line as HS-110 but is engineered to secrete OX40L-Fc fusion protein, a potent inducer of antigen-specific CD8+ T cell proliferation. The first-in-human study aims to evaluate the safety and dose-response of HS-130 in combination with HS-110 in patients with advanced solid tumors (NCT04116710).

About Heat Biologics, Inc.

Heat Biologics is a clinical-stage biopharmaceutical company developing novel therapeutics designed to activate a patient's immune system against cancer using CD8+ "Killer" T-cells. Pelican Therapeutics, Inc., 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. 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, expectation, and assumptions and include statements regarding the expected enrollment of up to 30 patients in the first in human study, the sharing of clinical proof of concept data to enable the development of a new generation of allogeneic therapy drug candidates in 2020 . 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 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 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 for the year ended December 31, 2018 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.

Reference

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Media and Investor Relations Contact

David Waldman
+1 919 289 4017
investorrelations@heatbio.com

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