March 19, 2014

Heat Biologics, Inc. Submits Revised Protocol to FDA for Phase 2 Clinical Study of HS-110 for the Treatment of Non-Small Cell Lung Cancer

Revised Protocol Specifically Designed to Mimic Expected Future Combinations With Checkpoint Inhibitors in Preparation of Next Generation of Oncology Treatment

Company to Host Live Conference Call and Webcast With Investment Community on Thursday, March 20 at 11:00 a.m. ET to Discuss HS-110 Trial Design and Outcome Goals

CHAPEL HILL, NC -- (Marketwired) -- 03/19/14 -- ***Heat Biologics, Inc.*** (NASDAQ: HTBX), a clinical stage biopharmaceutical company focused on the development of novel cancer immunotherapies, announced today that the Company has submitted its revised Phase 2 clinical trial protocol for its HS-110 product candidate to the U.S. Food and Drug Administration for the treatment of patients with non-small cell lung cancer (NSCLC). HS-110 is Heat's first product candidate in a series of its proprietary Immune Pan Antigen Cytotoxic Therapy ("*ImPACT*") based allogeneic cell lines designed to direct killer T cells to attack cancer. HS-110 utilizes genetically modified lung cancer cells to stimulate a patient's immune system to activate a robust cytotoxic T cell response against a wide array of lung cancer antigens. The Company also announced that it will host a live conference call and webcast with the investment community on March 20, 2014 at 11:00 a.m. ET to discuss this revised trial.

Heat's Phase 2 NSCLC clinical trial is a multicenter, randomized study of approximately 120 patients expected to be enrolled in 20-30 clinical trial centers. This Phase 2 study in the 3rd line setting will evaluate multiple efficacy endpoints including overall survival and response rates as well as immune response to HS-110 in combination with low dose cyclophosphamide versus chemotherapy alone. The addition of low dose cyclophosphamide as an immune stimulator allows Heat to simulate the response to HS-110 that might occur if it is combined with other novel immune checkpoint inhibitors. The Company's lead investigator for this Phase 2 study is Roger B. Cohen, M.D., Professor of Medicine at the University of Pennsylvania and Associate Director for Clinical Research for the Abramson Cancer Center. Dr. Cohen played a critical role in the design and development of this Phase 2 protocol. He is an active investigator on a number of clinical trials with research interests that focus on evaluation of novel therapies, including monoclonal antibodies, immune therapies, and small molecule cell-signaling pathway inhibitors. He primarily sees patients

with lung and head and neck cancer.

"With the latest groundbreaking advancements being made in studying immune checkpoint inhibitors for treating cancer, it is clear where oncology treatment is heading," said Justin Stebbing, M.D., Ph.D., Heat's Clinical Advisory Board Chairman and Chief Medical Advisor. "We specifically designed Heat's NSCLC Phase 2 trial to continue our exploration of the potential of HS-110 therapeutic vaccine and to expand its utility for future combination regimens with checkpoint inhibitors as they come to the market."

Melissa Price, Ph.D., Heat's Vice President of Clinical and Regulatory Affairs, commented, "In addition to evaluating the combination of HS-110 with low-dose cyclophosphamide, in this Phase 2 trial we plan to evaluate the potential of this novel immune therapy to sensitize patient tumors to subsequent chemotherapy treatments. We will also obtain pre- and post-treatment biopsy specimens in order to correlate tumor infiltrating lymphocytes and T-cell receptor sequencing with patient outcomes, which we believe will lead to proof of concept and allow greater precision in patient selection for this therapy."

"There have been some advances in late stage lung cancer treatment options in the last several years but NSCLC remains the most common of all lethal cancers, with approximately 228,000 cases reported in 2013 in the U.S and approximately 160,000 deaths," said Jeff Wolf, Chief Executive Officer of Heat. "Heat's allogeneic, off-the-shelf HS-110 vaccine therapy has the potential to improve the lung cancer treatment landscape and address an unmet need by offering patients access to investigational agents in the 3rd-line setting where there are currently very few approved options."

Heat expects to begin patient enrollment and dosing of the Phase 2 NSCLC study in the third quarter of 2014.

Conference Call and Webcast Instructions
Heat's management team and its Clinical Advisory Board Chair and Chief Medical Advisor, Justin Stebbing, M.D., Ph.D., will host a conference call and live audio webcast on Thursday, March 20, 2014 at 11:00 a.m. ET.

Interested participants and investors may access this conference call by dialing 877-407-2985 (U.S./Canada) or 201-378-4915 (international).

A live audio webcast can also be accessed via the Investors section of the Heat Biologics' corporate web site at http://www.heatbio.com, and will be archived for 30 days. Web participants are encouraged to go to the web site 15 minutes prior to the start of the call to register, download and install any necessary software.

A replay of the conference call will be available until April 3, 2014. To access the replay, interested parties may dial 877-660-6853 (U.S./Canada) or 201-612-7415 (International); Conference ID: 13578188.

About Heat Biologics, Inc.
Heat Biologics, Inc. is a clinical-stage biopharmaceutical company focused on developing its novel, "off-the-shelf" *ImPACT* therapeutic vaccines to combat a wide range of cancers. Our *ImPACT* Therapy is designed to deliver live, genetically-modified, irradiated human cells which are reprogrammed to "pump out" a broad spectrum of cancer-associated antigens

together with a potent immune adjuvant called "gp96" to educate and activate a cancer patient's immune system to recognize and kill cancerous cells. Heat will be entering Phase 2 trials with its HS-110 against non-small cell lung cancer and is conducting Phase 1/2 clinical trials with its HS-410 against bladder cancer. For more information, please visit www.heatbio.com.

Forward Looking Statements

This press release includes forward-looking statements 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 regarding the potential for Heat's *ImPACT* Therapy and the expected trial results. These statements are subject to a number of risks and uncertainties, many of which are difficult to predict, including the ability for Heat's *ImPACT* Therapy to perform as designed and the results of the Phase 2 clinical trial. The information in this release is provided only as of the date of this release, and we undertake 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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