

# Heat Biologics Successfully Completes Manufacturing of HS-410 to Start Phase 1/2 Bladder Cancer Trial

## Company Remains on Track to Commence Patient Enrollment in Phase 1/2 Trial Before Year End

CHAPEL HILL, NC -- (Marketwired) -- 11/25/13 -- Heat Biologics, Inc. ("Heat Biologics," "Heat") (NASDAQ: HTBX), a clinical stage biopharmaceutical company focused on the development of novel cancer immunotherapies, announced today that the Company has successfully completed the manufacture of the first GMP-grade batch of its HS-410 investigational drug, a fully-allogeneic, "off-the-shelf" live-cell cancer immunotherapy, for its planned Phase 1/2 bladder cancer trial. Heat remains on track to commence patient enrollment before year-end.

Heat Biologics' allogeneic approach means that its live cell-based vaccines can be mass-produced and stockpiled for use on all patients, even before patients are identified and enrolled. Heat's drug is capable of being produced and administered at a fraction of the cost of autologous or "personalized" therapies. Unlike the current autologous cancer immunotherapies, Heat Biologics' proprietary, patented technology requires no invasive procedures to remove and re-deliver tumor or immune cells and therefore there are far fewer logistical hurdles in its production and delivery.

"The successful manufacture and delivery of our first clinical trial-grade drug for use in our upcoming Phase 1/2 bladder cancer study represents an important milestone for Heat and we believe clearly demonstrates the efficiency and effectiveness of our manufacturing efforts," said Jeff Wolf, CEO of Heat Biologics. "This is especially exciting as it showcases a true differentiation of Heat's proprietary technology and manufacturing platform."

Heat's proprietary Immune Pan Antigen Cytotoxic Therapy ("ImPACT") reprograms live cancer cells from a single tumor source to continually secrete gp96, a chaperone protein found in all human cells. In turn, gp96 chaperones tumor antigens to T-cells, which is designed to activate a robust, pan-antigen T-cell immune response and direct killer T-cells to attack the patient's cancer. Heat's "ImPACT" technology holds promise for treating a wide variety of different cancers.

According to the American Cancer Society, in 2012, there were 73,000 new cases of bladder cancer reported and 15,000 deaths from the disease in the U.S. alone. More than 500,000 people in the U.S. have been treated for bladder cancer. Importantly, the FDA has not approved any new drugs to treat bladder cancer in more than 25 years. Heat's HS-410 represents a viable opportunity to address a significant unmet medical need.

*About HS-410 for the Treatment of Advanced Bladder Cancer*

HS-410 is a biologic product candidate which consists of a bladder cancer cell line that has been genetically modified using Heat's ImPACT technology platform to secrete a wide range of bladder cancer antigens bound to a gp96 adjuvant and is designed to activate a T-cell mediated pan-antigen immune response against the patient's bladder cancer.

On October 1, 2013, the Company submitted an IND to the FDA to initiate a Phase 1/2 for use of its HS-410 to prevent the recurrence of bladder cancer. The Company expects to begin enrolling patients in this study by the end of December 2013.

The Phase 1/2 trial is designed to examine safety, tolerability, immune response and preliminary clinical activity of HS-410 in patients with high risk, superficial bladder cancer who have completed surgical resection and intravesical bacillus Calmet-Guerin (BCG) immunotherapy instillations. The Company anticipates including approximately 8-10 clinical sites.

#### *About Heat Biologics, Inc.*

Heat Biologics, Inc. ([www.heatbio.com](http://www.heatbio.com)) 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's HS-110 will be entering Phase 2 trials against non-small cell lung cancer and its HS-410 will be entering Phase 1/2 clinical trials against bladder cancer.

#### *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 manufacturing efficiency and effectiveness and the potential for Heat's ImPACT Therapy. 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 Heat's ability to commence enrollment and complete clinical trials as anticipated. 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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