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Heat Biologics Commences Dosing of First Patient in Phase 1/2 Study of Novel Cancer Immunotherapy Product Candidate HS-410 for the Treatment of Bladder Cancer

CHAPEL HILL, NC -- (Marketwired) -- 03/03/14 -- [Heat Biologics, Inc.](#) (NASDAQ: HTBX), a clinical stage biopharmaceutical company focused on the development of novel cancer immunotherapies, announced today the first patient has been dosed in its Phase 1/2 bladder cancer clinical study with product candidate, [HS-410](#). HS-410 is an investigational biologic designed to activate a T-cell mediated pan-antigen immune response for the treatment of bladder cancer. Dosing for the HS-410 Phase 1/2 study was initiated by clinical investigator Lawrence Karsh, M.D., F.A.C.S., at The Urology Center of Colorado in Denver.

"We are very pleased to begin dosing bladder cancer patients with HS-410. This represents a significant milestone for our Phase 1/2 study and an exciting step forward for Heat's clinical development program," said Jeff Wolf, Chief Executive Officer of Heat.

The multi-center Phase 1/2 study will enroll approximately 93 patients and is designed to determine whether vaccination with HS-410 after transurethral resection of bladder tumor (TURBT) and bacillus Calmette-Guérin (BCG) extends the time to disease recurrence compared to placebo. The trial will also test the safety of HS-410 in bladder cancer patients.

"This year our clinical team will be focused on operational excellence as we advance our lead product candidates, HS-410 for bladder cancer and [HS-110](#) for lung cancer," commented Melissa Price, Ph.D., Heat's Vice President of Clinical and Regulatory Affairs.

"Heat's [ImPACT technology](#) holds promise for treating a wide variety of cancers," said Justin Stebbing, M.D., Ph.D., Heat's Clinical Advisory Board Chairman and chief medical advisor, "and we plan to showcase its broad utility with these two clinical studies in this new era of innovation in cancer immunotherapy drug development."

For patients and physicians interested in enrollment information for the Phase 1/2 Study of HS-410 in patients with high-risk non-muscle invasive bladder cancer after TURBT and BCG, please visit clinicaltrials.gov and use Identifier **NCT02010203**.

About Bladder Cancer

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 U.S. Food and Drug Administration 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.

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's HS-110 will be entering Phase 2 trials against non-small cell lung cancer and its HS-410 has entered Phase 1/2 clinical trials 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, the timing and success of the clinical trials. 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 within the anticipated time periods. 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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