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Heat Biologics Provides Update at Key Opinion Leader Event

-Adding Monotherapy HS-410 Arm to Current Phase 2 Bladder Cancer Study

-Agreement With Society of Urologic Oncology Clinical Trials Consortium

DURHAM, N.C., Feb. 26, 2015 (GLOBE NEWSWIRE) -- [Heat Biologics, Inc.](#) (Nasdaq:HTBX), a clinical stage biopharmaceutical company focused on the development of cancer immunotherapies, is today providing an update on its clinical program in non-muscle invasive bladder cancer (NMIBC) at a Key Opinion Leader (KOL) event being held this morning in New York.

Adding Monotherapy Arm To Ongoing Phase 2 Trial For HS-410 In The Treatment Of Non-Muscle Invasive Bladder Cancer

Heat announced it is adding a fourth monotherapy arm to its ongoing Phase 2 study evaluating HS-410 (vesigenurtacel-L) in the treatment of NMIBC. The decision was made after observing a vaccine-induced immune response in Phase 1 patients who received HS-410 after BCG (Bacillus Calmette–Guérin). Additionally, an intermittent global shortage of BCG provides an opportunity to evaluate the efficacy of single agent HS-410 in the treatment of NMIBC. The additional arm will be open-label and should not disrupt the timeline for reporting on the existing randomized portion of the trial. Heat currently anticipates enrolling and randomizing 75 patients into the first three clinical trial arms by the end of the third quarter 2015 as previously reported, and enrolling an additional 25 patients in the monotherapy arm by the end of 2015. Data from this study will aid in the design of Heat's Phase 3 study of HS-410 in NMIBC. Depending on the results observed in the Phase 2 study, the Phase 3 may be designed to study HS-410 either as an adjunct to BCG or a replacement for BCG altogether.

The Company has also procured its own supply of BCG in order to ensure it has sufficient amount to continue treating patients and maintain its clinical program on schedule and to mitigate the risk of delays in the event of continued commercial shortages.

Forms Partnership With SUO-CTC To Support Accelerated Phase 2 Trial Enrollment

The Company also announced it has engaged with the Society of Urologic Oncology Clinical Trials Consortium (SUO-CTC), a cooperative group that represents urological oncologists and related specialists from over 160 institutions and hospitals in the United States and Canada, to support the goal of accelerating its Phase 2 enrollment in NMIBC and to begin planning for the Company's Phase 3 trial. The ongoing trial is actively enrolling from SUO-CTC centers and other non-affiliated centers.

Melissa Price, Ph.D., Heat Biologics' Vice President of Clinical and Regulatory Affairs, noted,

"Our new monotherapy arm enables us to evaluate HS-410 as a single agent which may play an important role in our eventual Phase 3 design. This addition, combined with the accelerated enrollment through our collaboration with SUO-CTC, enables more rapid advancement of our clinical development strategy.

"We will be reporting on a number of critical milestones in 2015 including an analysis of the immune response of bladder and lung cancer patients and the completion of enrollment expected from our two Phase 2 trials in bladder cancer and NSCLC, all in the second half of 2015. We are enthusiastic about Heat Biologics' potential to succeed in combating these cancers through our novel therapy."

A live webcast and replay of the KOL event will be available at the "Investors" section of the Company's website at <http://ir.heatbio.com/events-presentations>.

About Heat Biologics, Inc.

Heat Biologics, Inc. (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 is conducting a Phase 2 trial of its viagenpumatulcel-L ([HS-110](#)) in patients with non-small cell lung cancer as well as a Phase 2 trial with its vesigenurtacel-L ([HS-410](#)) in patients with non-muscle invasive 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 potential for impact of Heat's *ImPACT* Therapy, the role of HS-410 as a single agent and the expected timing of enrollment. 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, the ability to timely enroll patients and the other factors described in our annual report on Form 10-K for the year ended December 31, 2013 and our other filings with the SEC. 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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