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Heat Biologics, Inc. Presents Positive Immunological Data on HS-410 in Non-Muscle Invasive Bladder Cancer at the 7th Annual Phacilitate Immunotherapy Forum 2015

Strong Immune Response in Treated Patient Supports the Mechanism of Action of ImPACT Vaccines

DURHAM, N.C., Jan. 26, 2015 (GLOBE NEWSWIRE) --**Heat Biologics, Inc.** ("Heat") (Nasdaq:HTBX), a clinical stage biopharmaceutical company focused on the development of cancer immunotherapies, today announced positive data demonstrating substantially increased tumor infiltrating lymphocytes following treatment in its Phase 1 clinical trial of HS-410 in non-muscle invasive bladder cancer (NMIBC). The data are being presented today by Taylor Schreiber, MD, PhD, the Company's Vice President of Research and Development, during the 7th Annual Phacilitate Immunotherapy Forum 2015(1), held in Washington, D.C.

Biopsies were collected at baseline and at the appearance of suspicious lesions from all patients enrolled in the Phase 1 trial. Analysis of tumor-infiltrating lymphocytes in one patient after surgery and induction BCG (*bacillus Calmette-Guerin*) followed by 6 weeks of HS-410 demonstrated an approximately 70-fold increase in CD8 expression (a marker for CD8+ killer T cells) within the tumor, which was not associated with any increase in CD4 expression (a marker for CD4+ helper T cells). When this patient returned at week 21, the trend continued and an approximate 750-fold increase in CD8 was observed, without any increase in CD4 expression. This high degree of specific immune infiltrate is consistent with Heat's preclinical findings and the known mechanism of action for its gp96-Ig based vaccines. This patient currently remains disease-free.

The increase in levels of tumor infiltrating lymphocytes appeared to correlate with the clinical response observed with HS-410. In a second patient, a non-specific immune infiltrate was noted on week 7 to be slightly increased as compared to baseline, but which consisted of both CD4+ and CD8+ T cells. This patient returned with recurrent disease at week 13, when the repeat biopsy showed no further increase in the immune infiltrate.

"HS-410 has been engineered to specifically stimulate antigen specific cytotoxic T-cells (CD8+) that have anti-tumor activity," stated Dr. Schreiber. "Observation of a highly polarized immune response in favor of CD8+ T cells in a patient where residual disease was eliminated is encouraging, supports the mechanism of action of our *ImPACT* vaccines, and may represent a treatment effect. We are still evaluating many patients from the Phase 1, and in an ongoing Phase 2 study, and are hopeful to see similar responses in many more

patients. We look forward to presenting additional data from this trial in the future."

The Phase 1 trial enrolled patients who have had Ta, T1, or Tis NMIBC (tumor removed). For the open-label Phase 1 trial to assess safety and tolerability, 10 patients received 5-6 weekly doses of BCG before HS-410 administration. After BCG treatment, patients received a low dose of HS-410. Patients were given 12 weekly injections followed by 3 monthly injections. HS-410 was well-tolerated with no serious adverse events, allowing Heat to initiate its current Phase 2 trial. An interim analysis of the 10 patients in Phase 1 is expected in the first half of 2015.

About Bladder Cancer and HS-410

According to the American Cancer Society, bladder cancer is the fifth most common cancer in the US with approximately 75,000 new cases in 2014 and 16,000 deaths. About 75% of the newly diagnosed patients have NMIBC. A key issue for bladder cancer is the high rate of recurrence, for which limited treatment options are available beyond complete bladder removal. Heat Biologics is examining candidate HS-410 in conjunction with standard treatment to stimulate the immune system and eliminate remaining cancer cells to prevent recurrence. The Company completed enrollment in a Phase 1 study and is expected to release interim data on 9 patients in the first half of 2015. A Phase 2 clinical trial is ongoing with a primary endpoint of recurrence-free survival. Heat is expected to complete enrollment in the Phase 2 study in the third quarter of 2015, which would make topline data available in the second half of 2016.

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 viagenpumatucel-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 and the timing of the interim analysis. 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, Heat's ability to provide data and complete its trials when anticipated 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.

(1) These data are being presented as part of a discussion by Dr. Schreiber on the ongoing Phase II trial of HS-110 in combination with low-dose Metronomic Cyclophosphamide in late stage NSCLC.

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