October 8, 2015

Heat Biologics Completes Patient Enrollment for Randomized Arms of Its Phase 2 HS-410 Bladder Cancer Trial

- *Topline efficacy, immune-response and safety data expected 4Q:16*
- *Monotherapy trial arm without BCG continuing enrollment*

DURHAM, N.C., Oct. 8, 2015 (GLOBE NEWSWIRE) --Heat Biologics, Inc. ("Heat") (Nasdaq:HTBX), a clinical-stage cancer immunotherapy company, announced that it has completed enrollment of the full 75 patients in the blinded, randomized, placebo-controlled arms of the Phase 2 clinical trial of HS-410 (vesigenurtacel-L) for the treatment of high-risk, non-muscle invasive bladder cancer (NMIBC). In these three arms of the Phase 2 trial, Heat is evaluating the ability of HS-410 in combination with standard of care, Bacillus Calmette-Guerin (BCG), to stimulate the immune system and eliminate remaining cancer cells to prevent recurrence. The primary endpoint for the Phase 2 trial is one-year disease free survival. As previously announced, Heat is enrolling an additional 25 patients to evaluate HS-410 as a monotherapy in an unblinded, open-label arm, which the company expects to complete by late 2015/early 2016.

"This enrollment of the 75 randomized patients represents a significant milestone for the company and we continue to remain on track to report topline efficacy, immune-response and safety results in the fourth quarter of 2016," said Melissa Price, Ph.D., Vice President of Product Development, Heat Biologics. "These data will help guide the trial design, including patient selection and biomarker strategy, for our registration-directed trial as we move forward in our commitment to address the unmet needs of patients living with bladder cancer."

HS-410 is an investigational product candidate for NMIBC based on Heat's proprietary *ImPACT*™ immunotherapy platform that is designed to generate killer T cells to attack cancers.[i] In March 2015, Heat received U.S. FDA Fast Track Designation for HS-410 for the treatment of NMIBC, which is designed to facilitate the development and expedite the review of potential therapies.

Furthermore, Heat expects to report one-year safety and immune-response data from its Phase 1 trial evaluating HS-410 in patients with NMIBC by the end of 2015.

About Bladder Cancer

According to the American Cancer Society, bladder cancer is the fifth most common cancer

in the U.S. with approximately 75,000 new cases and 16,000 deaths in 2015. 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.

About Heat Biologics, Inc.

Heat Biologics is a clinical-stage biopharmaceutical company focused on developing its novel, "off-the-shelf" *ImPACT*™ and *ComPACT* therapeutic vaccines to combat a wide range of cancers. Our therapies are 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 with HS-410 (vesigenurtacel-L) in patients with non-muscle invasive bladder cancer, as well as a Phase 1b trial of HS-110 (viagenpumatucel-L) in combination with a PD-1 checkpoint inhibitor to treat patients with non-small cell lung cancer. For more information please visit the company's website at 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 expected completion date of enrollment for the additional 25 patients, the timing of the reporting of topline efficacy, immune-response and safety results, the expected timing of the one-year safety and immune-response data from the Phase 1 trial evaluating HS-410 and the potential of Heat's *ImPACT* and *ComPACT* therapy. These statements are subject to a number of risks and uncertainties, many of which are difficult to predict, including the ability of Heat's *ImPACT* and *ComPACT* therapies to perform as designed, the ability to enroll patients and complete the clinical trials on time, the other factors described in our annual report on Form 10-K for the year ended December 31, 2014 and Heat's 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.

[i] *ImPACT* is a registered trademark of Heat Biologics, Inc.

CONTACT: Heat Biologics, Inc.
Jennifer Almond
Investor and Media Relations
919-240-7133
investorrelations@heatbio.com

Source: Heat Biologics