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Heat Biologics, Inc. Commences Patient Dosing of Phase 2 Clinical Study of Vesigenurtacel-L for the Treatment of Bladder Cancer

DURHAM, N.C., Oct. 27, 2014 (GLOBE NEWSWIRE) --**Heat Biologics, Inc.** (Nasdaq:HTBX), a clinical stage biopharmaceutical company focused on the development of cancer immunotherapies, announced today that it has initiated patient dosing in its Phase 2 clinical trial of vesigenurtacel-L (HS-410) in subjects with high-risk, non-muscle invasive bladder cancer. Vesigenurtacel-L is Heat's investigational drug in a series of proprietary Immune Pan Antigen Cytotoxic Therapy ("*ImPACT*") based allogeneic cell lines designed to direct killer T cells to attack cancer. The primary endpoint for the Phase 2 portion of the bladder cancer study is one-year disease-free survival.

The multi-center Phase 2 portion of Heat's bladder cancer study is designed to determine whether vaccination with one of two doses of vesigenurtacel-L in combination with Bacillus Calmette-Guérin (BCG) after transurethral resection of bladder tumor (TURBT) increases disease-free survival at one year compared to BCG in combination with placebo. The blinded, randomized placebo-controlled study will enroll approximately 75 patients. Heat expects to complete patient enrollment of the Phase 2 study in the third quarter of 2015 and report topline results in third quarter of 2016.

"We have made substantial progress executing on our clinical strategy over the course of the year, specifically advancing our two lead product candidates for lung and bladder cancers into Phase 2 development," said Jeff Wolf, Chief Executive Officer of Heat Biologics. "The start of patient dosing of vesigenurtacel-L for bladder cancer, a full quarter ahead of schedule, is a major milestone for Heat and a clear example of the team's commitment to operational excellence."

Mr. Wolf concluded, "By accelerating the bladder cancer program into Phase 2, we are now well positioned to provide the disease-free survival data ahead of schedule and are another step closer to fulfilling a true unmet need for bladder cancer patients with the potential of providing a new, viable and effective treatment."

Patient enrollment and dosing in the vesigenurtacel-L Phase 2 study for the treatment of bladder cancer is expected to be completed in the third quarter of 2015. The Company anticipates reporting top-line results in the third quarter of 2016 after the study's twelve-month patient observation period concludes.

For patients and physicians interested in enrollment information for the Phase 2 portion of the study of vesigenurtacel-L in patients with high-risk non-muscle invasive bladder cancer,

please visit clinicaltrials.gov and use Identifier **NCT02010203**.

About Bladder Cancer

According to the American Cancer Society, in 2014, there will be 74,690 new bladder cancer diagnoses and 15,580 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 (FDA) has not approved any new drugs to treat bladder cancer in more than 25 years. Heat's vesigenurtacel-L (HS-410) represents a viable opportunity to address a significant unmet medical need.

About Vesigenurtacel-L (HS-410)

Vesigenurtacel-L (HS-410) is an investigational biologic originating from Heat's proprietary Immune Pan Antigen Cytotoxic Therapy (*ImPACT*) based allogeneic cell lines designed to activate a T-cell mediated pan-antigen immune response for the treatment of bladder cancer. *ImPACT* Therapy 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 to activate a robust, pan-antigen T-cell immune response and direct killer T-cells to attack the patient's cancer.

About the Vesigenurtacel-L (HS-410) Phase 1/2 Study

The multi-center Phase 1/2 study will enroll approximately 84 patients with non-muscle invasive bladder cancer and is designed to determine whether vaccination with vesigenurtacel-L after transurethral resection of bladder tumor (TURBT) extends the disease-free interval compared to placebo. The trial will also test the safety and immune response of vesigenurtacel-L in bladder cancer patients.

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's viagenpumatucel-L (HS-110) is being evaluated in a Phase 2 trial in patients with non-small cell lung cancer and its vesigenurtacel-L (HS-410) is being evaluated in an ongoing Phase 1/2 clinical trial 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 expected completion date of enrollment and dosing of the Phase 2 study, the date of release of top-line results, the market size 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 ability to enroll patients as planned, 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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