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Heat Biologics Receives Green Light to Expand Enrollment of Its Phase 1/2 Study of HS-410 in Bladder Cancer Based on Encouraging Preliminary Safety Results

DURHAM, NC -- (Marketwired) -- 05/30/14 -- Heat Biologics, Inc. (NASDAQ: HTBX), a clinical stage biopharmaceutical company focused on the development of novel cancer immunotherapies, announced today that its Dose Escalation Committee has approved the expansion of the first cohort to full enrollment in its ongoing Phase 1/2 study of HS-410 (Vesigenpumatucel-L) for the treatment of bladder cancer. The Committee unanimously agreed to expand the cohort to the full nine patients without delay.

The decision was based on pre-specified protocol criteria and was made after the initial three patients were dosed with Heat Biologic's off-the-shelf product candidate designed to activate a T-cell mediated pan-antigen immune response for the treatment of non-muscle invasive bladder cancer.

There were no serious adverse events reported in the initial three patients, and all non-serious adverse events and injection site reactions reported were Grade 1.

"We are delighted about the early reports of the safety of HS-410," said Jeff Wolf, CEO of Heat. "This early data appears to be consistent with the data from our successful Phase 1 lung cancer trial with our product candidate HS-110 (Viagenpumatucel-L) based on the same *ImPACT* platform."

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

Heat's proprietary Immune Pan Antigen Cytotoxic Therapy ("*ImPACT*") 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. Heat's *ImPACT* technology holds promise for treating a wide variety of different cancers.

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 "FDA" has not approved any new drugs to treat bladder cancer in more than 25 years. Heat's HS-410 (Vesigenpumatucel-L) represents a viable opportunity to address a significant unmet medical need.

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) will be entering Phase 2 trials against non-small cell lung cancer and its Vesigenpumatucel-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 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. 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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