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Heat Biologics Announces Initiation of Phase 1b Trial of Viagenpumatucel-L (HS-110) in Non-Small Cell Lung Cancer (NSCLC)

Trial Will Explore Combination of HS-110 With Various Immune Checkpoint Agents

DURHAM, N.C., May 11, 2015 (GLOBE NEWSWIRE) -- In a release issued under the same headline earlier today by Heat Biologics (Nasdaq:HTBX), please note that the first paragraph has been updated regarding the enrollment for the trial.

The corrected release follows:

DURHAM, N.C., May 11, 2015 (GLOBE NEWSWIRE) --**Heat Biologics, Inc.** ("Heat Biologics", "Heat" or the "Company") (Nasdaq:HTBX), a clinical stage cancer immunotherapy company, announced today that it has initiated a new Phase 1b trial of Viagenpumatucel-L (HS-110) in non-small cell lung cancer ("NSCLC") and expects to enroll the first patient shortly. This new trial enables Heat to combine its HS-110 with multiple immune modulating strategies. HS-110 is Heat's first product candidate in a series of proprietary ImPACT drugs designed to direct killer T cells to attack cancer. Daniel Morgensztern, M.D., Associate Professor of Medicine at the Washington University Siteman Cancer Center, is Lead Investigator of this new Phase 1b trial.

Dr. Morgensztern commented, "Non-small cell lung cancer (NSCLC) is now recognized as a disease that appears susceptible to an immune therapy approach, based on the significant benefit reported with various checkpoint inhibitors. This clinical study is an opportunity for us to explore the potential synergy of HS-110 in combination with various tumor anti-immunosuppressive agents."

The multicenter Phase 1b trial will enroll patients with NSCLC who have failed one or more prior lines of therapy. The clinical study will evaluate the safety and efficacy of HS-110 in combination with multiple tumor anti-immunosuppressive agents. Immunosuppression may develop in NSCLC patients in a variety of ways, and Heat's trial is designed to explore use of combination approaches against multiple immunosuppression pathways. One source of immunosuppression is tumor hypoxia. A general characteristic of NSCLC is a hypoxic tumor microenvironment which leads to production of adenosine, a highly immunosuppressive molecule for T cells when binding to the A2A receptor. Another source of tumor immunosuppression is expression of PD-L1 within the tumor microenvironment, which may also be regulated by tumor hypoxia. The first 3 combinations to be studied are based on exciting preclinical data which demonstrates that reduction of tumor adenosine is highly

synergistic with Heat's ImPACT vaccines. Future cohorts are expected to include combinations with checkpoint inhibitors and T-cell co-stimulators.

"We continue to expand our clinical knowledge of combination dosing with HS-110. This Phase 1b design framework will allow us to efficiently test HS-110 with multiple combination agents enabling us to continue to deliver combinations at the forefront of immunotherapy," said Jeff Wolf, Chief Executive Officer of Heat. "This single clinical protocol should enable us to efficiently evaluate many immunotherapy combinations to determine which combinations offer greatest benefit to patients with NSCLC."

The trial should enable Heat to compare and correlate multiple experimental endpoints with patient outcomes, with the goal of identifying the patients most likely to benefit from these combinations and selecting the most promising combinations to advance into randomized controlled trials.

About Viagenpumatucel-L (HS-110)

Viagenpumatucel-L (HS-110) ImPACT-modified cell lines are designed to stimulate a patient's immune system to activate a cytotoxic T cell response against a range of antigens that are known to be expressed by a high proportion of patients with NSCLC. The backbone cell line for HS-110 was selected based on antigenic overlap with patient tumor specimens, including known and unknown antigens. This approach is expected to provide a significant advantage over single antigen approaches by reducing the risk of antigen-loss variants emerging post-treatment and by addressing the underlying genetic and antigenic heterogeneity within tumors. Heat Biologics is in Phase 2 clinical trials using HS-110 for the treatment of NSCLC. For more information reference study protocol NCT02439450 on clinicaltrials.gov.

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 successful execution of Heat's business strategy, including with respect to Heat's clinical trials potential for impact of Heat's *ImPACT*™ Therapy, the advantage of Heat's approach, and the continued expansion of clinical knowledge. 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 complete the clinical trial on time, the other factors described in our annual report on Form 10-K for the year ended December 31, 2014 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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