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# Heat Biologics Presents Positive Preclinical Data on a Novel Approach to Combination Immunotherapy at the Keystone Symposia on Tumor Immunology

## Data Demonstrate Strategy for Vaccine and Co-Stimulation in a Single Cell-Based Product

DURHAM, N.C., Feb. 11, 2015 (GLOBE NEWSWIRE) --**Heat Biologics, Inc.** (Nasdaq:HTBX), a clinical stage biopharmaceutical company focused on the development of cancer immunotherapies, announced today the presentation of data demonstrating the incorporation of T-cell costimulatory fusion proteins into Heat's gp96-Ig vaccine platform, at a Keystone Symposia on "Tumor Immunology -- Multidisciplinary Science Driving Combination Therapy," which is being held in Banff, Canada. The study is part of ongoing development work at Heat to introduce a novel combination immunotherapy product simultaneously expressing its gp96-Ig vaccine and individual T-cell costimulatory fusion proteins.

"We are very excited about the prospects of our second generation vaccine construct, which incorporates a T-cell co-stimulatory fusion protein into the gp96-Ig vaccine," stated Taylor Schreiber, MD, Ph.D., Vice President of Research and Development, Heat Biologics, who is presenting these data today. "This construct may provide the benefit of combination immunotherapy without the risks of systemic toxicity observed with antibodies or the cost considerations of combining multiple independent products."

Presented data demonstrate unique synergy between gp96-Ig vaccination and OX40L-Fc fusion protein agonists. It has been previously established that secretable heat-shock protein gp96-Ig based allogeneic cellular vaccines achieve high-frequency polyclonal CD8+ T-cell responses to tumor antigens through antigen cross-priming *in vivo*. However, established tumors can evolve multiple immunosuppressive mechanisms that can reduce the activity of this vaccine approach; a potential solution to this would be development of combination immunotherapy approaches for patients with advanced disease.

The investigators in the study re-engineered the gp96-Ig plasmid to simultaneously co-express ICOSL-Ig, 4-1BBL-Ig or OX40L-Ig, thus providing co-stimulatory benefit without the need for additional antibody therapy. Several constructs were engineered so that the relative contribution of ICOSL-Ig, 4-1BBL-Ig and OX40L-Ig could all be systematically compared. The findings show that the co-secretion of gp96-Ig and OX40L-Ig provided the greatest benefit for enhanced activation of antigen-specific CD8+ T-cells. Thus, combination immunotherapy can be achieved by vector re-engineering, eliminating the need for separate

vaccine/antibody/fusion protein treatment and importantly, may reduce both total cost of therapy and the risk of systemic toxicity. Heat's George Fromm, Ph.D., Neal Schilling, Ph.D., Aditi Goyal and Taylor H. Schreiber, MD, Ph.D. conducted the study.

**About Keystone Symposia on Molecular and Cellular Biology**

Keystone Symposia on Molecular and Cellular Biology is a nonprofit organization that convenes open, peer-reviewed conferences across a broad range of the life sciences. New knowledge in the field of cancer immunotherapy, combined with new technologies, has given birth to the next generation of vaccines, adoptive cellular therapies and T-cell modulating agents, all of which are being investigated in preclinical models and patients. This meeting *"Tumor Immunology - Multidisciplinary Science Driving Combination Therapy"*brings together experts from academia and industry who are pioneers in these areas, and showcases the rapid translation of this increasingly complex knowledge into clinical applications. For more information, please go to http://www.keystonesymposia.org/15J7.

**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 benefits of Heat's second generation vaccine construct. 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 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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