Heat Biologics, Inc. Receives US FDA Fast Track Designation for HS-410 (Vesigenurtacel L) in Combination With BCG for the Treatment of Non-Muscle Invasive Bladder Cancer

-- Designation Expected to Expedite Development of Cutting-Edge Cancer Immunotherapy--

DURHAM, N.C., March 9, 2015 (GLOBE NEWSWIRE) -- Heat Biologics, Inc. ("Heat") (Nasdaq:HTBX), a clinical stage biopharmaceutical company focused on the development of cancer immunotherapies, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for HS-410 (vesigenurtacel-L) for the treatment of non-muscle invasive bladder cancer (NMIBC). HS-410 is Heat's NMIBC product candidate and is based on its cutting-edge Immune Pan Antigen Cytotoxic Therapy ("ImPACT") platform that is designed to generate killer T cells to attack cancers. HS-410 is currently being evaluated in a randomized Phase 2 trial in combination with BCG and as monotherapy for the treatment of NMIBC.

"We are very pleased that FDA has granted this important designation for HS-410," said Melissa Price, Ph.D., Heat's Vice President of Clinical Development and Regulatory Affairs. "The decision underscores the unmet need for bladder cancer treatments and serves as an additional validation for our clinical program. Currently there are limited therapeutic treatment options available for this patient population, with no new treatments approved in this setting in over 30 years."

About FDA Fast Track Designation

The FDA established the Fast Track Drug Development Program under the FDA Modernization Act of 1997. The program is designed to facilitate the development and expedite the review of therapies intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. The advantages of Fast Track designation include actions to expedite development, including opportunities for frequent interactions with the FDA review team to discuss all aspects of development to support approval and eligibility for priority review depending on clinical data at the time of Biologics License Application (BLA) submission.

About Bladder Cancer and HS-410

According to the American Cancer Society, bladder cancer is the fifth most common cancer in the US with approximately 75,000 new cases in 2014 and 16,000 deaths. 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. Heat Biologics is examining candidate HS-410 in conjunction with standard treatment to stimulate the immune system and eliminate remaining cancer cells to prevent recurrence. The Company completed enrollment in a Phase 1 study and is expected to release interim data on 10 patients in the first half of 2015. A Phase 2 clinical trial is ongoing with a primary endpoint of recurrence-free survival. Heat is expected to complete enrollment in the Phase 2 study in the third quarter of 2015, which would make topline data available in the second half of 2016.

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. OurImPACT 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 for impact of Heat's ImPACT Therapy, the effect of the FAST Track designation on the development of HS-410, the expected timing of the data release for the Phase 1 study and Phase 2 study and the timing of enrollment completion for the Phase 2 study of data. 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 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.

CONTACT: Heat Biologics, Inc. Contact Information:
Jeff Wolf
Chief Executive Officer
(919) 240-7133
investorrelations@heatbio.com

Investor Relations and Media Inquiries:
Michael Wood
LifeSci Advisors LLC
(646) 597-6983
mwood@lifesciadvisors.com

Source: Heat Biologics