

September 2, 2020



Heat Biologics Issued Key Patent on Combination Platform Therapy

Superior pre-clinical activity compared to conventional costimulatory antibody combination administered systemically

DURHAM, NC / ACCESSWIRE / September 2, 2020 /Heat Biologics, Inc. ("Heat") (NASDAQ:HTBX), a clinical-stage biopharmaceutical company focused on developing first-in-class therapies to modulate the immune system, including multiple oncology product candidates and a novel COVID-19 vaccine, today announced it has been issued a patent (US Patent No. 10,758,611) by the U.S. Patent and Trademark Office (USPTO) covering compositions of matter that are part of Heat's gp96 platform in combination with a T cell costimulatory agonist in a single therapy. This newly issued US patent compliments Heat's growing patent estate on this platform technology, which also includes US Patent No. 10,046,047, with claims to compositions of matter covering Heat's gp96 platform in combination with OX40L, a T cell costimulatory agonist.

Pre-clinical studies combining Heat's secreted gp96 plus OX40L T cell co-stimulator in a single therapy, administered locally, have demonstrated superior activity in preclinical studies compared to gp96 in combination with conventional OX40 antibody administered systemically by IV infusion. Additional potential advantages of this novel combination approach include enhanced memory T cell response, limited systemic toxicity and cost advantages compared to multiple systemic therapies.

Jeff Wolf, Chief Executive Officer of Heat, commented, "This newly issued patent represents a potential breakthrough in combination drug development. Current combination approaches under development hold significant promise but also face meaningful challenges such as systemic toxicity and a lack of measurable synergistic effect. In contrast, we have developed a unique approach, combining the strengths of our gp96 platform (including antigen presentation, T cell activation, and TLR activation) with an immune booster (providing, for instance, localized T cell co-stimulation) in a single therapy. We believe this combination therapy holds enormous promise in the treatment of cancer and infectious diseases, potentially including COVID-19."

"Specifically, our preclinical studies have demonstrated more pronounced CD8+ T cell prime and memory response; increased antigen specificity; no off-target systemic inflammatory cytokines; greater anti-tumor immunity; and increased overall survival. Our Phase 1 trials with gp96 (HS-110) in combination with OX40L (HS-130) and checkpoint inhibition are now underway, and we look forward to providing further clinical updates."

About Heat Biologics, Inc.

Heat Biologics is a biopharmaceutical company focused on developing first-in-class

therapies to modulate the immune system. The company's gp96 platform is designed to activate immune responses against cancer or pathogenic antigens. The Company has multiple product candidates in development leveraging the gp96 platform, including HS-110, which has completed enrollment in its Phase 2 trial, HS-130 in Phase 1, and a COVID-19 vaccine program in preclinical development. In addition, Heat is also developing a pipeline of proprietary immunomodulatory antibodies, including PTX-35 which is enrolling in a Phase 1 trial.

For more information, please visit: www.heatbio.com, and also follow us on [Twitter](#).

Forward Looking Statement

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 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, expectation, and assumptions and include statements such as the potential advantages of this novel combination approach including enhanced memory T cell response, limited systemic toxicity and cost advantages compared to multiple systemic therapies, the new patent representing a potential breakthrough in combination drug development, and the combination therapy holding enormous promise in the treatment of cancer and infectious diseases, potentially including COVID-19. These statements are subject to a number of risks and uncertainties, many of which are difficult to predict, including the ability of the novel combination to enhance memory T cell response, limit systemic toxicity and have cost advantages compared to multiple systemic therapies, the ability to use the combination therapy to treat cancer and infectious diseases, potentially including COVID-19, the ability of Heat's therapies to perform as designed, to demonstrate safety and efficacy, as well as results that are consistent with prior results, the ability to enroll patients and complete the clinical trials on time and achieve desired results and benefits, especially in light of COVID-19, Heat's ability to obtain regulatory approvals for commercialization of product candidates or to comply with ongoing regulatory requirements, regulatory limitations relating to Heat's ability to promote or commercialize its product candidates for specific indications, acceptance of its product candidates in the marketplace and the successful development, marketing or sale of products, Heat's ability to maintain its license agreements, the continued maintenance and growth of its patent estate, its ability to establish and maintain collaborations, its ability to obtain or maintain the capital or grants necessary to fund its research and development activities, its ability to continue to maintain its listing on the Nasdaq Capital Market and its ability to retain its key scientists or management personnel, and the other factors described in Heat's most recent annual report on Form 10-K filed with the SEC, and other subsequent filings with the SEC. The information in this release is provided only as of the date of this release, and Heat undertakes 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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