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Heat Biologics Unveils Enhanced Allogeneic Cell Manufacturing Process

New 3-D process designed to increase yield and improve operating efficiency for rapid and scalable manufacturing of HS-110, gp-96 based cell therapies and other cellular products

DURHAM, N.C., March 25, 2022 (GLOBE NEWSWIRE) -- **Heat Biologics, Inc. ("Heat") (NYSE American: HTBX)**, a clinical-stage biopharmaceutical company focused on developing novel biodefense assets and first-in-class therapies to modulate the immune system, today unveiled enhanced allogeneic cell therapy manufacturing capabilities through its Scorpion Biological Services subsidiary.

Jeff Wolf, Chief Executive Officer of Heat, commented, "We are excited to rollout our new 3-D allogeneic cell manufacturing capabilities to replace our current 2-D HS-110 manufacturing. This new process is designed to increase yield, improve operating efficiency, as well as provide both a rapid and scalable solution to support Phase 3 trials and commercialization. We plan to implement these processes for the manufacturing of our own therapies, including HS-110, as well as provide these services to other biopharma companies on a fee-for-service basis through our Scorpion subsidiary. One of the greatest challenges to broad adoption of cell therapies has been the time and cost of production. We believe these capabilities will help position Scorpion as a leading contract development and manufacturing organization (CDMO), as we advance our mission to become a fully-integrated biopharmaceutical company."

Wolf continued, "We are incorporating these manufacturing changes into our clinical and commercial plans for HS-110 and plan to discuss these changes with the FDA during our Type C meeting scheduled for next quarter. We have received positive industry feedback on our new 3-D process, as well as the clinical results of our Phase 2 trial of HS-110, and plan to accelerate discussions with potential partners following our FDA interaction. We then plan to resubmit a Type B meeting request, including clinical setting and selection of the checkpoint inhibitor to be used in combination with HS-110, in collaboration with a potential partner."

About Heat Biologics, Inc.
Heat Biologics is a biopharmaceutical company focused on developing first-in-class therapies and vaccines to modulate the immune system. Heat's gp96 platform is designed to activate immune responses against cancer or infectious diseases. The Company has multiple product candidates in development leveraging the gp96 platform, including HS-110, which has completed enrollment in a Phase 2 trial, various infectious disease/biological threat programs in preclinical development and a pipeline of proprietary immunomodulatory antibodies and cell-based therapies, including PTX-35 and HS-130 in Phase 1 clinical trials.

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 regarding the new process increasing yield, improving operating efficiency, as well as providing both a rapid and scalable solution to support Phase 3 trials and commercialization; plans to implement processes for the manufacturing of Heat's own therapies, including HS-110, as well as provide these services to other biopharma companies on a fee-for-service basis through our Scorpion subsidiary, the capabilities helping position Scorpion as a leading contract development and manufacturing organization (CDMO), Heat's mission to become a fully-integrated biopharmaceutical company, plans to discuss manufacturing changes with the FDA during Heat's Type C meeting scheduled for next quarter, plans to accelerate discussions with potential partners following our FDA interaction and plans to resubmit a Type B ("End of Phase 2 Meeting") meeting request, including clinical setting and selection of the checkpoint inhibitor to be used in combination with HS-110, in collaboration with a potential partner. These statements are subject to a number of risks and uncertainties, many of which are difficult to predict, including Heat's ability to become a fully-integrated biopharmaceutical company and offer manufacturing capabilities to other biopharma companies and utilize them for Heat's own therapies, the ability to meet with the FDA as planned, Heat's ability to increase yield, improve operating efficiency, as well as provide both a rapid and scalable solution to support Phase 3 trials and commercialization; the ability to Heat's ability to successfully consummate the merger of Elusys, Heat's ability to provide further near-term updates on its biodefense efforts, execute on key upcoming milestones and drive shareholder value, Heat's ability to augment its clinical programs and enhance and expand its therapeutic pipeline, 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, 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 and its cash and short-term investments providing significant runway to fund Heat's current clinical programs and further expand Heat's therapeutic portfolio , 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 for the year ended December 31, 2021 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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Source: Heat Biologics