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Heat Biologics (“NightHawk Biosciences”) Completes Acquisition of Elusys Therapeutics

Elusys becomes wholly-owned biodefense subsidiary of NightHawk

Plans to expand ANTHIM® distribution abroad

DURHAM, N.C., April 20, 2022 (GLOBE NEWSWIRE) -- **Heat Biologics, Inc. (NYSE American: HTBX)** (to be renamed “NightHawk Biosciences”), a fully-integrated biopharmaceutical company focused on developing first-in-class therapies to modulate the immune system, today announced it has completed the acquisition of Elusys Therapeutics, Inc. a commercial-stage biodefense company and developer of ANTHIM® (obiltoximab), a treatment for inhalation anthrax. ANTHIM® is approved for use in the U.S. and Canada, and under the brand name Obiltoximab SFL in Europe and the United Kingdom.

Nighthawk acquired all outstanding shares of Elusys, which will continue to operate as a wholly-owned subsidiary of NightHawk. No stock or warrants were issued in connection with the acquisition, and Elusys had no outstanding term debt.

The strategic acquisition of Elusys significantly expands the Company’s role in the biodefense space, complementing NightHawk’s RapidVax® platform, which is designed to target emerging biological threats. Pursuant to this acquisition, NightHawk also announced it plans to migrate manufacturing of ANTHIM® to its planned 500,000 square foot Scorpion biomanufacturing facility in Manhattan, Kansas, which is being constructed to support development of commercial-scale biologics and large molecules.

To date, Elusys has been awarded over \$350 million in research and development grants, contracts and procurement orders from the Biomedical Advanced Research and Development Authority (BARDA) and the U. S. Strategic National Stockpile (SNS). Through ongoing, multi-year partnerships with the U.S. government, Elusys has been supplying ANTHIM® to the SNS - the government’s repository of critical medical supplies for biodefense preparedness.

Jeff Wolf, CEO of NightHawk, commented, “We are excited to announce the closing of this transformative acquisition, which provides us with a solid foothold in the biodefense space. Elusys has an established a successful track record collaborating with U.S. government agencies including BARDA, NIH, SNS and DOD. We plan to leverage Elusys’ existing relationships and distribution channels as a launching pad for RapidVax®, our “plug and

play” platform designed for rapid development and delivery of new vaccines. In addition, we look forward to leveraging our new Kansas facility, which will enable us to manufacture these therapies internally and therefore benefit from significant operating synergies, as well as enhanced oversight, quality control, and speed to market. We are also exploring opportunities to expand ANTHIM® distribution abroad. This transaction is perfectly aligned with our overall vision to establish a fully-integrated ecosystem to deliver medical innovations faster, better, and more efficiently.”

David Lasseter, former Deputy Assistant Secretary of Defense for Countering Weapons of Mass Destruction, and a member of NightHawk’s Biothreat Advisory Board, commented, “This transaction is extremely timely, given the global uncertainty and unprecedented threats from foreign nations and rogue actors. Anthrax is one of the most significant biological warfare threats facing our country, with real potential for mass casualties. ANTHIM® represents a key medical countermeasure for the treatment of inhalation Anthrax.”

A special committee of Heat’s Board of Directors negotiated and approved the transaction and Cassel Salpeter & Co. provided a fairness opinion in connection with the transaction. Blank Rome LLP acted as legal counsel to Heat. Elusys was advised by RBC Capital Markets, LLC. Additional details on the transaction are outlined in Company’s Form 8-K, which will be filed with the Securities and Exchange Commission and will be available on the Company’s website.

About ANTHIM

Anthrax is a life-threatening infectious disease caused by *Bacillus anthracis*. Cases of inhalational anthrax in humans can occur through intentional spread of *B. anthracis* spores as a biowarfare or bioterrorism agent. *B. anthracis* spores introduced through the lungs lead to inhalational anthrax, which is deadly in humans.

ANTHIM is a monoclonal antibody that binds to the protective antigen (PA) component of anthrax toxin. ANTHIM’s toxin neutralizing activity prevents entry of anthrax toxin into susceptible cells, avoiding further spread of the toxin throughout the body and the ensuing tissue damage that leads to death. ANTHIM is supplied as single-dose vials for IV infusion.

Indications and Usage

ANTHIM is indicated in adult and pediatric patients for the treatment of inhalational anthrax due to *Bacillus anthracis* in combination with appropriate antibacterial drugs, and for prophylaxis of inhalational anthrax when alternative therapies are not available or are not appropriate. ANTHIM should only be used for prophylaxis when its benefit for prevention of inhalational anthrax outweighs the risk of hypersensitivity and anaphylaxis. The effectiveness of ANTHIM is based solely on efficacy studies in animal models of inhalational anthrax. There have been no studies of the safety or pharmacokinetics (PK) of ANTHIM in the pediatric population. Dosing in pediatric patients was derived using a population PK approach. ANTHIM does not have direct antibacterial activity. ANTHIM should be used in combination with appropriate antibacterial drugs. ANTHIM is not expected to cross the blood-brain barrier and does not prevent or treat meningitis.

IMPORTANT SAFETY INFORMATION Including BOXED WARNING

WARNING: HYPERSENSITIVITY and ANAPHYLAXIS

Hypersensitivity reactions, including anaphylaxis, have been reported during ANTHIM infusion. ANTHIM should be administered in monitored settings by personnel trained and equipped to manage anaphylaxis. Stop ANTHIM infusion immediately and treat appropriately if hypersensitivity or anaphylaxis occurs.

WARNINGS AND PRECAUTIONS

Hypersensitivity and anaphylaxis have been reported during the IV infusion of ANTHIM. Due to the risk of hypersensitivity and anaphylaxis, ANTHIM should be administered in monitored settings by personnel trained and equipped to manage anaphylaxis. Monitor individuals who receive ANTHIM closely for signs and symptoms of hypersensitivity reactions throughout the infusion and for a period of time after administration. Stop ANTHIM infusion immediately and treat appropriately if hypersensitivity or anaphylaxis occurs. Pre-medication with diphenhydramine is recommended prior to administration of ANTHIM. Diphenhydramine pre-medication does not prevent anaphylaxis and may mask or delay onset of symptoms of hypersensitivity.

ADVERSE REACTIONS

The safety of ANTHIM has been studied only in healthy volunteers. It has not been studied in patients with inhalational anthrax. The most frequently reported adverse reactions were headache, pruritus, infections of the upper respiratory tract, cough, vessel puncture site bruise, infusion site swelling, urticaria, nasal congestion, infusion site pain, and pain in extremity.

USE IN SPECIFIC POPULATIONS

Pediatric Use: There have been no studies of the safety or PK of ANTHIM in the pediatric population.

To see the complete prescribing information for ANTHIM, [click here](#).

About Heat Biologics, Inc. / NightHawk Biosciences, Inc.

Heat Biologics (to become "NightHawk Biosciences") is a fully-integrated biopharmaceutical company focused on the development of new drugs from discovery through biomanufacturing. The Company leverages its integrated ecosystem of subsidiaries to accelerate the creation of novel therapies that arm the immune system, breaking through barriers that prolong traditional drug development. This empowers us to bring our ideas to life with efficient control, superior quality, and uncharacteristic agility.

For more information on the Company and its subsidiaries, please visit: www.nighthawkbio.com, and also follow us on [Twitter](#).

Forward Looking Statement

This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. 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, and include statements regarding *plans to migrate manufacturing of ANTHIM® to the planned 500,000*

square foot biomanufacturing facility in Manhattan, Kansas, plans to leverage Elusys' existing relationships and distribution channels as a launching pad for RapidVax, leveraging the new Kansas facility to enable Heat to manufacture therapies internally, expected benefit to be derived from significant operating synergies, as well as enhanced oversight, quality control, and speed to market, exploring opportunities to expand ANTHIM® distribution abroad and establishing a fully-integrated ecosystem to deliver medical innovations faster, better, and more efficiently. Important factors that could cause actual results to differ materially from current expectations include, among others, the ability to migrate manufacturing of ANTHIM® to the Manhattan, Kansas facility, the ability to expand ANTHIM® sales beyond the U.S., the ability to leverage Elusys' existing relationships and distribution channels as a launching pad for RapidVax, the ability to expand ANTHIM® distribution abroad, the ability to derive benefit from operating synergies, as well as enhanced oversight, quality control, and speed to market, the ability to establish a fully-integrated ecosystem to deliver medical innovations faster, better, and more efficiently, whether the combined business of Heat and Elusys will be successful, Heat's and Elusys' ability to maintain license agreements, the continued maintenance and growth of Heat's and Elusys' patent estate, Heat's product candidates demonstrating safety and effectiveness, as well as results that are consistent with prior results, the ability to initiate clinical trials and if initiated, the ability to complete them on time and achieve the desired results and benefits continuing enrollment as expected, the ability to obtain regulatory approval 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 the specific indications, acceptance of product candidates in the marketplace and the successful development, marketing or sale of Heat's, developments by competitors that render such products obsolete or non-competitive, and other factors described in Heat's annual report on Form 10-K for the year ended December 31, 2021, subsequent quarterly reports on Form 10-Qs and any other filings Heat makes with the SEC. Heat can give no assurance that the conditions to the Merger will be satisfied. The information in this presentation is provided only as of the date presented, and Heat undertakes no obligation to update any forward-looking statements contained in this presentation on account of new information, future events, or otherwise, except as required by law.

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