SAB Biotherapeutics Announces Clinical Partnership with Naval Medical Research Center to Advance Potential Influenza Treatment

March 25, 2024 2:15 PM EDT

SIOUX FALLS, S.D., March 25, 2024 (GLOBE NEWSWIRE) -- SAB Biotherapeutics, Inc. (Nasdaq: SABS), ("SAB" or the "Company"), a clinical-stage biopharmaceutical company with a novel immunotherapy platform that is developing fully-human anti-thymocyte immunoglobulin (hIgG) for delaying the onset or progression of type 1 diabetes (T1D), today announced that the Navy Medical Research Command (NMRC) is moving forward with a safety and tolerability study to evaluate SAB-176, a therapy being investigated for use as a pre- and post-exposure prophylactic treatment for influenza type A and type B, pursuant to the Cooperative Research and Development Agreement that governs the relationship between SAB and the NMRC.

With funding for research provided by the Henry Jackson Foundation, this partnership will move forward a pharmacokinetic (PK), safety and tolerability study designed as a double-blinded, randomized study with intramuscular SAB-176 administered to healthy volunteers. The NMRC Clinical Trials Center, located in Bethesda, Maryland, will be conducting this PK study under the leadership of Cmdr. Nehkonti Adams, Director, NMRC Clinical Trials Center.

SAB has utilized its proprietary DiversitAb™ platform to manufacture SAB-176, fully human polyclonal antibodies targeting influenza from Transchromosomic (Tc) Bovine™. SAB-176 is a novel multi-target biologic that has shown sustained neutralization activity across multiple virus strains of Influenza A and B. In 2023, the U.S. Food and Drug Administration granted Breakthrough Therapy and Fast Track Designations to SAB-176 based on the results of the completed clinical proof-of-concept Phase 2 study in an influenza challenge model with intravenous (IV) formulation. SAB-176, along with several other fully human anti-infective immunoglobulins developed by SAB have been administered through IV to over 700 healthy volunteers and patients. This will be the first study to examine intramuscular administration of any DiversitAb™ platform product. The DiversitAb™ platform produces fully human target-specific biologics that can be delivered across a range of therapeutic areas, including infectious diseases and autoimmune conditions like type 1 diabetes (T1D).

SAB Chairman and CEO Samuel J. Reich stated that "we are pleased to continue our collaboration with the NMRC to explore new routes of administration for our products. While T1D remains our primary focus, studying the novel administration of a therapy using our proprietary platform could have tremendous positive health impacts and is a logical next step for SAB's other therapeutic products as well."

"It is important to support studies that advance therapeutics that can be feasibly delivered in a deployed setting," explained Cmdr. Nehkonti Adams, in a recent NMRC press release. "This research could impact thousands of lives, providing the capacity to rapidly respond to influenza and other infectious diseases."

According to the CDC, influenza causes substantial morbidity and mortality worldwide despite available antivirals and vaccines. Influenza is responsible for approximately 226,000 excess hospitalizations and 30,000 to 50,000 deaths each year in the United States alone. Despite the demonstrated reduction in disease rates following vaccination, the efficacy of annual influenza vaccination peaks around 60%. This sub-optimal effect is often due to antigenic drift and mismatches between the vaccine and circulating strains in any given influenza season, thus, one potential solution is to utilize fully human IgG isolated from transchromosomic bovine hyperimmunized with numerous representative influenza strains.

About SAB Biotherapeutics, Inc.

SAB Biotherapeutics (SAB) is a clinical-stage biopharmaceutical company focused on developing fully human, multi- targeted, high-potency immunoglobulins (IgGs), without the need for human donors or convalescent plasma, to treat and prevent immune and autoimmune disorders. The Company's lead asset, SAB-142, targets type 1 diabetes (T1D) with a disease-modifying therapeutic approach that aims to change the treatment paradigm by delaying onset and potentially preventing disease progression. Using advanced genetic engineering and antibody science to develop Transchromosomic (Tc) Bovine™, the only transgenic animal with a human artificial chromosome, SAB's DiversitAb™ drug development production system is able to generate a diverse repertoire of specifically targeted, high-potency, fully-human IgGs that can address a wide range of serious unmet needs in human diseases without the need for convalescent plasma or human donors. For more information on SAB, visit: https://www.SAb.bio/ and follow SAB on Twitter and LinkedIn.

Forward-Looking Statements

Certain statements made herein that are not historical facts are forward-looking statements for purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995. Forward-looking statements generally are accompanied by words such as "believe," "may," "will," "to be," "estimate," "continue," "anticipate," "intend," "expect," "should," "would," "plan," "predict," "potential," "seem," "seek," "future," "outlook," and similar expressions that predict or indicate future events or trends or that are not statements of historical matters. These forward-looking statements include, but are not limited to, statements regarding future events, including the development and efficacy of our SAB 176 influenza program, our T1D program, and other discovery programs, the outcome of the Navy Medical Research Command collaboration, and other third-party collaborations or funded programs.

These statements are based on the current expectations of SAB and are not predictions of actual performance, and are not intended to serve as, and must not be relied on, by any investor as a guarantee, prediction, definitive statement, or an assurance, of fact or probability. These statements are only current predictions or expectations, and are subject to known and unknown risks, uncertainties and other factors which may be beyond our control. Actual events and circumstances are difficult or impossible to predict, and these risks and uncertainties may cause our or our industry's results, performance, or achievements to be materially different from those anticipated by these forward-looking statements. A further description of risks and uncertainties can be found in the sections captioned "Risk Factors" in our most recent annual report on Form 10-K, as amended, subsequent quarterly reports on Form 10-Q, as may be amended or supplemented from time to time, and other filings with or submissions to, the U.S. Securities and Exchange Commission, which are available at https://www.sec.gov/. Except as otherwise required by law, SAB disclaims any intention or obligation to update or revise any forward-looking statements, which speak only as of the date they were made, whether as a result of new information, future events, or circumstances or otherwise.

CONTACTS

Media Relations:
khollon@sab.bio

Investor Relations:
matt@milestone-advisorsllc.com