SAB Biotherapeutics Announces SAB-176 Met its Primary Endpoint in Phase 2a Challenge Study in Adults Infected with Influenza Virus

December 1, 2021 12:01 PM EST

Topline data show SAB-176 achieved statistically significant reductions in viral load and clinical symptoms and it appeared safe and well-tolerated

Second clinical proof of concept achieved by DiversitAb™ platform in past two months

Positive clinical results confirm that SAB's fully-human polyclonal antibodies can be broadly neutralizing to both known and unknown viral variants—a valuable feature when addressing rapidly mutating pathogens

SAB plans to further evaluate SAB-176 in a Phase 2 influenza clinical trial slated to begin in 2Q 2022

SIOUX FALLS, S.D., Dec. 01, 2021 (GLOBE NEWSWIRE) -- SAB Biotherapeutics (Nasdaq: SABS), (SAB), a clinical-stage biopharmaceutical company with a novel immunotherapy platform that produces specifically targeted, high-potency, fully-human polyclonal antibodies without the need for human donors, today announced that SAB-176, its investigational therapeutic for the treatment of seasonal influenza, achieved statistically significant ($p = 0.026$) reductions in viral load and clinical signs and symptoms compared to placebo in a Phase 2a challenge study. In the study, SAB-176 appeared to be safe and well-tolerated. SAB-176 is a quadrivalent fully human polyclonal antibody therapeutic candidate designed for the treatment of moderate to severe Type A and B seasonal influenza viruses.

"We are highly encouraged by these topline results showing that treatment with SAB-176 achieved statistical significance in reducing influenza viral load and clinical signs and symptoms in treated subjects, despite the small size of this first Phase 2 study. These data suggest that SAB-176 has the potential to be an effective treatment for this prevalent, highly-mutating virus that resurfaces annually and is a major source of hospitalizations and deaths," said Tom Luke, MD, Chief Medical Officer of SAB Biotherapeutics. "These trial results support advancing SAB-176 as a potential treatment for seasonal influenza through further clinical studies, and we look forward to sharing additional data as it becomes available."

"These positive efficacy data for SAB-176 represent the second clinical proof of concept achieved by our DiversitAb™ platform in the past two months," said Eddie J. Sullivan, PhD, Co-Founder, President, and Chief Executive Officer of SAB Biotherapeutics. "In September our investigational COVID-19 therapy SAB-185 met the pre-defined efficacy goal for advancement from Phase 2 to Phase 3 in the NIH-sponsored ACTIV-2 trial. These back-to-back clinical successes for our first two pipeline products give us confidence that the DiversitAb™ platform is clinically validated. They reinforce our commitment to advancing this unique platform, with its demonstrated ability to rapidly generate therapeutic candidates for highly mutating pathogen targets with ongoing resurgence and pandemic potential, including influenza and COVID-19."

About SAB-176 Challenge Study
The Phase 2a challenge study, initiated in June 2021, was a randomized, double-blind, placebo-controlled study evaluating the safety and treatment efficacy of SAB-176 in 60 healthy adults challenged with a pandemic influenza virus strain (pH1N1). Participants were randomized to receive either SAB-176 (25 mg/kg dose) or placebo and were intranasally inoculated with pandemic H1N1 (2009/California) virus, and nasopharyngeal swabs were taken 8 days after inoculation.

The primary endpoint of the study was reduction of the nasopharyngeal viral load of subjects treated with SAB-176 (expressed as area under the curve, or AUC) compared to those receiving placebo over an 8-day timepoint as measured by qRT-PCR. SAB-176 met the primary endpoint of significantly reducing patient pH1N1 influenza viral load in the treated subjects ($p = 0.026$, one sided).

A secondary endpoint of the challenge study was reduction of clinical flu signs and symptoms in the subjects receiving active treatment ($n=8$) compared to placebo controls ($n=12$) for those who had signs and symptoms. SAB-176 achieved statistical significance in meeting the secondary endpoint at Day 4 ($p = 0.013$, one sided) in symptomatic patients. Additional analyses of secondary endpoint data are underway.

In this study SAB-176 also appeared to be safe and well tolerated. No SAB-176-related serious adverse events (SAEs) were observed, and most adverse events were mild to moderate. Based on these positive efficacy and safety results, SAB plans to further evaluate SAB-176 in advanced clinical trials.

"One remarkable aspect of these results is that SAB's Tc Bovine™ were not immunized to the specific influenza virus strain that was used in the challenge study," added Christoph Bausch, PhD, Chief Scientific Officer of SAB Biotherapeutics. "Nonetheless, the statistically significant reduction in virus load and symptoms that were achieved confirm that SAB-176 demonstrated high cross reactivity to this pandemic strain. This reinforces a unique and timely feature of our DiversitAb™ platform—the diversity of the human antibodies it produces gives our therapeutics the potential to be broadly neutralizing to both known and unknown viral variants—a very valuable feature when addressing rapidly mutating pathogens."

For more information on the Phase 2a clinical trial, visit clinicaltrials.gov (Identifier NCT04850898).

About SAB-176
SAB-176 is a multivalent, broadly neutralizing fully-human polyclonal antibody therapeutic candidate in development for the treatment or prevention of severe influenza. The novel, specifically-targeted therapeutic leverages the natural human biological immune response to specifically bind to Type A and Type B influenza viruses. Like vaccines, it can be modified to address annual strain changes, when needed, to maintain broader coverage as the flu virus mutates. Preclinical data suggests that SAB-176 offers broad protection against diverse influenza strains.

SAB's novel DiversitAb™ immunotherapy platform enables the production of large amounts of targeted, highly potent human polyclonal antibodies. The platform leverages transchromosomic cattle (Tc Bovine™) that have been genetically designed to generate fully human antibodies (immunoglobulin G) rather than bovine antibodies, in response to inoculation with an immunogen.

To develop and produce SAB-176, Tc Bovine were hyperimmunized with a quadrivalent antigen, including a number of influenza strains. Within a brief

period of time, the Tc Bovine generated significant amounts of fully-human antibodies to combat the virus, driving titers beyond the levels known to be protective. Plasma was collected (in a similar manner as from human plasma donors), then purified to isolate the antibodies that comprise the therapeutic treatment.

About Seasonal Influenza
Influenza virus infection is one of the most common infectious diseases and can lead to severe illness, and death. According to the US Centers for Disease Control (CDC), on average about 8% of the US population gets sick each flu season and between 12,000 and 61,000 infected Americans die, depending on the severity of the flu season. In 2019-2020, considered a moderate flu season, 38 million people in the US became ill with the flu, 18 million saw a healthcare provider for treatment, 400,000 were hospitalized and an estimated 22,000 died. Globally, there are between 2.5 and 5 million influenza-related hospitalizations per year. The CDC recommends an annual flu shot for almost everyone over the age of six months, but each year less than half the population is vaccinated. In addition, because influenza viruses are highly mutating, the vaccines have varying levels of protection in any year, but rarely exceed 50% protection. Young children, the elderly, immune-compromised individuals, and patients with chronic health conditions are especially at risk of poor outcomes from influenza, yet there are few approved therapies for the treatment of influenza.

About SAB Biotherapeutics, Inc.
SAB Biotherapeutics, Inc. (SAB) is a clinical-stage, biopharmaceutical company advancing a new class of immunotherapies leveraging fully human polyclonal antibodies. SAB has applied advanced genetic engineering and antibody science to develop transchromosomic (Tc) Bovine™ that produce fully-human antibodies targeted at specific diseases, including infectious diseases such as COVID-19 and influenza, immune system disorders including type 1 diabetes and organ transplantation, and cancer. SAB's versatile DiversitAb™ platform is applicable to a wide range of serious unmet needs in human diseases. It produces natural, specifically targeted, high-potency, human polyclonal immunotherapies. SAB is currently advancing multiple clinical programs. For more information on SAB, visit: https://www.sabbiotherapeutics.com/ and follow @SABBantibody on Twitter.

Contacts:
Melissa Ullerich
+1 605-679-4609
mullerich@sabbiotherapeutics.com

Courtney Turiano (investors)
Stern IR
+1 212-698-8687
Courtney.Turiano@sternir.com

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,” “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. These statements are based on the current expectations of SAB and are not predictions of actual performance. These forward-looking statements are provided for illustrative purposes only and are not intended to serve as, and must not be relied on, by any investor as a guarantee, an assurance, a prediction or a definitive statement of fact or probability. Actual events and circumstances are difficult or impossible to predict, will differ from assumption and are beyond the control of SAB. Forward-looking statements are subject to various risks and uncertainties, including, among others, those related to the COVID-19 pandemic; SAB's ability achieve successful results for its product candidates, the availability of financing, and trends affecting SAB's financial condition or results of operations. These factors should not be construed as exhaustive and should be read in conjunction with the other cautionary statements that are described under the sections entitled "Risk Factors" in the Company's proxy statement/prospectus filed with the Securities and Exchange Commission (the "SEC") on September 24, 2021. Such factors may be updated from time to time in SAB's periodic filings with the SEC, which are accessible on the SEC's website at www.sec.gov. Accordingly, there are or will be important factors that could cause actual outcomes or results to differ materially from those indicated in these statements. The forward-looking statements speak only as of the date of this press release, and SAB expressly disclaims any obligation or undertaking to publicly update or review any forward-looking statement.