SAB Biotherapeutics Reports NIH is Discontinuing Phase 3 ACTIV-2 Trial Assessing SAB-185 for Treatment of COVID-19 Due to Declining COVID Hospitalizations

March 2, 2022 11:00 AM EST

NIH is closing enrollment in its ACTIV-2 trial due to low Omicron-related COVID-19 hospitalization and death rates that have made the current study design statistically unworkable

SAB-185 had advanced into Phase 3 after meeting pre-specified efficacy and safety criteria

SAB-185's targeted, highly potent, fully human polyclonal antibodies have demonstrated neutralization of multiple SARS-CoV-2 variants in vitro, including Delta and Omicron

SAB is evaluating future clinical plans for SAB-185 including potential targeted applications such as prophylaxis and treatment in high-risk patient groups

SIOUX FALLS, S.D., March 02, 2022 (GLOBE NEWSWIRE) -- SAB Biotherapeutics (SAB) (Nasdaq: SABS), 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 reported that due to low hospitalization and death rates in the trial, the National Institutes of Health's (NIH) ACTIV-2 Program is discontinuing enrollment in its Phase 3 COVID-19 trial.

SAB-185 was being assessed as part of the Phase 3 ACTIV-2 master protocol evaluating treatments for COVID-19 in patients with mild-moderate infections at higher risk for progression to hospitalization. Reductions in hospitalization and death rates were included as primary endpoints of the Phase 3 trial. However, low hospitalization and death rates recently observed in the study have led the sponsors to conclude that, notwithstanding the potential efficacy of SAB 185, it would not be possible to demonstrate statistically significant clinical efficacy with the existing study design, since so few of the enrolled COVID-19 patients had an observable study endpoint event such as hospitalization.

While SAB-185 previously met the initial pre-specified safety and efficacy criteria to continue to the next phase of the Phase 3 ACTIV-2 trial, the independent Data and Safety Monitoring Board (DSMB) recommended that the study be stopped for reasons of "operational futility", meaning that hospitalization rates had declined to the point where the study was no longer large enough to ensure that statistically significant findings could be obtained.

"The NIH-sponsored ACTIV-2 Phase 3 master protocol was designed when previous COVID-19 variants resulted in high infection and hospitalization rates," said Eddie J. Sullivan, Ph.D., co-founder, President, and Chief Executive Officer of SAB Biotherapeutics. "The good news is that infections and hospitalizations are now falling sharply in the US. But this decrease also has had the effect of making the current ACTIV-2 Phase 3 study design statistically unworkable, and the NIH has therefore decided to stop patient enrollment."

Dr. Sullivan continued, "Our team continuously monitors the evolving pandemic to plan for the further development of SAB-185, focusing on identifying COVID-19 patient groups who could potentially benefit from SAB-185, including the potential for prophylactic or therapeutic use in targeted high-risk populations and in those who will become ill from newly emerging variants, along with the potential development of an injectable formulation. We look forward to analyzing data from the ACTIV-2 trial to help inform our future clinical initiatives when it becomes available. We appreciate the support of the NIH, FDA and ACTG in the clinical development of SAB-185 up to this point, and we plan to build on this foundation in the continuing battle to manage this virus that has so upended our world."

"We want to thank the many patients and their caregivers who participated in the ACTIV-2 trials to evaluate the first targeted, high potency fully human polyclonal antibody therapeutic," said Tom Luke, MD, Chief Medical Officer of SAB Biotherapeutics. "Data from this study is expected to provide valuable insights about SAB-185 and the potential therapeutic benefits of our fully human polyclonal therapies, which we are planning to develop to address a variety of acute and chronic unmet medical needs, along with their potential to provide a model for future rapid response to medical emergencies."

Direct support for the development of SAB-185 is provided by the US Department of Defense's (DoD) Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) on behalf of the Office of the Assistant Secretary of Defense for Health Affairs (OASD-HA), and the Defense Health Agency (DHA) and by the Biomedical Advanced Research and Development Authority (BARDA), part of the Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response, under contract number MCDC 2019-448.

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 currently has multiple drug development programs underway and collaborations with the US government and global pharmaceutical companies. 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
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, including the efficacy of SAB-185, the expected utility to be derived from an analysis of interim data, future development of SAB-185 for certain populations or new virus strains and the development of additional therapeutics to address medical needs and future pandemics.

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. A further description of risks and uncertainties can be found in the prospectus filed by SAB Biotherapeutics, Inc. on December 29, 2021, including in the sections thereof captioned “Risk Factors” as well as in its subsequent reports on Form 10-K, 10-Q and Form 8-K, all of which will be filed with the U.S. Securities and Exchange Commission and available at https://www.sec.gov/