SAB Biotherapeutics Announces Update to the Phase 3 NIH ACTIV-2 Trial Design Evaluating SAB-185 for Treatment of COVID-19

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ACTIV-2 Phase 3 trial continuing as placebo-controlled study in Omicron variant COVID participants

SIOUX FALLS, S.D., Feb. 25, 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 announced an update to the design of the ongoing Phase 3 ACTIV-2 trial evaluating the clinical efficacy and safety of SAB-185 for the treatment of participants with mild-moderate COVID infections at higher risk for progression to hospitalization. The Phase 3 trial had been designed as an open-label, randomized non-inferiority study comparing SAB-185 to an active comparator—a monoclonal antibody cocktail (casirivimab and imdevimab) authorized for treatment of COVID-19. Going forward, the active comparator will be replaced with a placebo.

The trial is sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), part of the US National Institutes of Health (NIH) in collaboration with the AIDS Clinical Trials Group. SAB-185 is a fully-human, specifically targeted, broadly neutralizing polyclonal antibody therapeutic candidate. *In vitro* testing has confirmed that SAB-185 retains neutralizing activity against COVID variants of concern, including the Omicron variant.

“We welcome the fast action to modify the ACTIV-2 Phase 3 trial once it became clear that the active comparator was not effective against the Omicron variant, which now represents about 95% of new COVID-19 cases in the US,” said Eddie J. Sullivan, Ph.D., co-founder, President, and Chief Executive Officer of SAB Biotherapeutics. “SAB-185 is designed to be a broadly neutralizing therapeutic, and in laboratory studies, it has demonstrated continuing neutralizing ability against Omicron and other COVID variants. We are encouraged that NIH chose to update and continue this Phase 3 study as a placebo-controlled trial.”

The ACTIV-2 trial is designed to rapidly assess potential new therapies for COVID-19 utilizing an adaptive platform trial design. Under the new update, the Phase 3 trial design is amended to pivot to a blinded, randomized, placebo-controlled superiority trial. Participants in both study arms will be encouraged to access standard of care therapy for the treatment of COVID-19 if available to them outside the trial.

The study endpoints remain unchanged. Since the trial is focusing on Omicron and potential future SARS-CoV-2 variants, an additional 800 participants will be enrolled to supplement the approximately 400 participants already participating in the SAB-185 Phase 3 trial (of the more than 700 total COVID-19 participants who had been enrolled prior to the study redesign). The trial is expected to restart in the coming weeks, allowing for minimal disruption of data collection.

For more information on the Phase 3 ACTIV-2 trial, visit clinicaltrials.gov (Identifier NCT04518410).

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.

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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/