SAB Biotherapeutics Announces Publication of Nonclinical Data Demonstrating SAB-185 Has High Potency for Effectively Neutralizing Circulating and Emerging SARS-CoV-2 Variants

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In the FDA-conducted study, SAB-185 consistently demonstrated high avidity and high potency for effectively neutralizing a broad range of SARS-CoV-2 strains and variants through Delta

SAB-185 additionally outperformed convalescent plasma

Findings published in The Journal of Infectious Diseases

SIOUX FALLS, S.D., March 01, 2022 (GLOBE NEWSWIRE) -- SAB Biotherapeutics (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 the publication of nonclinical data from a study conducted in collaboration with the Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) Division of Viral Products highlighting that SAB-185 effectively neutralizes multiple SARS-CoV-2 strains and that it is superior to convalescent plasma in neutralizing COVID variants. SAB-185, a fully-human, specifically targeted, broadly neutralizing polyclonal antibody candidate for the treatment of high-risk non-hospitalized patients with mild to moderate COVID-19, is currently being assessed in the US National Institutes of Health (NIH) COVID-19 Phase 3 ACTIV-2 Trial.

The article, "*Increased antibody avidity and cross-neutralization of SARS-CoV-2 variants by hyperimmunized Tc-Bovine derived human immunoglobulins for treatment of COVID-19*," is published in the online edition of *The Journal of Infectious Diseases*. SAB-185 demonstrated high antibody avidity and potency of cross-neutralizing activity in the tested variants and outperformed convalescent plasma in these assays. The study concluded that SAB-185 offers potential as a therapeutic candidate for treatment of SARS-CoV-2, including potentially addressing variants of concern.

"These promising nonclinical data, generated by the FDA, are another indicator that SAB-185 may have broad potential as an effective therapy for the treatment of COVID-19 infections across both circulating and emerging variants," said Tom Luke, MD, Chief Medical Officer for SAB Biotherapeutics. "SAB-185 retained its ability to neutralize all of the tested SARS-CoV-2 mutant strains, and as we expected, outperformed convalescent plasma in the study."

Dr. Luke continued, "The loss of efficacy of some current COVID-19 therapies against the prevalent Omicron strain highlights the potential of high potency, broadly neutralizing fully human polyclonal therapies such as SAB-185 against COVID-19 and other rapidly mutating viruses."

Study researchers conducted neutralization assays with seven variant SARS-CoV-2 strains, including the *Alpha, Epsilon, Iota, Gamma, Beta, Kappa* and *Delta* strains, comparing performance of convalescent plasma from recovered COVID-19 patients against several variants of SAB-185. They evaluated antibody binding, avidity maturation, and SARS-CoV-2 virus neutralizing capacity. Compared with post-infection human convalescent plasma, SAB-185 demonstrated higher antibody avidity and more potent cross-neutralizing activity of both the variants of interest and variants of concern. The study authors concluded that SAB-185 may likely lead to effective virus neutralization and protection against previous, current and/or emerging SARS-CoV-2 strains and could potentially serve as an effective therapy for the treatment of COVID-19 patients.

In September 2021, a pre-specified interim analysis of ACTIV-2 Phase 2 data, reviewed by a Data Safety Monitoring Board, concluded that SAB-185 met the efficacy and safety criteria for advancement to the ACTIV-2 Phase 3 trial. This interim data analysis was recently confirmed by Phase 2 data from all the study participants. Both the Phase 2 and Phase 3 ACTIV-2 trials are sponsored and conducted by the National Institute of Allergy and Infectious Diseases (NIAID), part of the NIH, in collaboration with the AIDS Clinical Trials Group (ACTG).

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/