SAB Biotherapeutics Announces SAB-185 Retains Neutralization Against Omicron SARS-CoV-2 Variant In Vitro

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FDA laboratory testing confirms SAB-185 neutralizes Omicron and other variants of concern with in vitro pseudovirus model

SAB's targeted, highly potent and fully-human polyclonal antibodies continue to show broad neutralization to viral variants

SAB-185 currently being evaluated in NIH-sponsored Phase 3 COVID trial

SIOUX FALLS, S.D., Dec. 16, 2021 (GLOBE NEWSWIRE) -- SAB Biotherapeutics (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 data demonstrating that SAB-185, the company's therapeutic candidate for the treatment of COVID-19 infections, retains neutralization activity against the Omicron SARS-CoV-2 variant in an *in vitro* pseudovirus model. The data were generated by scientists at the US Food and Drug Administration (FDA) Center for Biologics Evaluation and Research (CBER).

"These *in vitro* data demonstrate that SAB-185 retains neutralization activity against the Omicron variant as has been consistently shown with previous SARS-CoV-2 variants of concern," said Eddie J. Sullivan, PhD, Co-founder, President and CEO of SAB Biotherapeutics. "These encouraging data come at a critical time as COVID continues to assert its resilience in the human population around the globe. It also provides further evidence of the potential therapeutic importance of our polyclonal antibody approach to a highly mutating virus such as SARS-CoV-2."

In the study, FDA researchers evaluated SAB-185 using a lentiviral-based pseudovirus assay conducted in a BSL2 environment that incorporates a stable 293T cell line expressing human angiotensin converting enzyme 2 (ACE2) and transmembrane serine protease 2 (TMPRSS2). The results indicate that SAB-185 retains a potent ability to neutralize recombinant S protein lentiviral pseudovirus that mimics the SARS-CoV-2 Omicron (B.1.1.529) variant. Although SAB-185 retained potent neutralization of the Omicron variant, it did show a mild-moderate reduction in potency compared to the wild type. Additional analyses are ongoing, and the full data set is being prepared for bioRxiv, the online life sciences archive for COVID-19 SARS-CoV-2 preprints.

"As a targeted, high potency fully-human polyclonal antibody therapeutic candidate, SAB-185 is highly differentiated in the way by which it can address viral mutation potentially providing a more broadly active treatment option against COVID variants," added Sullivan. "In addition to the retained neutralization activity of SAB-185 to the Omicron variant, it's also important to note that there are multiple properties of polyclonal antibodies that can potentially provide therapeutic benefit to patients. For example, polyclonal antibodies can effectively block receptors used for viral entry by binding to multiple epitopes on the receptor binding domain, and they also may activate immune effector cells, further enhancing the individual's immune response."

SAB-185 is currently being assessed in a Phase 3 trial that has been enrolling patients since October. The antibodies within SAB-185 are directed against multiple epitopes within the full-length spike protein of the SARS-CoV-2 Wuhan strain. SAB-185 neutralizes the Munich, South African, Delta, Lambda, and other circulating variant strains in nonclinical studies. Preclinical data has also indicated that SAB-185 is significantly more potent than human-derived convalescent immunoglobulin G (IgG).

"Our versatile platform provides the capability to quickly add strains and adjust to new variants. We're moving to optimize SAB-185 by adding activity directed to the Omicron variant," added Christoph Bausch, PhD, Chief Scientific Officer of SAB Biotherapeutics. "SAB remains committed to monitoring the course of the disease and aiming to provide a polyclonal therapeutic response. We look forward to working with our US government collaborators and regulatory authorities to advance our COVID-19 program, with the goal of making SAB-185 available to patients, as quickly as possible once its clinical efficacy is confirmed."

About SAB-185
SAB-185 is a fully-human, specifically targeted and broadly neutralizing polyclonal antibody therapeutic candidate currently being assessed in a Phase 3 trial. It is the first polyclonal antibody therapeutic included in the ACTIV-2 master protocol, a study sponsored, funded, and conducted by the National Institute of Allergy and Infectious Diseases (NIAID), part of the US National Institutes of Health (NIH). SAB-185 was developed in collaboration with the US government using SAB's novel proprietary DiversitAb™ Rapid Response Antibody Program, as part of the Countermeasures Acceleration Group, formerly Operation Warp Speed.

The Phase 3 ACTIV-2 trial is a randomized, unblinded, active comparator-controlled adaptive platform non-inferiority study that is assessing the clinical safety and efficacy of SAB-185 compared to active control monoclonal antibody treatment in people with mild to moderate COVID-19 who are at higher risk for progression to hospitalization. It is enrolling approximately 600 participants to receive the investigational agent SAB-185 and 600 to receive an active comparator. The primary outcome measures of the Phase 3 trial include safety and non-inferiority for the prevention of a composite endpoint of either hospitalization or death from any cause through study day 28.

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 the Biomedical Advanced Research and Development Authority (BARDA), part of the Department of Health and Human Services (DHHS) Office of the Assistant Secretary for Preparedness and Response, under contract #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™ herds 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 specifically targeted, high-potency, human polyclonal immunotherapies. SAB is currently advancing multiple clinical programs and has a number of collaborations with the US government and global pharmaceutical companies. For more information on SAB, visit: http://www.sabbiotherapeutics.com and follow @SABBantibody on Twitter.

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