SAB Biotherapeutics Reports Positive Phase 2 Virology Data Demonstrating SAB-185 Met Criteria for Advancement to Phase 3 in NIH ACTIV-2 Trial for Treatment of COVID-19

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SAB-185 is being evaluated in Phase 3 NIH-Sponsored ACTIV-2 COVID trial of high-risk patients following positive DSMB review of interim Phase 2 safety and efficacy data in September

More than 700 patients have been enrolled in the Phase 3 trial, exceeding 50% enrollment

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

SAB-185 was safe and well-tolerated at both doses tested in Phase 2

SIOUX FALLS, S.D., Jan. 24, 2022 (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 reported positive Phase 2 safety and efficacy data demonstrating that SAB-185 met the criteria required for advancement to Phase 3 in the US National Institutes of Health (NIH) COVID-19 ACTIV-2 Trial.

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 Phase 3 ACTIV-2 trial. It met the criteria for advancement to Phase 3 with Day 3 viral load data from a pre-specified interim data analysis reviewed by the Data Safety Monitoring Board (DSMB) in September. 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).

“These positive clinical results from the NIH ACTIV-2 trial are another sign that SAB-185 may have therapeutic potential for the treatment of COVID-19,” said Eddie J. Sullivan, PhD, co-founder, President, and Chief Executive Officer of SAB Biotherapeutics. “SAB-185 appeared safe and achieved a key virologic efficacy criterion, despite a change in protocol early in the study that resulted in enrollment comprised predominantly of patients at low-risk of severe disease. The original protocol focused on high-risk patients, who are most likely to benefit from treatment with SAB-185. Data from a very small subset of high-risk patients treated with SAB-185 showed sharp declines in viral load compared to high-risk placebo controls. In the Phase 3 trial, SAB-185 is being assessed in a high-risk population.”

Sullivan added, “The Phase 3 study in high-risk patients is more than 50% enrolled, and we look forward to those results later this year.”

The ACTIV-2 Phase 2 trial was designed to test whether SAB-185 met the pre-specified virology criteria necessary to advance to Phase 3. SAB-185 achieved this goal in the interim analysis of the data, as well as in the full data set. Specifically, SAB-185 met the criteria for advancement to Phase 3 with Day 3 viral load data from the pre-specified interim analysis. The specified threshold was 0.5 $\log_{10}$ copies/ml as measured by nasopharyngeal viral qRT-PCR reduction as defined with a Bayesian posterior probability of at least 0.6. The Phase 2 interim analysis showed nasopharyngeal viral qRT-PCR reductions of 1.48 $\log_{10}$ (low dose, Probability 0.91) and 0.67 $\log_{10}$ (high dose, Probability 0.75) versus placebo. The full enrollment Phase 2 data showed viral load reductions of 0.5 $\log_{10}$ versus placebo for both the low and high doses.

Assessment of other endpoints was affected by the fact that the sample size for the Phase 2 trial was selected primarily to assess virologic outcomes, rather than to differentiate symptom outcomes with any precision. Aside from the key virologic efficacy measure used to determine advancement to Phase 3, other endpoints measured in the trial did not achieve statistical significance. Similarly, the limited sample size and protocol shift to low-risk patients also meant that low numbers of hospitalizations or deaths were expected in this population, and few were seen.

The Phase 2 trial of SAB-185, as part of the ACTIV-2 master protocol, was a randomized, double-blind, adaptive study evaluating the clinical safety and efficacy of SAB-185 in non-hospitalized patients with mild to moderate COVID-19 at risk for disease progression. Each sub-study in ACTIV-2 shares the placebo group and enrolled 110 participants. SAB-185 was administered intravenously and evaluated in high- and low-dose arms.

The Phase 2 ACTIV-2 trial was initially designed as a study of high-risk patients, since it was expected these patients were the most likely to benefit from anti-viral treatment. However, once the FDA approved several anti-COVID therapies for high-risk patients as part of the Emergency Use Authorization (EUA) program, NIH amended the master protocol to limit enrollment to low-risk patients in Phase 2 and to replace the placebo arm with an active comparator in Phase 3. As a result of these changes, overall, only about 12.5% of Phase 2 study participants treated with SAB-185 were high-risk, making it more challenging to achieve results that were statistically significant. Nonetheless, both the low and high doses of SAB-185 met the virology criteria for advancement to Phase 3.

“These Phase 2 data again demonstrate that SAB-185 met the safety and efficacy criteria to be advanced to the NIH-sponsored Phase 3 clinical trial,” said Tom Luke, MD, Chief Medical Officer of SAB Biotherapeutics. “One striking finding in the Phase 2 study was an analysis of a very small sub-group that showed the pronounced impact of both the low and high doses of SAB-185 on reducing viral loads in COVID patients at high risk of severe disease. While the patient sample size does not support statistical significance, these results suggests that SAB-185 could be efficacious in the current Phase 3 trial, which is being conducted solely in high-risk patients.”

The ongoing Phase 3 ACTIV-2 trial is a non-inferiority randomized, unblinded, active comparator-controlled study that is assessing the safety and efficacy of SAB-185 compared to an active control monoclonal antibody treatment in people with mild to moderate COVID-19 who are at high risk for hospitalization. It is enrolling approximately 600 participants to receive SAB-185 and 600 to receive the 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. The trial has enrolled more than 700 patients of the 1,200 total targeted for the trial.

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 #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/