October 4, 2021

SAB Biotherapeutics Announces First Patient Dosed in Phase 3 NIH ACTIV-2 Trial Evaluating SAB-185 for Treatment of COVID-19

SIOUX FALLS, S.D.--(BUSINESS WIRE)-- 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 that the first patient has been dosed with SAB-185 in the Phase 3 ACTIV-2 COVID-19 trial.

SAB-185 is a fully human, specifically targeted, broadly neutralizing polyclonal antibody therapeutic candidate for the treatment of non-hospitalized patients with mild to moderate COVID-19. The candidate is being assessed in the ACTIV-2 trial led 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 the second agent to graduate to Phase 3 and the first polyclonal antibody therapeutic candidate in ACTIV-2, which is evaluating multiple investigational agents to treat early symptomatic COVID-19 in non-hospitalized individuals.

SAB-185 advanced from Phase 2 to the Phase 3 portion of the ACTIV-2 trial based on meeting pre-defined graduation criteria. The interim analysis demonstrated that both the lower and higher doses of SAB-185 tested in Phase 2 met the pre-defined efficacy goal for advancement to Phase 3 and appeared safe. SAB researchers in consultation with NIAID have determined the lower dose of SAB-185 (3,840 Units/kg) will be assessed in Phase 3.

“We are delighted that the Phase 3 trial is underway, just days after the decision by the independent Data Safety Monitoring Board to advance SAB-185 to Phase 3,” said Eddie J. Sullivan, PhD, co-Founder, President, and Chief Executive Officer of SAB Biotherapeutics. “The joint decision with NIAID to evaluate the lower dose of SAB-185 in the Phase 3 trial is a testament to the potency of our human polyclonal antibody therapeutic candidate, which has demonstrated neutralization of multiple emerging SARS-CoV-2 variants in recently published nonclinical studies.”

The Phase 3 portion of the 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).

On June 22, 2021, SAB announced a planned merger with Big Cypress Acquisition Corp. (NASDAQ: BCYP). The transaction is expected to close in the fourth quarter of 2021.

About SAB-185

SAB-185 is a fully human polyclonal antibody therapeutic entering a Phase 3 study for the treatment of non-hospitalized patients with mild to moderate COVID-19. It 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. In nonclinical studies, the novel therapeutic candidate has shown potent neutralization of the Munich, Washington and other variant strains, including Delta and Lambda. Preclinical data has also indicated that SAB-185 is significantly more potent than human-derived convalescent immunoglobulin G (IgG).

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 natural, 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.

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, the development of SAB-185, and the proposed business combination between Big Cypress and SAB. 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.

Additional Information and Where to Find It

In connection with the proposed business combination, Big Cypress has filed with the SEC a definitive proxy statement/prospectus. Big Cypress commenced mailing of the definitive proxy statement/prospectus to its stockholders on September 23, 2021. A proxy statement/prospectus has been sent to all Big Cypress stockholders as of the record date of September 17, 2021. This communication is not a substitute for the Registration Statement, the definitive proxy statement/final prospectus or any other document that Big Cypress will send to its stockholders in connection with the proposed business combination. Investors and security holders of Big Cypress are advised to read the proxy statement/prospectus in connection with Big Cypress’ solicitation of proxies for its special meeting of stockholders to be held to approve the proposed business combination (and related matters) because the proxy statement/prospectus contains important information about the proposed business combination and the parties to the proposed business combination. Stockholders will also be able to obtain copies of the proxy statement/prospectus, without charge at the SEC’s website http://www.sec.gov or by directing a request toir@bigcypressaccorp.com.

Participants in the Solicitation

Big Cypress, SAB and their respective directors, executive officers, other members of management, and employees, under SEC rules, may be deemed to be participants in the solicitation of proxies of Big Cypress’ stockholders in connection with the proposed business combination. Investors and security holders may obtain more detailed information regarding the names and interests in the proposed business combination of Big Cypress’ directors and officers in Big Cypress’ filings with the SEC including the Registration Statement that has been submitted to the SEC by Big Cypress, once finalized, which will include the proxy statement of Big Cypress for the proposed business combination, and such information and names of SAB’s directors and executive officers also be in the Registration Statement submitted to the SEC by Big Cypress, which will include the proxy statement of Big Cypress for the proposed business combination.

Non-Solicitation

This press release is not a proxy statement or solicitation of a proxy, consent or authorization with respect to any securities or in respect of the potential transaction and shall not constitute an offer to sell or a solicitation of an offer to buy the securities of Big Cypress

or SAB, nor shall there be any sale of any such securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of such state or jurisdiction. No offer of securities shall be made except by means of a prospectus meeting the requirements of the Securities Act of 1933, as amended.

View source version on businesswire.com:
https://www.businesswire.com/news/home/20211004005414/en/

Melissa Ullerich
+1 605-679-4609
mullerich@sabbiotherapeutics.com

Source: SAB Biotherapeutics, Inc.