SAB Biotherapeutics Unveils New Data at ISIRV OPTIONS XI Conference Validating SAB-176 Proof of Concept in Reducing Viral Load and Improving Symptoms of Influenza and Showing SAB-185 Effective Against Multiple COVID-19 Variants Including Omicron

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SAB's fully-human polyclonal antibody platform maintains its efficacy against multiple variants of several highly mutating viruses

SIOUX FALLS, S.D., Sept. 28, 2022 (GLOBE NEWSWIRE) -- SAB Biotherapeutics (Nasdaq: SABS), ("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, released today new data presented at the Options for Control of Influenza (OPTIONS XI) conference, which is hosted by the International Society for Influenza and other Respiratory Virus Diseases (ISIRV) in Belfast, Northern Ireland, from Sept. 26-29, showing its fully-human polyclonal antibody platform maintains its efficacy against multiple variants of several highly mutating viruses.

On Thursday, Sept. 29, at 11:24 am BST, SAB will deliver an oral presentation of its Phase 2a challenge trial that shows SAB-176 reduced the viral load in subjects exposed to H1N1 influenza virus, improved symptoms by day four and shortened the timeframe for viral shedding. On Tuesday, Sept. 27, SAB conducted a poster presentation highlighting data that its SAB-185 COVID-19 polyclonal antibody therapeutic candidate was effective in animal models against the majority of known SARS-CoV2 variants, including the recently evolving Omicron variants.

"Both of these programs show the power of polyclonal antibodies to neutralize highly mutating viruses and the differentiation of SAB's novel therapeutic products," said Eddie Sullivan, co-founder, President, and Chief Executive Officer of SAB. "These data highlight that our technology produces neutralizing antibodies that create an envisioned evergreen therapeutic aimed to maintain efficacy against rapidly mutating pathogens."

SAB's oral presentation, titled "Efficacy and Safety of SAB-176, a Novel Anti-Type A and B Influenza Immunotherapeutic: A Phase 2a, Randomized, Double-Blind Trial in H1N1 Challenged Adults," presents clinical data that SAB-176 met its primary endpoint of reducing the nasopharyngeal viral load in subjects challenged with H1N1 A/California/2009-like virus. SAB-176 also met secondary endpoints of reducing symptoms by day four and shortened the timeframe of the ability to culture virus *in vitro*, suggesting reduced viral shedding, and was safe and well tolerated.

For this randomized and double-blinded trial, 60 participants were randomized in 1:1 fashion – 30 participants received SAB-176 and 30 received placebo 20-24 hours after influenza H1N1 virus challenge on day 0. Participants received 25 mg/kg of SAB-176 diluted in normal saline or an equivalent volume of normal saline (placebo) in a single IV infusion. Participants were quarantined for up to 11 days (day 2 to 8) and were discharged on day 8. Participants returned for one outpatient visit on day 28.

The trial achieved a statistically significant reduction in nasopharyngeal viral load and symptom reduction at day 4, shortened the time of viable virus shedding and demonstrated safety. Further, SAB-176 developed against recent seasonal influenza A and B strains, demonstrated efficacy against the 2009 pandemic H1N1 strain in this clinical trial. These clinical results were anticipated as SAB-176 showed significant preclinical HAI titers to multiple current and previous seasonal Type A and Type B influenza strains.

"SAB's challenge trial for SAB-176 established proof of concept for this important clinical program," said Alexandra Kropotova, M.D., Chief Medical Officer at SAB. "The trial not only proved that viral load and symptoms could be reduced, but it also reinforced SAB-176's ability to generate broadly neutralizing antibodies to H1N1 pandemic strain as well as all tested viral variants of influenza A and B. Overall, these results demonstrate the potential for broad efficacy against current and unknown future influenza strains that will undergo mutational changes. This trial is an important leap forward in SAB's clinical progress."

SAB's poster presentation, titled "Transchromosomic Bovine-Derived Human Anti-SARS-CoV-2 Polyclonal Antibodies Protect hACE2 Transgenic Syrian Hamsters Against Multiple SARS CoV-2 Variants," presented on Tuesday, Sept. 27, detailed SAB's approach using a human anti-SARS-CoV-2 polyclonal antibody (pAb) generated through SAB's DiversitAb ™ platform, which uses human artificial chromosome-transgenic bovines to produce human IgG preparations after hyperimmunization.

The *in vitro* neutralizing capacity of SAB-185 was tested against 10 variant SARS-CoV-2 strains, including several Omicron variants. SAB-185 exhibited equivalent neutralization of the Munich, Alpha, Beta, Gamma and D144-146 variants, and retained neutralization of the delta variant AY.1 and Omicron variants BA.1.1.529, BA.2.12.1, BA.4 and BA.5, with only modest losses of neutralization activity. For *in vivo* protection studies, SAB used a human ACE2 (hACE2) transgenic Syrian hamster model that exhibits rapid lethality after intratracheal SARS-CoV-2 challenge with the Munich, Alpha, Beta, Delta, and D144-146 variants; the Omicron B.1.1529 variant resulted in a delayed, less severe, and non-lethal disease. Prophylactic SAB-185 treatment protected the hamsters from death and minimized clinical signs of infection when challenged with the variant viruses tested.

"This data suggests that SAB-185 may be an effective immunotherapy even in the presence of ongoing viral mutation," Dr. Kropotova said. "SAB's data showing efficacy for all tested prominent COVID variants points to the benefits of our approach to use fully-human polyclonal antibodies in effectively targeting pathogens that mutate over time. The loss of efficacy of some current COVID-19 therapies against prevalent COVID strain highlights the potential of high potency, broadly neutralizing fully-human polyclonal therapies such as SAB-185 against SARS-CoV2 and other rapidly mutating viruses."

About SAB Biotherapeutics, Inc.

SAB Biotherapeutics, Inc. (SAB) We are a clinical-stage biopharmaceutical company focused on the development of powerful and proprietary immunotherapeutic polyclonal human antibodies to treat and prevent infectious diseases and immune and autoimmune disorders. Our development programs include infectious diseases resulting from outbreaks and pandemics, as well as immunological, gastroenterological, and respiratory diseases that have significant mortality and health impacts on immune compromised patients. SAB has applied advanced genetic engineering and antibody science to develop transchromosomic (Tc) Bovine™. Our versatile DiversitAb™ platform is applicable to a wide range of serious unmet needs in human diseases. It produces natural, specifically targeted, high-potency, fully-human polyclonal immunotherapies without the need for human donors. 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.SAb.bio/ and follow SAB on Twitter and LinkedIn.

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, including the development and efficacy of our influenza program, C. diff. program, Type 1 Diabetes program, and other discovery programs, the likelihood that a patent will issue from any patent application, the results, including timing, of the development of SAB-195 (including any IND filing or proposed clinical trials), financial projections and future financial and operating results (including estimated cost savings and cash runway), the outcome of and potential future government and other third-party collaborations or funded programs (including negotiations with the DoD). These statements are based on the current expectations of SAB and are not predictions of actual performance, and are not intended to serve as, and must not be relied on, by any investor as a guarantee, prediction, definitive statement, or an assurance, of fact or probability. These statements are only current predictions or expectations, and are subject to known and unknown risks, uncertainties and other factors which may be beyond our control. Actual events and circumstances are difficult or impossible to predict, and these risks and uncertainties may cause our or our industry’s results, performance, or achievements to be materially different from those anticipated by these forward-looking statements. A further description of risks and uncertainties can be found in the sections captioned “Risk Factors” in our most recent annual report on Form 10-K, subsequent quarterly reports on Form 10-Q, and other filings with or submissions to, the U.S. Securities and Exchange Commission, which are available at https://www.sec.gov/ Except as otherwise required by law, SAB disclaims any intention or obligation to update or revise any forward-looking statements, which speak only as of the date they were made, whether as a result of new information, future events or circumstances or otherwise.

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