SAB Biotherapeutics Announces Progress on U.S. FDA's Phased Review of Company's Groundbreaking DiversitAb™ Platform

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- *FDA has approved five of seven sections in a rolling submission required for a New Animal Drug Application (NADA) for Company's antibody generating DiversitAb™ platform in Transchromosomic (Tc) Bovine™*

- *Announcement further solidifies SAB leading position in delivering, fully-human high-potency target-specific multi-epitope binding immunoglobulin (hIgG) antibody treatments without the need for human donors*

SIOUX FALLS, S.D., May 09, 2023 (GLOBE NEWSWIRE) -- SAB Biotherapeutics (SAB, Nasdaq: SABS), a clinical-stage biopharmaceutical company with a novel immunotherapy platform that produces specifically targeted fully-human multi-epitope binding immunoglobulin (hIgG) antibodies, also known as fully-human polyclonal antibodies, without the need for human donors, today announced the U.S. Food and Drug Administration has approved five of seven sections required for the Company's pending New Animal Drug Application (NADA) for the company's antibody-generating platform in Transchromosomic (Tc) bovine.

SAB is in the process of completing the remaining two sections of the NADA. Upon formal acceptance of the seven-step safety and effectiveness evaluation, the company will use this approval in support of Biologics License Applications (BLAs) with the FDA Center for Biologics Evaluation and Research (CBER) for its hIgG antibody investigational drugs.

"SAB is the only company in the world progressing this kind of advanced genetic engineering to develop rapid, scalable production of highly potent, fully-human polyclonal IgG antibodies, without the need for human donors," said Eddie J. Sullivan, Ph.D., co-founder, President, and Chief Executive Officer of SAB Biotherapeutics. "The FDA has an established regulatory pathway to review our cutting-edge science, and we are pleased to be making significant progress. This process is a one-time approval that will be applicable for all subsequent investigational products produced from the DiversitAb™ platform using our transchromosomic bovine. SAB is focused on a successful completion of NADA to rapidly pursue BLA approvals for our investigational therapeutics."

SAB continues to work closely with the FDA's Center for Veterinary Medicine (CVM) and CBER to establish a NADA approval for the Company's Tc bovine-based antibody-generating platform. In following this regulatory pathway, SAB's proprietary platform will be further protected from any potential future generic competition beyond the 12-year exclusivity timeframe typically granted to newly approved biologics. Other FDA approved human therapeutics for patients have successfully utilized the NADA process.

"The NADA process is complex and our progress in completing five out of seven sections further solidifies our leading position in delivering fully human multi-epitope binding antibody treatments without a need for human donors," said Alexandra Kropotova, MD, Chief Medical Officer of SAB Biotherapeutics. "We have a clinically validated platform with a clear regulatory path which has been used to develop products that we've taken to Phase II and III clinical trials. Recent Breakthrough Therapy and Fast Track designations for one of our leading compounds further support our regulatory path that is well-established and de-risked. Few, if any, other companies have the same capability."

SAB's Tc Bovine are a unique and proprietary component of SAB's DiversitAb™ platform that creates exponentially higher amounts of hIgG antibody treatments with preferential pharmacological properties compared to animal-derived or synthetic human monoclonal immunotherapies. Cows are ruminant animals that inherently have a more robust immune response than humans. This response is stimulated when an immunogen specific and exclusive to a target is introduced to SAB's Tc Bovine and boosted further with a specialized formulation and strategy that maintains a high level of antibody production over an extended period of time. This technology enables batch-to-batch consistency of large amounts of diverse, high-titer, high-avidity hIgG antibodies, which lead to a nearly endless supply of high-potency therapeutics—without the need for human donors.

SAB is leveraging its DiversitAb platform to discover and develop product candidates with the potential to be first-in-class or best-in-class against complex targets to treat or prevent diseases with significant unmet medical needs. These include infectious respiratory and gastroenterological diseases, autoimmune disorders, and oncology. DiversitAb™ is a proven platform with recent regulatory validation, with the FDA granting both Fast Track designation and Breakthrough Therapy designation to SAB-176, an investigational therapeutic for Type A and Type B influenza illness in high-risk patients, including those who have anti-viral resistant strains. SAB also recently announced positive top-line results from the Phase 3 National Institutes of Health's (NIH) ACTIV-2 clinical trial that assessed SAB-185 in non-hospitalized people with COVID-19 who were at high risk for severe outcomes with demonstrated efficacy against the Omicron variant.

About SAB Biotherapeutics, Inc.
SAB Biotherapeutics, Inc. (SAB) is 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 unme 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, the development and efficacy of our influenza program, C. diff. program, type 1 diabetes

program, and other discovery programs, the results, including timing, of the development of SAB-176, SAB-185, SAB-142 and SAB-195, including SAB-176 Fast Track designation and Breakthrough Therapy designation, and the outcome of potential future government and other third-party collaborations or funded programs.

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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