SAB Biotherapeutics Advancing Pipeline and Expands into Treatment for C. Diff. as DoD Contract Winds Down

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SIOUX FALLS, S.D., Aug. 09, 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, announced that it will be discontinuing its work with the U.S. Department of Defense (DoD) under a prototype research and development agreement. The agreement, which was awarded in the summer of 2019, underwent significant modifications as a result of the COVID-19 pandemic, and the government's evolving requirements no longer align with the goals of the agreement as originally contemplated. As part of the closeout process, SAB and the DoD will engage in a comprehensive negotiation to address all open items under the agreement, which is expected to include a multi-million-dollar payment to SAB.

The conclusion of SAB's agreement with the DoD will allow the company to focus on its core priorities and expand its current pipeline, as illustrated by today's announcement regarding the launch of SAB's new, differentiated research program to use its first-of-its-kind polyclonal antibody technology to treat Clostridioides difficile Infection (CDI or C. diff.), a potentially terminal gastrointestinal infectious disease with few effective treatments and the most common healthcare-acquired pathogen.

"Our work with the federal government has accelerated SAB's proof of concept and scientific prowess of our unique antibody platform," said Eddie Sullivan, co-founder, President and Chief Executive Officer of SAB Biotherapeutics. "We wish to thank our DoD partners for their support, collaboration, and belief in SAB's science. We stand ready to support our nation's men and women in uniform as they address our national security needs. We're excited to lean fully into our own cutting edge research programs which we believe will result in the development of accessible life-changing medications to patients in need. This renewed focus on our core mission also allows us to expand our pipeline, including the addition of our new treatment for Clostridioides difficile Infection, a devasting disease with few effective treatment options."

SAB has advanced its preclinical program, SAB-195, a polyclonal antibody treatment for C. diff., one of the most prevalent healthcare-associated bacterial infections in the US and the developed world. The CDC estimates that about 500,000 people are infected per year and about 30,000 patients die annually from C. diff. in the US alone. C. diff. is a bacterial infection of the large intestine (colon). Symptoms range from mild diarrhea to severe infection characterized by abdominal pain, fever, diarrhea, nausea, and vomiting. Complications of severe C. diff. include kidney failure, toxic megacolon, bowel perforation, and death.

While treatments exist, they are associated with high rates of recurrent disease that are even more difficult to treat than the primary infection. It is established that antibiotics, the current standard of care for C. diff., are associated with emergence of bacterial resistance. Fecal transplants, the last-line treatment of C. diff., are not FDA-approved, have been associated with severe E Coli and other infections, are contraindicated to immuno-compromised patients who are at highest risk for C. diff. and lack standardization in manufacturing. SAB believes SAB-195 can have neutralizing activity against both C. diff. bacteria and multiple strains of toxins.

"The dual mechanism of action is not only comprehensively targeting the entire complex life-cycle of this pathogen, but also aims at providing superior efficacy in reducing infection recurrence, hospitalizations, and duration of hospital stay," said Alexandra Kropotova, M.D., Chief Medical Officer at SAB Biotherapeutics. "Unlike current treatments, SAB-195 is being developed for two indications – treatment of C. diff. and prevention of recurrence of C. diff. in high-risk patients."

SAB expects filing an IND within 18 months and announcing topline results, including indication of biological activity, from a Phase 1 clinical trial in 2024.

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.

CONTACTS:

Investor Relations:
SABIR@westwicke.com

Media Relations:
SABPR@westwicke.com