SAB Biotherapeutics Announces Exclusive Manufacturing Partnership with Emergent BioSolutions

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SIOUX FALLS, S.D. and GAITHERSBURG, Md., Oct. 27, 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, today announced the company has entered into an exclusive manufacturing services agreement with Emergent BioSolutions Inc. (NYSE: EBS). Emergent will provide contract development and manufacturing (CDMO) services to produce SAB's fully-human polyclonal antibody products. Currently, SAB has clinical-stage programs in pan-influenza treatment, treatment of acute and recurrent C. diff., prevention of Type 1 diabetes, and discovery assets in immunology and oncology.

Under the terms of the agreement, Emergent will provide end-to-end Good Manufacturing Practice (cGMP) manufacturing services to SAB, including process development and manufacturing clinical investigational drug product to support SAB's clinical programs, and commercial manufacturing services upon regulatory approval of SAB's therapeutics. The agreement also provides the opportunity for Emergent to utilize SAB's novel DiversitAb™ platform, the only one in the world that produces fully-human polyclonal antibodies utilizing transchromosomic cows, for future development of undisclosed programs. Financial details of the agreement were not disclosed.

"Emergent is a world leader in plasma purification from both humans and animals and excels in this specialized area of drug development and manufacturing," said Eddie Sullivan, co-founder, President and Chief Executive Officer of SAB Biotherapeutics. "Partnering with Emergent at this stage allows SAB to focus solely on research and development of our polyclonal antibody drug candidates. In Emergent, we've found a terrific partner with highly specialized expertise and experience with our novel approach."

SAB's technology platform leverages the natural human immune response to develop next-generation, fully-human polyclonal antibody therapeutics without the need for human plasma, extending both safety and potency. These high-avidity antibodies have proven to neutralize a broad spectrum of pathogens and treat disease, and address mutation, an advantage over monoclonal antibody therapeutics. SAB's platform represents, for the first time, the ability to produce targeted, fully-human, high-potency polyclonal therapies on a commercial scale. SAB's novel platform can consistently and reliably produce fully human antibodies without the need for convalescent plasma from human donors. Tc Bovine™ – SAB's genetically engineered cows – mount the same immune response as humans, only with a much higher concentration and potency of targeted neutralizing antibodies directed at multiple pathogens and in large quantities, through a more simplified and controlled process than has previously been possible.

"Emergent is pleased to leverage its deep expertise in the complex process development and manufacturing of plasma-derived therapies to support SAB's clinical and potentially commercial therapeutic programs," said Bill Hartzel, senior vice president and Head of the CDMO Business at Emergent BioSolutions. "As one of Canada's most successful, longest standing pharmaceutical manufacturing sites, Emergent's Winnipeg facility is uniquely equipped to offer integrated drug substance and drug product manufacturing services to help bring SAB's critical and novel drug candidates to patients around the globe."

Emergent has deep expertise with plasma products generated for targeted therapies. For decades, Emergent's hyperimmune specialty plasma antibody manufacturing platform has been used to create multiple drugs up to a scale of 1000L. This includes its human platform, purified gamma globulin (IgG) containing polyclonal antibodies to specific antigens obtained from human plasma, and its equine platform, purified immunoglobulin fragments derived from polyclonal antibodies to specific antigens obtained from equine plasma.

About SAB Biotherapeutics
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. I 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.

About Emergent BioSolutions
At Emergent, our mission is to protect and enhance life. For over 20 years, we've been at work defending people from things we hope will never happen—so we are prepared just in case they ever do. We provide solutions for complex and urgent public health threats through a portfolio of vaccines and therapeutics that we develop and manufacture for governments and consumers. We also offer a range of integrated contract development and manufacturing services for pharmaceutical and biotechnology customers. To learn more about how we plan to protect or enhance 1 billion lives by 2030, visit our website and follow us on LinkedIn, Twitter, and Instagram.

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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