

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): November 01, 2022**

**SAB BIOTHERAPEUTICS, INC.**

(Exact name of Registrant as Specified in Its Charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-39871**  
(Commission File Number)

**85-3899721**  
(IRS Employer  
Identification No.)

**2100 East 54th Street North**  
**Sioux Falls, South Dakota**  
(Address of Principal Executive Offices)

**57104**  
(Zip Code)

**Registrant's Telephone Number, Including Area Code: 605 679-6980**

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Securities registered pursuant to Section 12(b) of the Act:**

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, \$0.0001 par value per share	SABS	The NASDAQ Stock Market LLC
Warrants, each exercisable for one share of Common Stock at an exercise price of \$11.50 per share	SABSW	The NASDAQ Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

#### **Item 7.01 Regulation FD Disclosure.**

On November 01, 2022, SAB Biotherapeutics, Inc. (the “Company” or “SAB”) led two PowerPoint presentations titled, “*Plasma fractionation and downstream processing of human polyclonal antibodies from the DiversitAb platform*” and “*Phase 2 efficacy and safety of two novel SAB immunotherapies against respiratory disease indications associated with highly mutating viruses*” at the 2022 Plasma Product Biotechnology Conference held in Limassol, Cyprus.

The Company's first presentation provided an overview of SAB's novel immunotherapy platform utilizing a specialized manufacturing process to enable a scalable and reliable production of targeted, higher-potency neutralizing antibody products than has been previously possible. A copy of the first presentation is furnished herewith as Exhibit 99.1 and is incorporated herein by reference.

The Company's second presentation provided data on SAB-185 for COVID-19 and SAB-176 for seasonal and pandemic influenza. The data show that SAB-185 and SAB-176 are highly effective against variants of several highly mutating viruses associated with the diseases, a major challenge in currently available treatments for COVID-19 and influenza. A copy of the second presentation is furnished herewith as Exhibit 99.2 and is incorporated herein by reference.

The foregoing (including Exhibit 99.1 and 99.2) is being furnished pursuant to Item 7.01 of Form 8-K and will not be deemed to be filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise be subject to the liabilities of that section, nor will it be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended (the “Securities Act”), or the Exchange Act. The information contained in each presentation is summary information that should be considered in the context of the Company's filings with the Securities and Exchange Commission and other public announcements the Company may make by press release or otherwise from time to time.

#### *Cautionary Note Regarding 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-176, SAB-185, and 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 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.

#### **Item 8.01 Other Events.**

On November 3, 2022, the Company issued a press release announcing that the Company presented an overview of its DiversitAb™ polyclonal platform and data on SAB-176 and SAB-185 showing the benefits of fully-human polyclonal antibodies derived from SAB's Transchromosomal (“Tc”) Bovine™ over plasma derived antibodies from humans, at the 2022 Plasma Product Biotechnology Conference in Limassol, Cyprus, which concluded on November 03, 2022.

A copy of the press release is attached as Exhibit 99.3 to this Current Report on Form 8-K and is hereby incorporated by reference herein.

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**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits. The exhibits listed on the Exhibit Index are incorporated herein by reference.

<b>Exhibit Number</b>	<b>Description</b>
99.1	<a href="#"><u>Presentation titled, "Plasma fractionation and downstream processing of human polyclonal antibodies from the DiversitAb platform."</u></a>
99.2	<a href="#"><u>Presentation titled, "Phase 2 efficacy and safety of two novel SAB immunotherapies against respiratory disease indications associated with highly mutating viruses."</u></a>
99.3	<a href="#"><u>Press Release of the Company, dated November 3, 2022.</u></a>
104	Cover Page Interactive Data File-the cover page XBRL tags are embedded within the Inline XBRL document.

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SAB Biotherapeutics, Inc.

Date: November 07, 2022

By: /s/ Eddie J. Sullivan  
Eddie J. Sullivan  
Chief Executive Officer

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# Plasma Fractionation and Downstream Processing of Human Polyclonal Antibodies from the DiversitAb™ Platform

**Plasma Product Biotechnology Conference | 2022**

Christoph Bausch, PhD, Chief Operating Officer

## Forward Looking Statements



The material in this presentation has been prepared by SAB Biotherapeutics, Inc. (SAB) and is general background information about SAB's activities current as of the date of this presentation. This information is given in summary form and is not intended to be complete. Information in this presentation, including financial forecasts, should not be considered advice or a recommendation to investors or potential investors in relation to holding, purchasing or selling securities or other financial products or instruments and does not take into account any particular investment objectives, financial situation or needs.

This presentation may contain forward looking statements including statements regarding our intent, belief or current expectations with respect to SAB's businesses and operations, market conditions, results of operations and financial condition, capital adequacy, specific provisions and risk management practices. Readers are cautioned not to place undue reliance on these forward-looking statements. SAB does not undertake any obligation to update any information herein for any reason or to publicly release the result of any revisions to these forward-looking statements to reflect events or circumstances after the date hereof to reflect the occurrence of unanticipated events. While due care has been used in the preparation of forecast information, actual results may vary in a materially positive or negative manner and the presentation may contain errors or omissions. Forecasts and hypothetical examples are subject to uncertainty and contingencies outside SAB's control. Past performance is not a reliable indication of future performance.

Unless otherwise specified, information is current at the date hereof, unless specifically noted.

# Novel DiversitAb™ Platform for Developing Highly-Differentiated Immunotherapies



Robust, growing clinical-stage pipeline spanning multiple therapeutic areas



Vertical integration enables rapid, scalable development of multi-targeted products



Leveraged advanced genetic engineering & antibody science to develop Tc bovine-derived fully-human polyclonal antibodies



Established proof-of-concept through US Government funded programs & partnerships totaling ~\$200MM



Strong corporate position with experienced leadership team and growing infrastructure



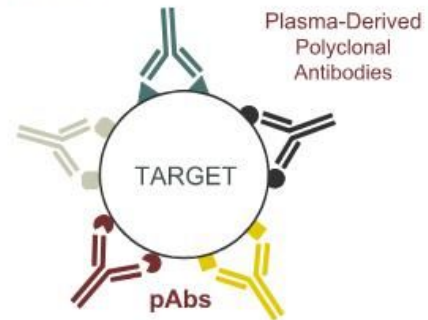
**Innovative DiversitAb™ platform produces a new class of targeted fully-human, highly-potent polyclonal antibodies**

# SAB Polyclonal Antibodies: Next Generation of Biologics

## Key Product Differentiators:

- Multi-target capability in a single therapeutic
  - ✓ Natural multi-epitope targeted pAb selected and produced *in vivo*
  - ✓ Ability to target multiple antigens to disease
- Specifically driven high-potency antibody titers and avidity
- Naturally activates cellular immunity
- Ability to target human antigens

FDA: CENTER FOR **BIOLOGICS** EVALUATION & RESEARCH (CBER)

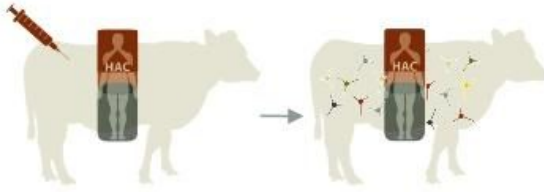


Natural mixture of many **human** antibodies that bind to multiple epitopes

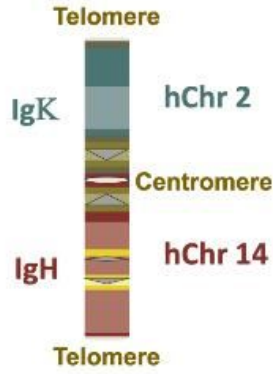


# A Natural Way to Produce Human Polyclonal Antibodies

Tc Bovine™ contain all the human immunoglobulin genes



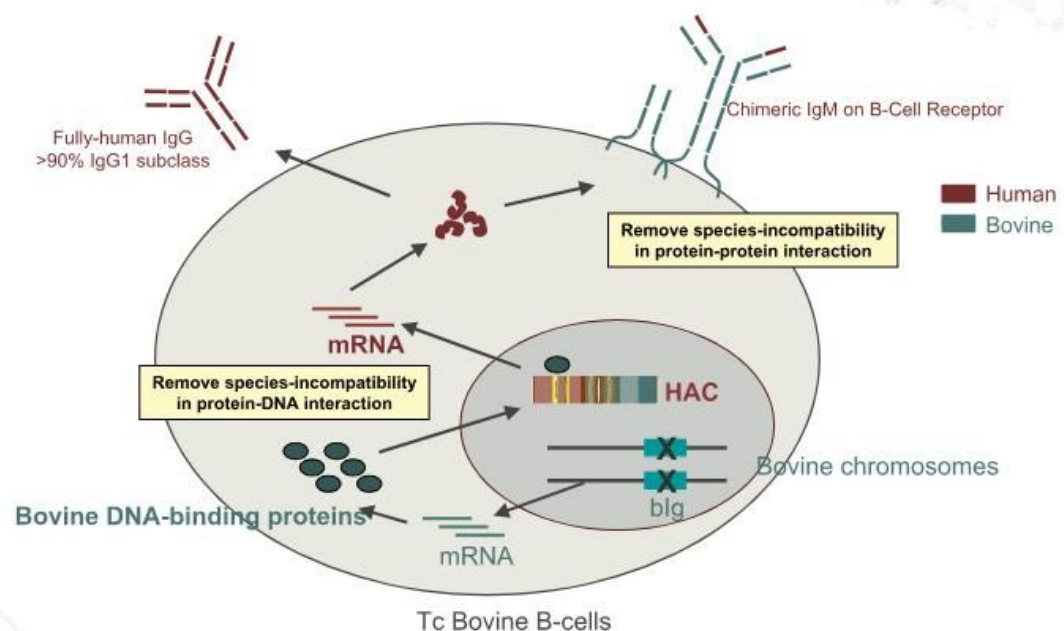
**Human artificial chromosome (HAC)**  
~17Mb contains the entire unarranged VDJ human immunoglobulin loci (IgH + IgK)



## Tc Bovine

- Only transgenic animal that carries the entire human immunoglobulin (Ig) heavy and light ( $\kappa$ ) chain loci.
- HAC is subject to mitosis along with the other 60 Tc Bovine chromosomes.
- HAC present in the Tc Bovine allows for the highest production of human antibody repertoire most similar to humans.

# Human Antibody Production in Bovine B-Cell



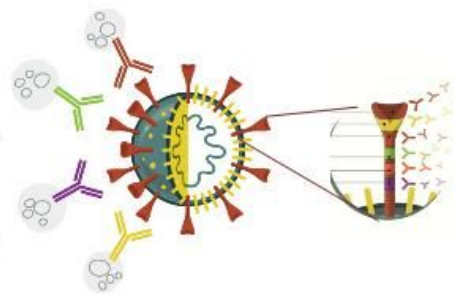
# B-Cells Produce Anti-Target Fully-Human Polyclonal Antibodies



Antigen



Transferred full germline repertoire of human antibody response



Rich diversity of IgG antibodies to Spike protein epitopes  
Fc binding to FcR ligands allows effector cell recruitment & activates complement



**Hyperimmunization**  
Multiple immunizations drive titers to extremely high levels with exceptional avidity maturation and potency

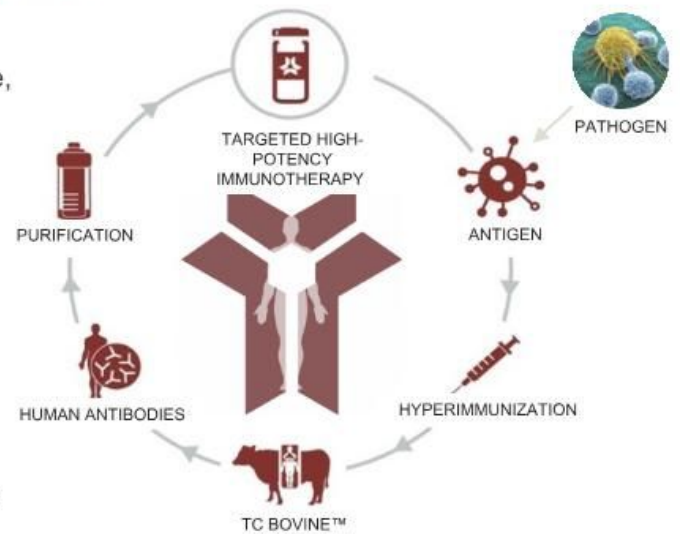
**B-Cells Produce Human Antibodies**  
Natural and somatic mutation drives very high-level B-cell clone avidity maturation in Tc Bovine

**Therapeutic**  
Diverse mixture of anti-Target human polyclonal antibodies allowing production of a fully-human immunoglobulin (hIgG)

## First of its Kind DiversitAb™ Platform

Advancing a new class of fully-human polyclonal Tc bovine-derived antibodies without the need for human serum

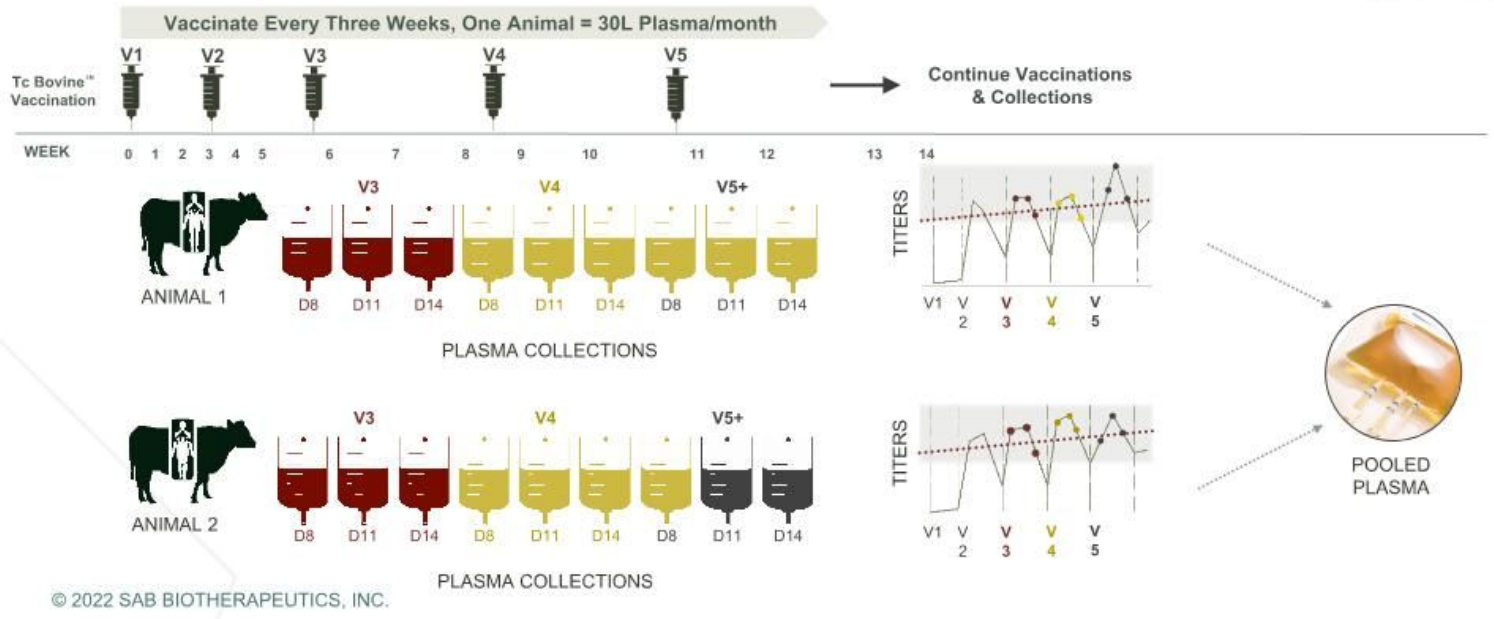
- Reliable, controlled, consistent production of diverse, high-titer, high-avidity, fully-human polyclonal antibodies
- Generated antibodies behave similarly to human-derived with ability to specifically target
- Proprietary immunization strategies and robust immune response drive extremely high potency
- Well-established and understood regulatory path as biologic through FDA-CBER
- Vertical integration enabling rapid, scalable development and production of multivalent products



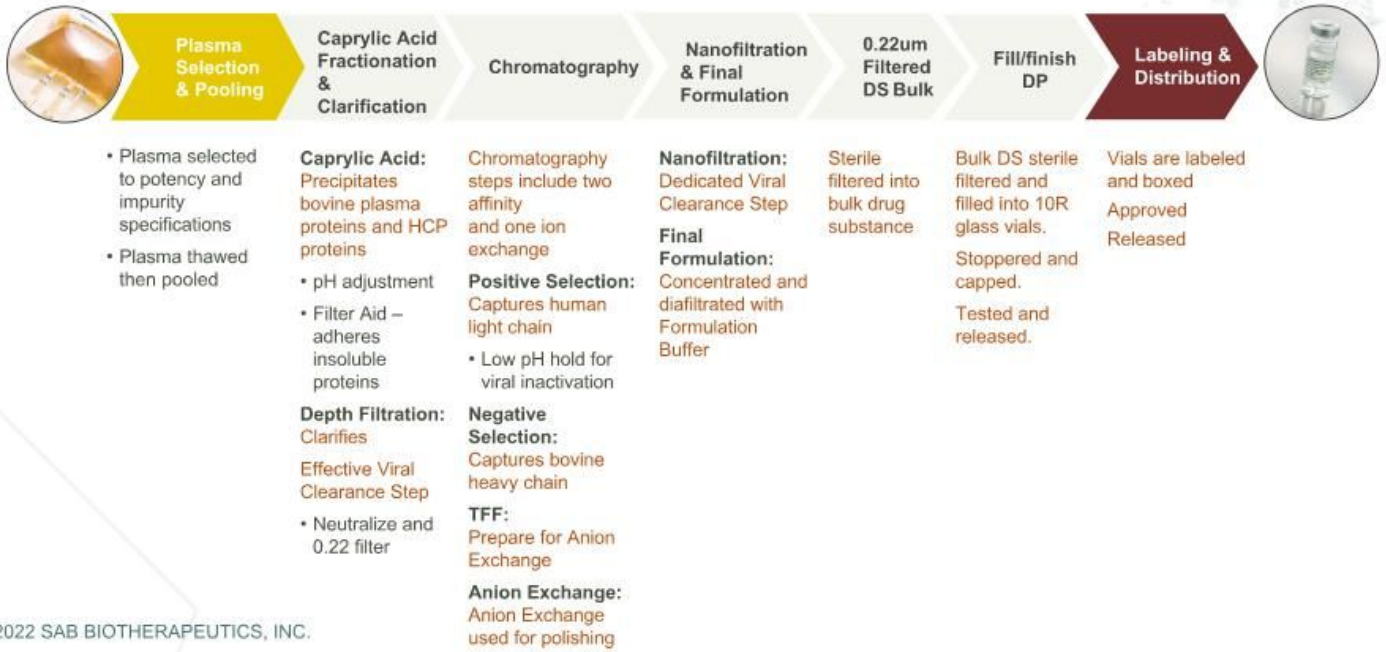
# Upstream Antibody Production



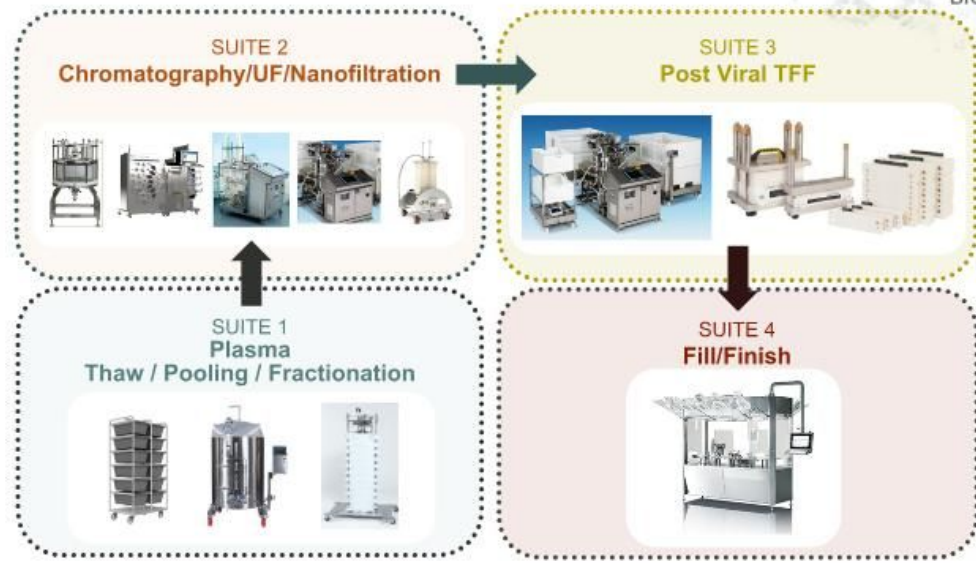
## Procedures for Heterogeneity and Consistent Neutralizing Titers



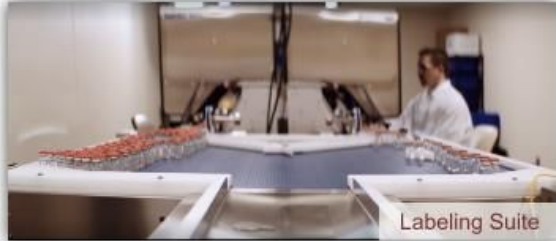
# Downstream Manufacturing Process



# Manufacturing Step Process Overview



# Scaled Infrastructure & Capacity: Laboratory & Manufacturing





# Scaled Infrastructure & Capacity: Tc Bovine & Plasma Production Facility

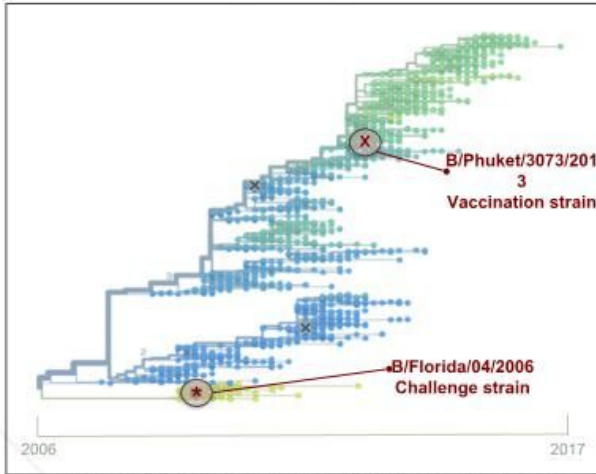


# Efficacy Against Mutational Drift

*Adaptive & Cross Reactive to Mutating Strains*

## Highly-Mutational Influenza Virus

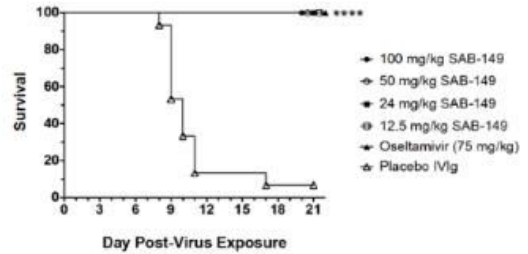
BYAM PHYLOGENIC TREE



SOURCE: NEXTFLU AT [HTTPS://NEXTFLU.ORG/VIC/12Y/](https://nextflu.org/vic/12y/)

## 100% Protection at All Dose Levels in Influenza Mouse Challenge

Antibodies produced to B/Phuket/3073/2013– like virus protected against B/Florida/04/2006



# Highly-Potent: Exceeds Titers of Human Hyperimmune IVIg by up to 128X



## SAB-176 protects against seasonal and pandemic influenza vaccine strains past & future non-vaccine strains

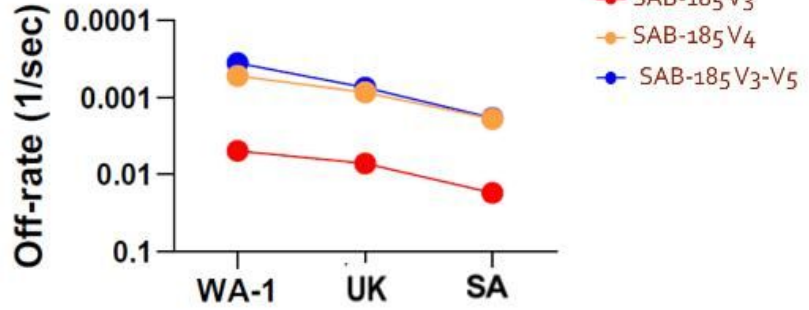
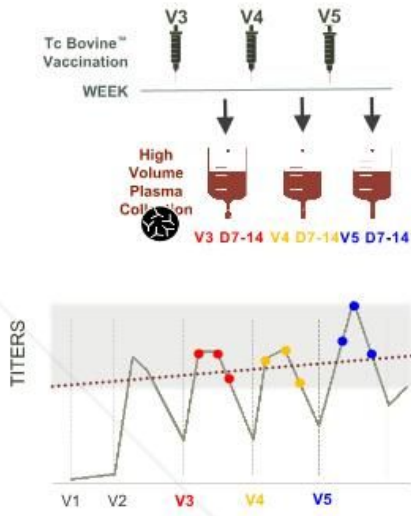
Sample Started at 5mg/ml	H1N1				H3N2			B-Vic			B Yam	
	A/California/4/2009 (Pandemic Strain)	A/Michigan/45/2015	A/Brisbane/02/2018	A/Guangdong-g-maonan/2019	A/Singapore/IN16/2016	A/Kansas/14/2017	A/Hong Kong/45/2019	B/Maryland/15/2016	B/Colorado/06/2017	B/Washington/02/2019	B/Phuket/3073/2013	B/California/12/2015
<b>Anti-Influenza (Tc Bovine-derived quadrivalent hyperimmune)</b>	<b>SAB-176</b>	<b>1:1,024</b>	<b>1:512</b>	<b>1:512</b>	<b>1:512</b>	<b>1:512</b>	<b>1:256</b>	<b>1:256</b>	<b>1:256</b>	<b>1:128</b>	<b>1:256</b>	<b>1:128</b>
		<b>32X</b>	<b>16X</b>	<b>16-32X</b>	<b>16-32X</b>	<b>8-32X</b>	<b>16-128X</b>	<b>16-32X</b>	<b>16-32X</b>	<b>16-32X</b>	<b>32X</b>	<b>16-32X</b>
<b>Anti-Influenza hIVIg (human-derived)</b>	2018	1:32	1:32	1:32	1:32	1:64	1:16	1:16	1:16	1:8	1:8	1:8
	2017	1:32	1:32	1:16	1:16	1:64	1:32	1:16	1:16	1:8	1:8	1:8
	2013	1:32	1:32	1:32	1:16	1:16	1:4	1:8	1:8	1:4	1:8	1:4
Negative Control Antibody		<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1

Vaccine strain (season): 18-19 19-20 20-21 18-21

SAB-176 purified from TcB plasma vaccinated with 18-21 vaccine strain  
HUBER LAB, USD, JUL 2021

# High Avidity: Driven By Hyperimmunization

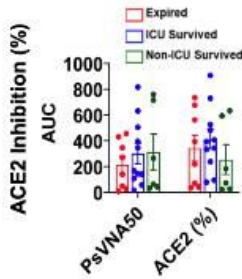
## SAB-185 (Anti-SARS-CoV2) avidity increases with affinity maturation driven by hyperimmunization



SURENDER LAB; DIVISION OF VIRAL PRODUCTS, CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER) FDA 05 APR 2021  
 JOURNAL OF INFECTIOUS DISEASE (2022) SEP 4;226(4):655-663

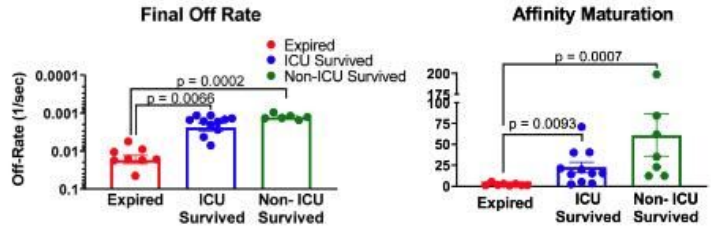
# High Avidity More Closely Linked to Patient Outcomes than Neutralizing Titers

## Neutralization Titers Demonstrate Discordance to Disease Severity & Outcome



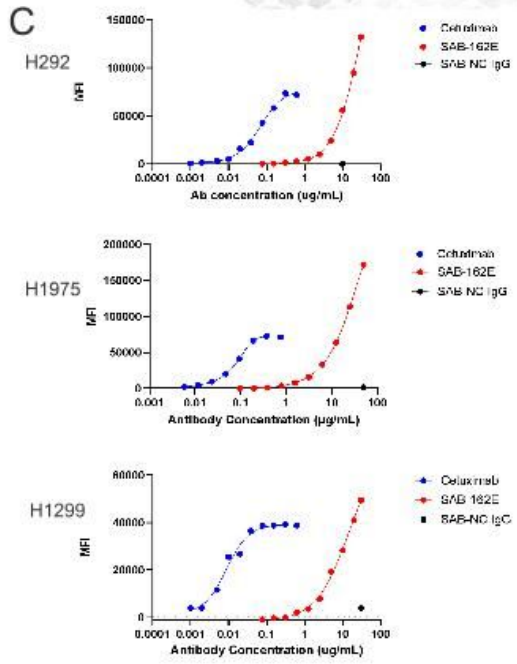
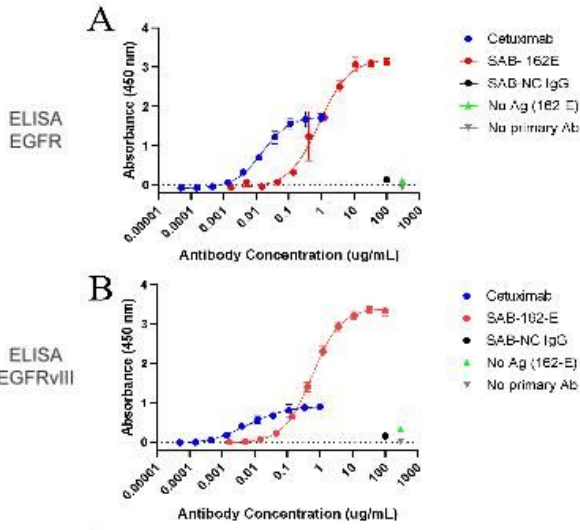
Neutralizing antibody titers and hACE2 receptor inhibition activity of COVID-19 patients' plasma during hospitalization

## High Avidity Shows Direct Correlation to Patient Survival



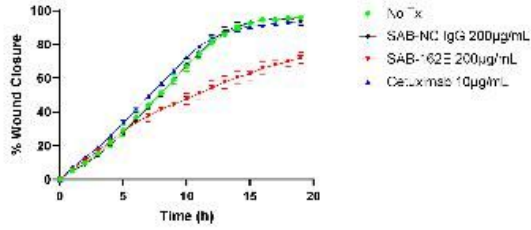
SURENDER LAB; DIVISION OF VIRAL PRODUCTS,  
 CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER) FDA;  
 NATURE COMMUNICATIONS (2021) 12:1221

# Oncology SAB-162E (Human Anti-Human EGFR pAbs) Exhibits High Binding Capability

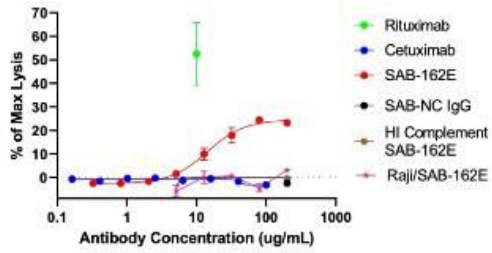


# SAB-162E has Functional Properties for Addressing the Complexity of Cancer

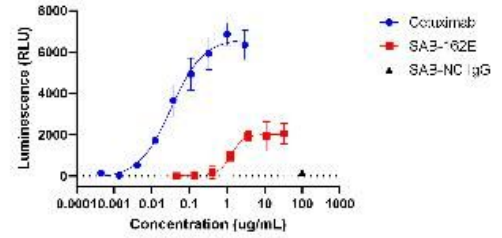
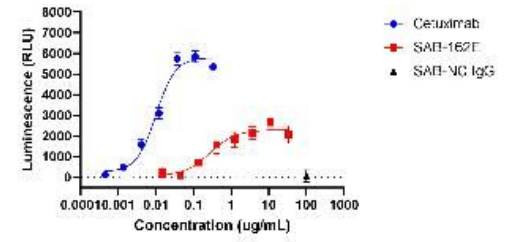
## A SAB-162E inhibits cellular migration of NSCLC cells

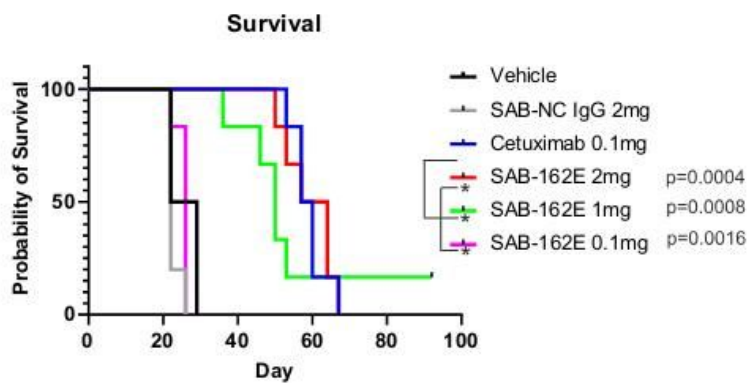
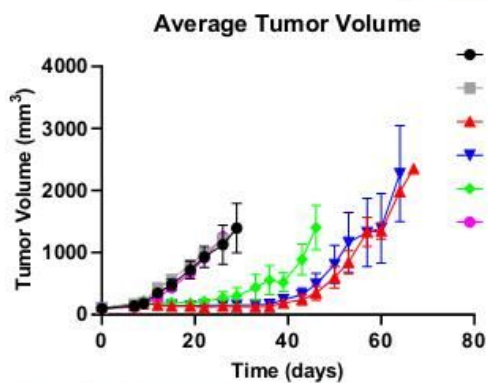
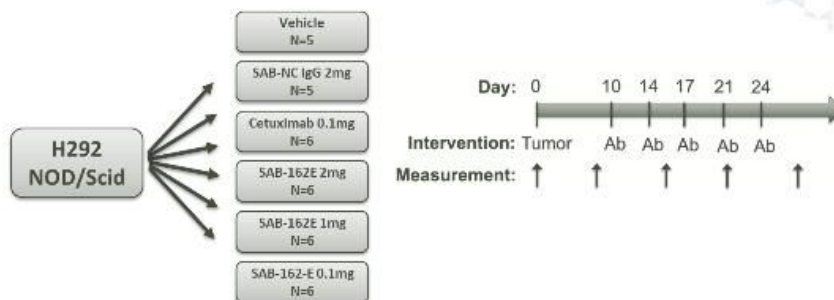


## B SAB-162E activates CDC effector function



## C SAB-162E activates ADCC effector function







## Consistent, Replicable Platform

### *In Vivo Efficacy Demonstrated Across a Broad Range Targets*

TARGET	EFFICACY	MODEL(S)	COLLABORATORS
<b>Anthrax</b>	<b>100%</b>	mouse (lethal)	Food and Drug Administration
<b>Alphaviruses</b>	<b>100%</b> <b>100%</b>	mouse (lethal aerosol) non-human primate (viral clearance)	Naval Medical Research Center, University of Pittsburgh, NIH: National Institute of Allergy and Infectious Diseases
<b>Clostridioides Difficile</b>	<b>100%</b> <b>87%</b>	hamster (lethal) mouse (lethal)	Novavax
<b>Dengue</b>	<b>100%</b>	non-human primate (viral clearance)	Naval Medical Research Center
<b>Ebola</b>	<b>90%</b> <b>100%</b>	mouse (lethal) non-human primate (lethal)	Naval Medical Research Center, NIH: National Institute of Allergy and Infectious Diseases, Novavax
<b>Hantavirus</b>	<b>80-100%</b> <b>100%</b>	hamster (lethal) non-human primate (viral clearance)	United States Army Medical Research Institute of Infectious Diseases
<b>Influenza</b>	<b>100%</b> <b>100%</b>	mouse (lethal) mouse (lethal aerosol)	National Institutes of Health, University of South Dakota, Utah State University, Naval Medical Research Center
<b>Plague</b>	<b>100%</b>	Mouse (lethal aerosolized)	United States Army Medical Research Institute of Infectious Diseases
<b>MERS-CoV</b>	<b>100%</b>	mouse (viral clearance)	Biomedical Advanced Research and Development Authority, Naval Medical Research Center, NIH: National Institute of Allergy and Infectious Diseases, Novavax
<b>SARS-CoV2</b>	<b>100%</b>	hACE2 hamster (lethal)	Biomedical Advanced Research and Development Authority, Naval Medical Research Center, University of Pittsburgh
<b>Zika</b>	<b>100%</b> <b>100%</b> <b>100%</b>	mouse (lethal) hamster (lethal) non-human primate (viral clearance)	Public Health Agency of Canada, Utah State University Harvard University



# Tc Goats™ - Expanding The Human Immunotherapeutic Platform for Personalized Medicine



## Genetic Engineering Science Applied Across Multiple Species



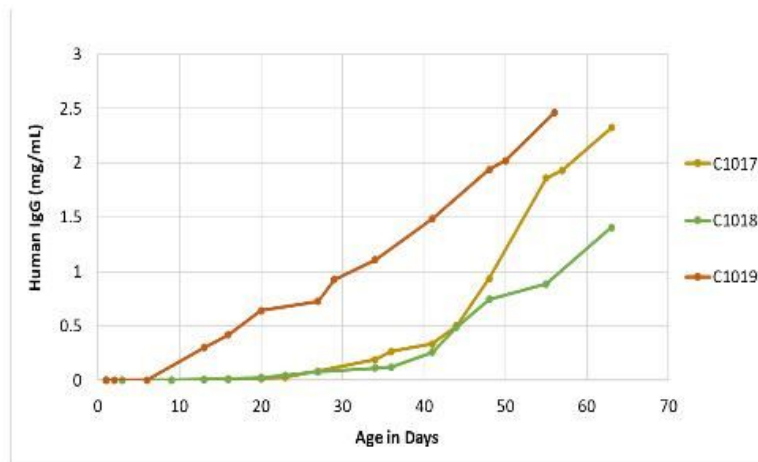
- SAB Capra, LLC. is a wholly-owned subsidiary of SAB Biotherapeutics, Inc.
- Advancing novel antibody production platform leveraging transgenic goats
- Functionality of the HAC proven in a second species (ruminant ungulate)
- Generated H7N9-specific human polyclonal antibodies from Tc Goat (caprine) platform. Scientific Reports, 2019
- SAB Capra Phase 2 STTR Grant (NIH/NIAID): in collaboration with Utah State University
- Total funding \$1,501,157 (\$926,194 to SABC, \$574,963 to USU)
- Two years: 18 Apr 2019 – 31 Mar 2021
- Two times of 12-month no cost extension granted—new end date 31 Mar 2023
- Genetic optimization in our Tc Bovine was done in 10 years while the goat optimization was done in 2 years.

# Demonstrated Fully Human IgG in Tc Goat



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## Human IgG in Tc Capra Kids



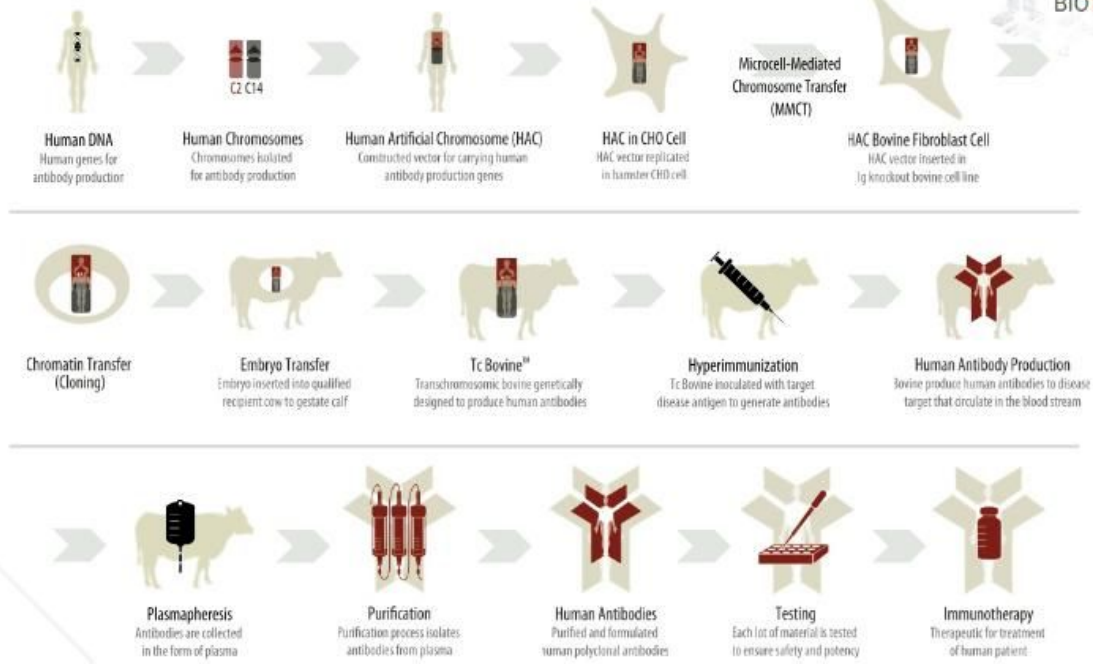
## Advancing the Tc Platform for Continued Advancement of Human Health



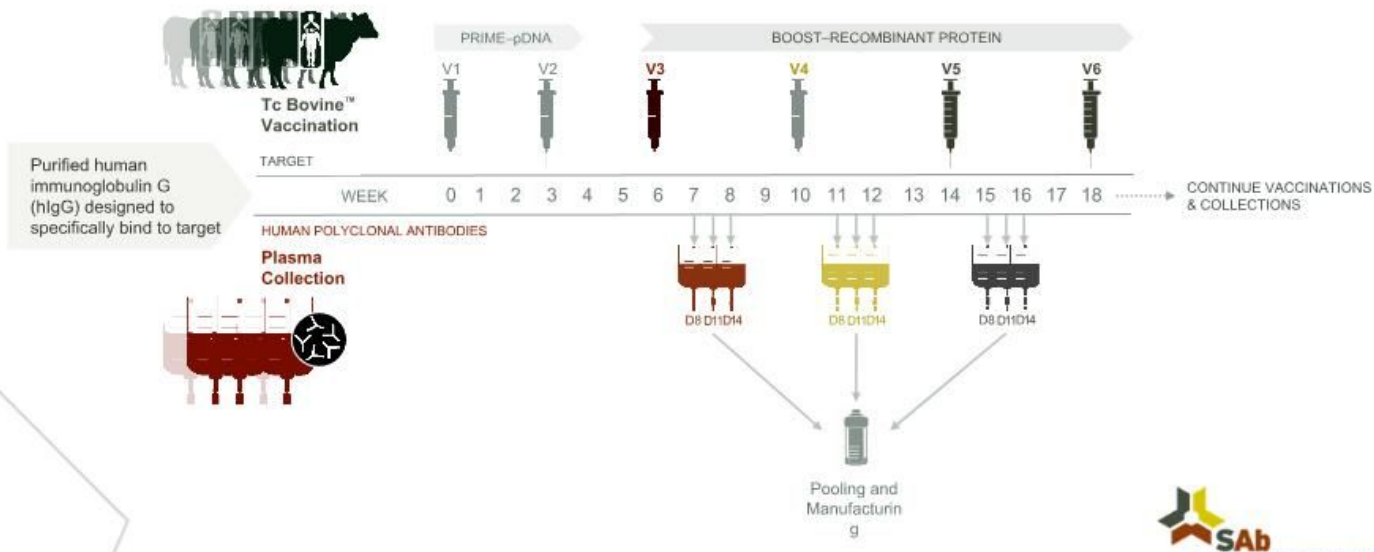
- Developing targeted human polyclonal antibodies for use in personalized medicine
- Tc Goat platform production ready for producing diagnostics and testing reagent applications.
- Accommodating smaller volume markets, lower cost of development and maintenance, and accelerated scaling (shorter gestation, multiple births)



# DiversitAb™ Proprietary Platform Technology

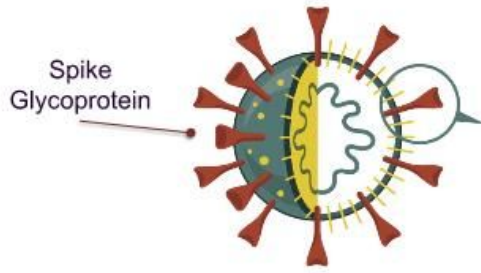


# DiversitAb™ Development Process for Rapid High Titer & Avidity Maturation



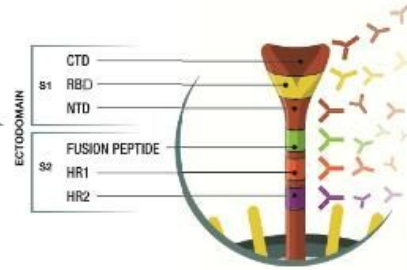
# SAB-185: Specifically Targeted Human Immune Response

## MOA of Novel Polyclonal Antibody Raised Against SARS-CoV-2 Spike Protein



### Spike Glycoprotein

Receptor binding domain in S1 spike protein binds to ACE-2 receptor on human cells; then undergoes a conformational change to allow the S2 spike protein domain to fuse with the cellular membrane leading to infection of the cell



### SAB-185 Polyclonal Spike Protein MOA

Antibodies bind multiple conformations of SARS-CoV-2 extracellular spike protein epitope and appears to prevent most all conformations of the infectious determinant spike protein from interacting with ACE-2 receptors on host cells, allowing effector cells to phagocytize virus and eliminate/lyse infected cells via complement

Multiple blocking and neutralizing antibody species bind to single epitope  
**Multiple blocking and neutralizing** antibodies with uniquely determined and multifactorial paratopes bind to single multi-conformational antigen epitope  
 Diversity of antibodies and uniquely combinatorial paratopes drives effector functions including antibody and complement dependent cellular cytotoxicity



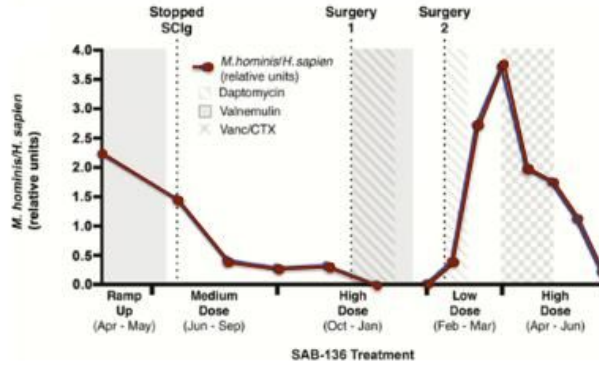
# Positioned for Personalized Medicine

Confirms Feasibility of Multi-dosing

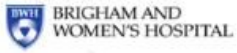
High-dose therapy resulted in improved clinical parameters associated with reduced *M. hominis* burden following two subsequent infections



Open wound persisted ~7 years prior to treatment

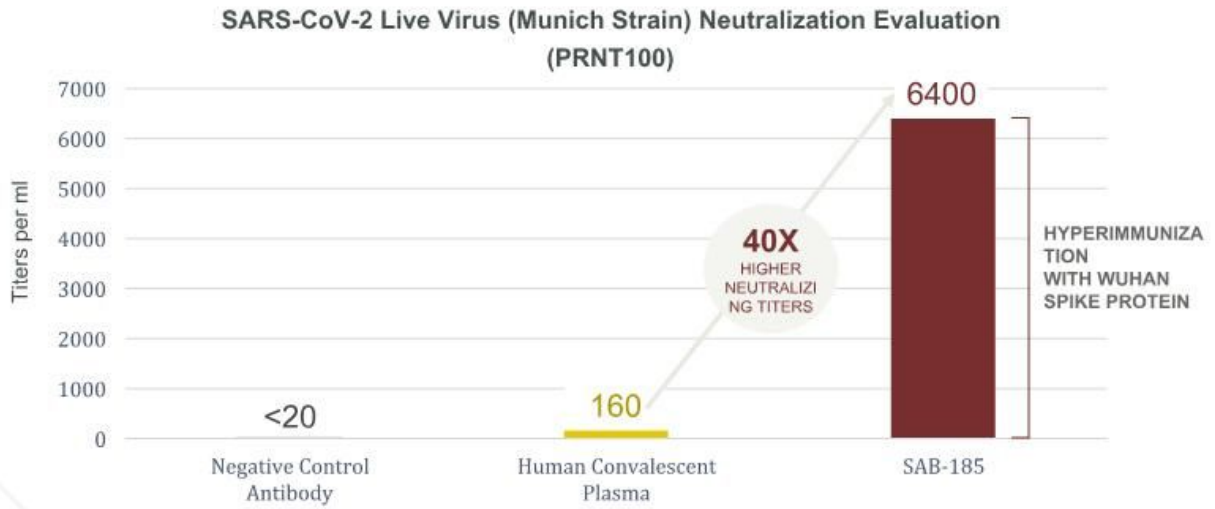


Same area following treatment with SAB - 136



JARED N SILVER, CAMERON D ASHBAUGH, JACOB J MILES, HUA WU, GREGORY T MARECKI, JOYCE K HWANG, JIN-AN JIAO, MARK ABRAMS, EDDIE J SULLIVAN, DUANE R WESEMANN, DEPLOYMENT OF TRANSCROMOSOMAL BOVINE FOR PERSONALIZED ANTIMICROBIAL THERAPY, CLINICAL INFECTIOUS DISEASES, VOLUME 66, ISSUE 7, 1 APRIL 2018, PAGES 1116-1119

# Highly-Potent: Exceeds Titers of Human Convalescent Plasma by 40X



WILLIAM B. KLIMSTRA, PH.D. DEPARTMENT OF IMMUNOLOGY ; MEMBER, CENTER FOR VACCINE RESEARCH; THE UNIVERSITY OF PITTSBURGH

# High Potency and Broad Cross Protective Neutralization



## H1N1

## H3N2

## B-Vic

## B-Yam

Sample Started at 5mg/ml	H1N1								H3N2				B-Vic			B-Yam		G4HA
	A/California/4/2009 (hVIVO)	A/California/4/2009 (Huber stock)	A/Michigan/45/2015	A/Brisbane/02/2018	A/Guangdong/maonan/2019 (Egg)	A/Guangdong/maonan/2019 (Cell)	A/Victoria/2570/2019 (2021-22)	A/Singapore/IN/16-0019/2016	A/Kansas/14/2017	A/Hong Kong/2671/2019 (Egg)	A/Cambodia/e/0826360/2020 (2021-22)	B/Maryland/15/2016	B/Colorado/06/2017	B/Washington/02/2019	B/Phuket/3073/2013	B/California/12/2015		
SAB-176 Lot 4 V3-V12	1:512 (8X)	1:512 (8-16X)	1:512 (16X)	1:512 (16-32X)	1:512 (16-32X)	1:512 (16X)	1:256 (16-32X)	1:512 (8-32X)	1:256 (8-64X)	1:256 (16-32X)	1:256 (8-16X)	1:256 (16-32X)	1:256 (16-32X)	1:128 (16-32X)	1:128 (16X)	1:128 (16-32X)	1:512 (16X)	
SAB-176 Lot 3 V3-V12	1:512 (8X)	1:512 (8-16X)	1:512 (16X)	1:512 (16-32X)	1:512 (16-32X)	1:512 (16X)	1:256 (16-32X)	1:512 (8-32X)	1:512 (16-128X)	1:256 (16-32X)	1:256 (8-16X)	1:128 (8-16X)	1:256 (16-32X)	1:64 (8-16X)	1:128 (16X)	1:128 (16-32X)	1:512 (16X)	
SAB-176 Lot 2 V3-V5	1:1024 (16X)	1:512 (8-16X)	1:512 (16X)	1:512 (16-32X)	1:512 (16-32X)	1:512 (16X)	1:256 (16-32X)	1:512 (8-32X)	1:64 (2-16X)	1:128 (8-16X)	1:256 (8-16X)	1:256 (16-32X)	1:256 (16-32X)	1:128 (16-32X)	1:256 (32X)	1:128 (16-32X)	1:512 (16X)	
SAB-176 Lot 1 V3	1:512 (8X)	1:512 (8-16X)	1:512 (16X)	1:512 (16-32X)	1:512 (16-32X)	1:512 (16X)	1:256 (16-32X)	1:512 (8-32X)	1:64 (2-16X)	1:64 (4-8X)	1:128 (4-8X)	1:256 (16-32X)	1:256 (16-32X)	1:64 (8-16X)	1:128 (16X)	1:128 (16-32X)	1:512 (16X)	
Anti-Flu h1VIG 2013	1:64	1:32	1:32	1:32	1:16	1:32	1:8	1:16	1:4	1:8	1:16	1:8	1:8	1:4	1:8	1:4	1:32	
Anti-Flu h1VIG 2017	1:64	1:32	1:32	1:16	1:16	1:32	1:16	1:64	1:32	1:16	1:32	1:16	1:16	1:8	1:8	1:8	1:32	
Anti-Flu h1VIG 2018	1:64	1:64	1:32	1:32	1:32	1:32	1:16	1:64	1:32	1:16	1:32	1:16	1:16	1:8	1:8	1:8	1:32	
NC Ab	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	

Non-Vaccine strains

Vaccine strains

Dr. Victor Huber, University of South Dakota

# One of Its Kind DiversitAb™ Platform



**Chromatin Transfer  
(Cloning)**



**Embryo Transfer**  
Embryo inserted into qualified  
recipient cow to gestate calf



**Tc Bovine™**  
Transchromosomic bovine genetically  
designed to produce human antibodies



**Hyperimmunization**  
Tc Bovine inoculated with target  
disease antigen to generate antibodies



**Human Antibody Production**  
Bovine produce human antibodies to disease  
target that circulate in the blood stream



**Plasmapheresis**  
Antibodies are collected  
in the form of plasma



**Purification**  
Purification process isolates  
antibodies from plasma



**Human Antibodies**  
Purified and formulated  
human polyclonal antibodies



**Testing**  
Each lot of material is tested  
to ensure safety and potency



**Immunotherapy**  
Therapeutic for treatment  
of human patient

# Manufacturing Process hlgG purification overview



Plasma Request & Pooling

Caprylic Acid Fractionation

Kappa Select Capture Affinity

HC15 (Neg Affinity)

Q-Seph (Polish)



Plasma thawed and pooled to titer and impurity specifications



Fully hlgG

Precipitates bovine plasma proteins and HCP. Viral & Pathogen Reduction



Fully hlgG

Captures Kappa IgG (Reduces clgG and blgG impurities)



Fully hlgG

Captures BlgG HC molecules and enriches for hlgG



Fully hlgG

Polishes and reduces IgA, IgM host cell proteins, DNA, and endotoxin



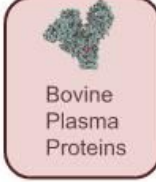
Fully hlgG



Bovine Plasma Proteins



clgG



Bovine Plasma Proteins



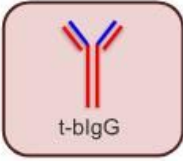
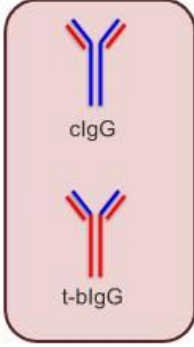
clgG



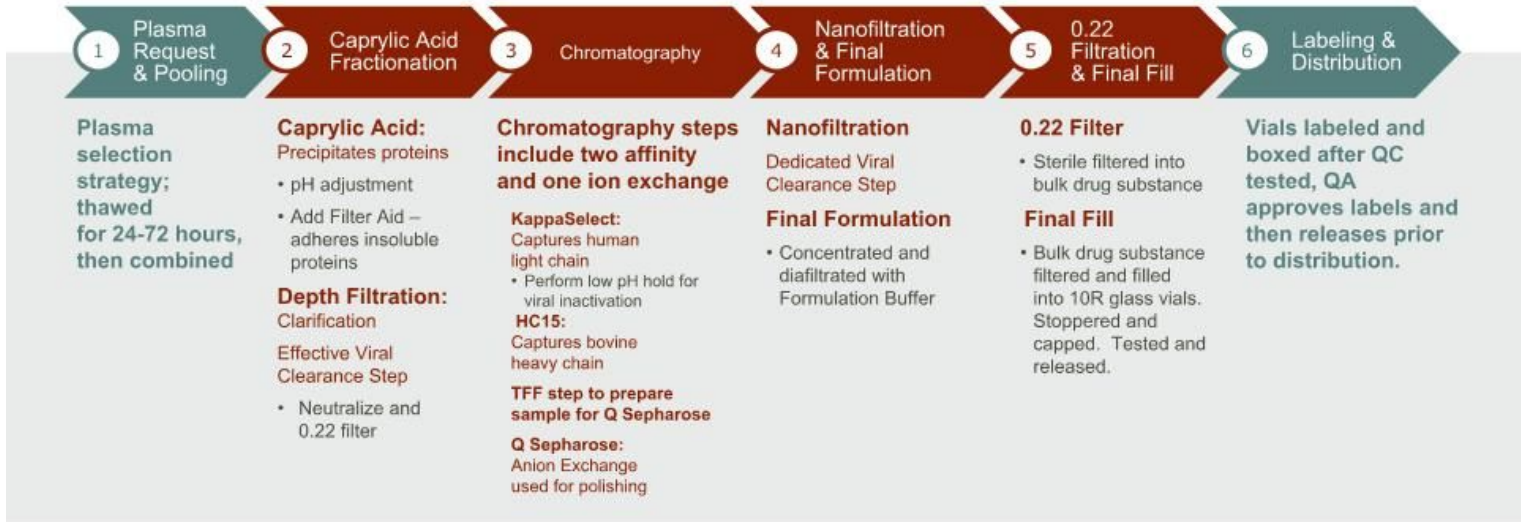
t-blgG



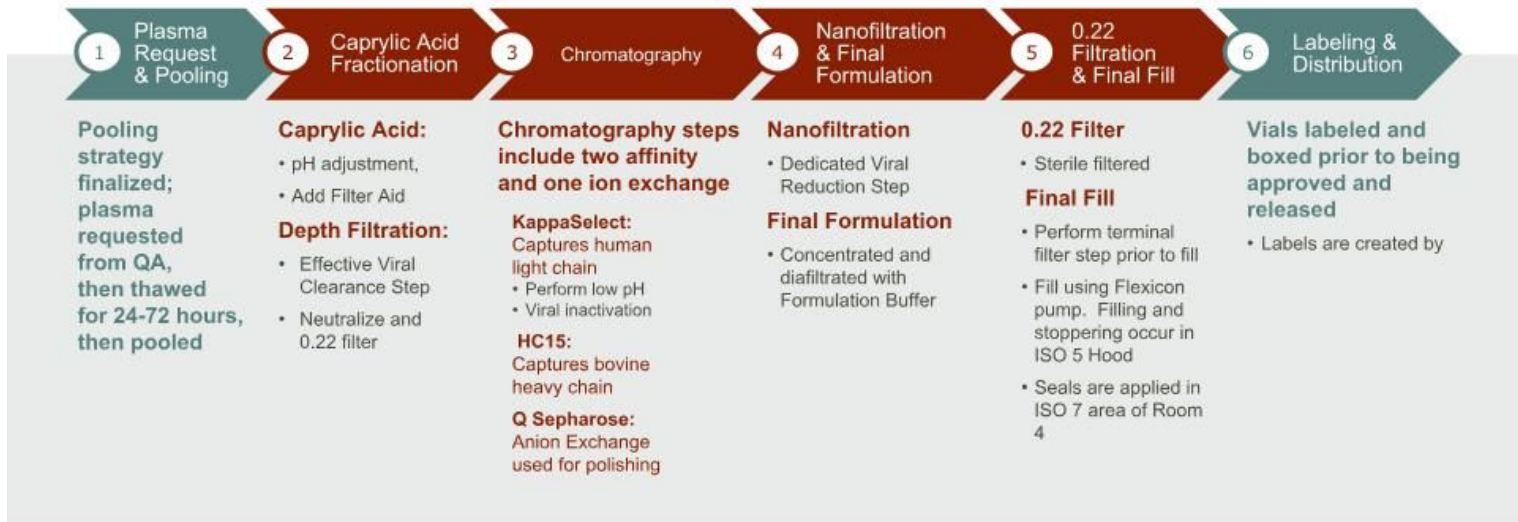
t-blgG



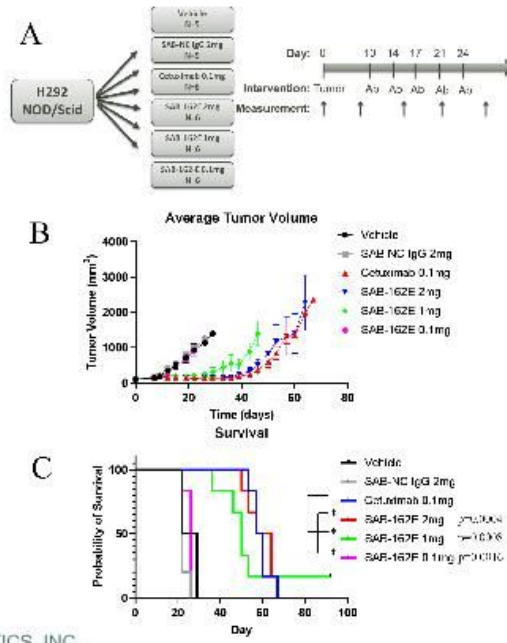
# Downstream Manufacturing Process



# Downstream Manufacturing Process



# SAB-162E decreased mouse in vivo tumor growth and almost tripled survival time







## Phase 2 Efficacy and Safety of Two Novel SAB Immunotherapies Against Respiratory Disease Indications Associated with Highly Mutating Viruses

- SAB-185: A SARS-CoV-2 Immunotherapeutic
- SAB-176: A Pan Influenza Immunotherapeutic

### **Plasma Product Biotechnology Conference | 2022**

*Christoph Bausch, PhD, Chief Operating Officer*

# Forward Looking Statements

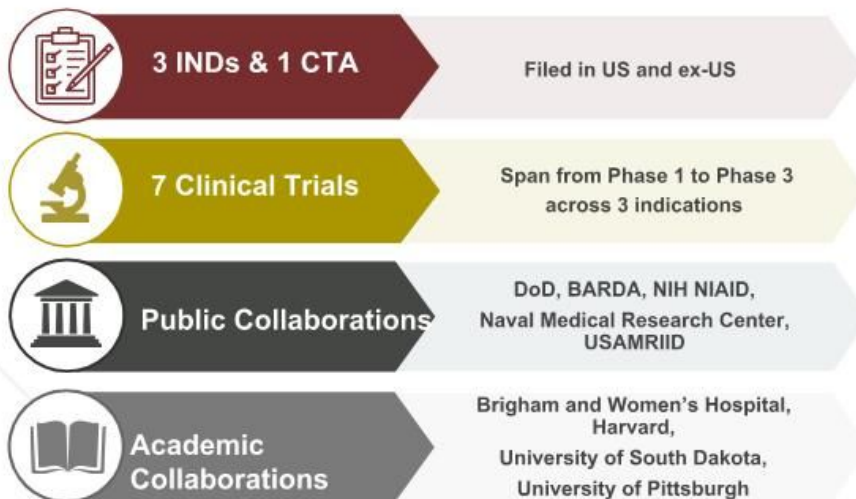


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Unless otherwise specified, information is current at the date hereof, unless specifically noted.

# DiversitAb™ Platform is Clinically Validated Across Several Targets



## Referenced Trials:

- ❑ [Safety, Tolerability, and Pharmacokinetics of SAB-176 in Healthy Participants – Full Text View - ClinicalTrials.gov](#)
- ❑ [Study of SAB-176 in Healthy Adult Participants - Full Text View - ClinicalTrials.gov](#)
- ❑ [Safety, Tolerability, and Pharmacokinetics of SAB-185 in Healthy Participants – Full Text View - ClinicalTrials.gov](#)
- ❑ [Safety, Tolerability, and Pharmacokinetics of SAB-185 in Ambulatory Participants With COVID-19 - Full Text View - ClinicalTrials.gov](#)
- ❑ [ACTIV-2: A Study for Outpatients With COVID-19 - Full Text View - ClinicalTrials.gov](#)
- ❑ [Safety, Tolerability, and Pharmacokinetics of SAB-301 in Healthy Adults – Full Text View - ClinicalTrials.gov](#)



# Robust Biologic Pipeline with Broad Polyclonal Therapeutic Reach

Ongoing discovery programs in oncology, autoimmune, infectious and anti-idiotype diseases								
	PRODUCT	INDICATION	DISCOVERY	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	COMMERCIAL
GASTROINTESTINAL	SAB-195	CLOSTRIDIODES DIFFICILE	[Progress bar]					
RESPIRATORY	SAB-176	PAN INFLUENZA	Phase 1 Trial & Phase 2a Challenge Study Top line results available					
IMMUNOLOGY	SAB-142	TYPE 1 DIABETES	[Progress bar]					
	SAB-142	IMMUNOLOGY	[Progress bar]					
Government-funded Phase 3 clinical-stage program								
RESPIRATORY	SAB-185	COVID-19	Phase 3 Trial (NIH ACTIV-2)					



# SAB-185 Anti-SARS-CoV2

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# DiversitAb™ Rapid Discovery and Development Process for SAB-185

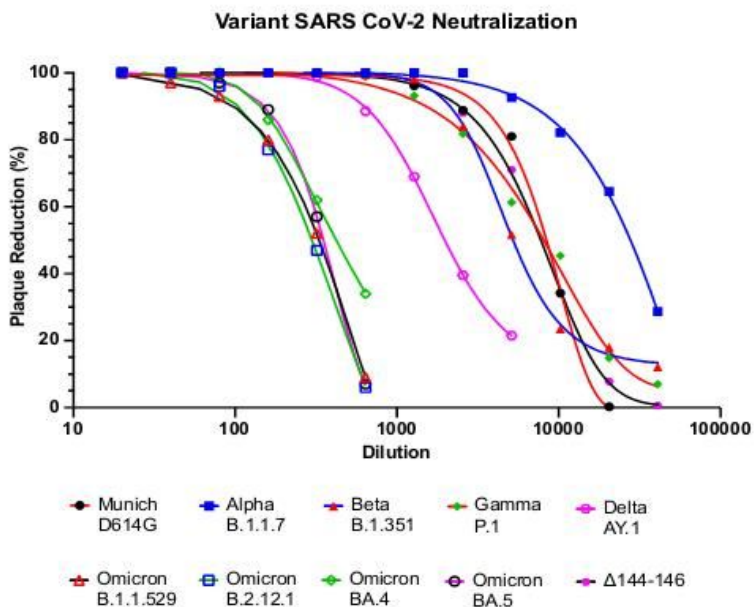


**Project Start to IND Filing <125 Days, and First Subject In <160 Days**

**Project Start to Ph 3 <2 Years**



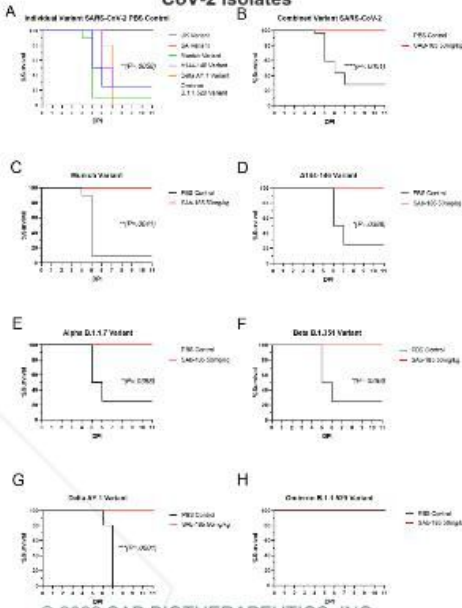
# SAB-185 Neutralization Potential vs. the Munich Variant (Spike D614G) and Other Variants



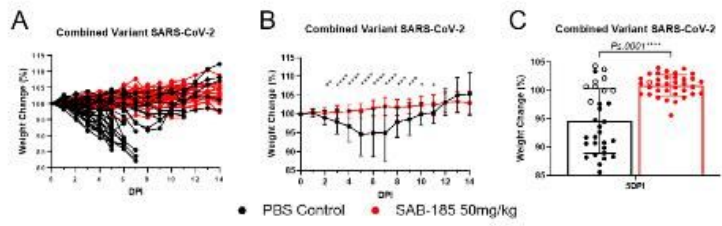
# SAB-185 Protects Recombinant hACE2 Hamsters from Mortality and/or Severe Morbidity from SARS CoV-2 Variants Including Omicron



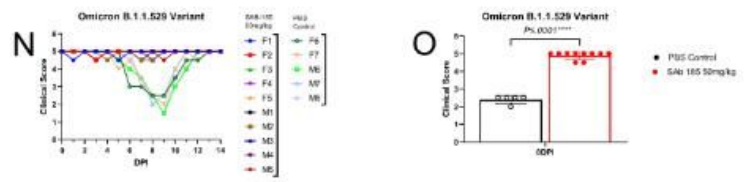
**SAB-185 protection from mortality in hamsters challenged with six variant SARS CoV-2 isolates**



**SAB-185 protection from weight loss in hamsters challenged with six variant SARS CoV-2 isolates**



**SAB-185 protection from Weight Loss in hamsters challenged with Omicron variant SA**



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# Addresses Escape Mutants: SAB-185 Superior to Monoclonal Antibody

## Selection for VSV-SARS-CoV-2 Wild Type Escape Mutation



WASHINGTON UNIVERSITY SCHOOL OF MEDICINE-ST. LOUIS; 15  
JAN 2021



# Phase 2 Data from NIH ACTIV-2 Trial Confirms SAB-185 Met Virology Endpoints for Graduation to Phase 3

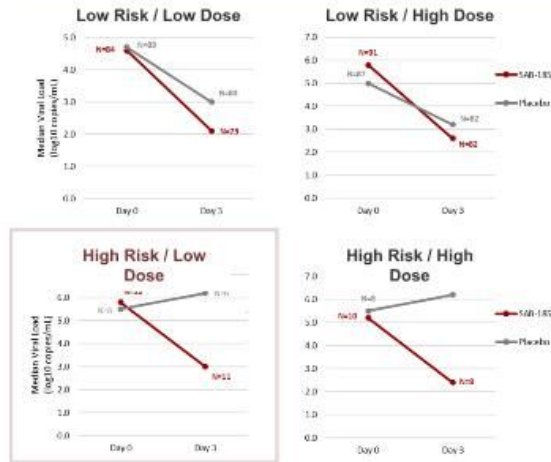
Viral load reductions of  $\geq 0.5 \log_{10}$  for both lower and higher dose at Day 3

### INTERIM ANALYSIS

	LOW-DOSE (3,840 UNITS/KG)	HIGH-DOSE (10,240 UNITS/KG)
Difference from PBO for RNA level ( $\log_{10}$ copies/ml)	<b>1.48</b>	<b>0.67</b>
Minimum RNA level difference ( $\log_{10}$ copies/ml)	<b>0.5</b>	<b>0.5</b>
Minimum Posterior Probability	<b>0.6*</b>	<b>0.6*</b>
Actual Posterior Probability	<b>0.91</b>	<b>0.75</b>

\* The choice of 0.6 for this Bayesian probability indicates that there is a 3 to 2 odds of the agent being better than placebo by the desired amount ( $\geq 0.5 \log_{10}$  /ml) for the outcome measure.

Sub-analysis\*\* of viral load reduction shows pronounced impact in small subset of high-risk patients given either lower or higher dose



\*\* Results shown are not statistically significant



# SAB-176 Pan Influenza Therapeutic

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## Targeted Product Profile and Administration Routes

**Treat high-risk influenza adult patients prior to the development of severe disease:**

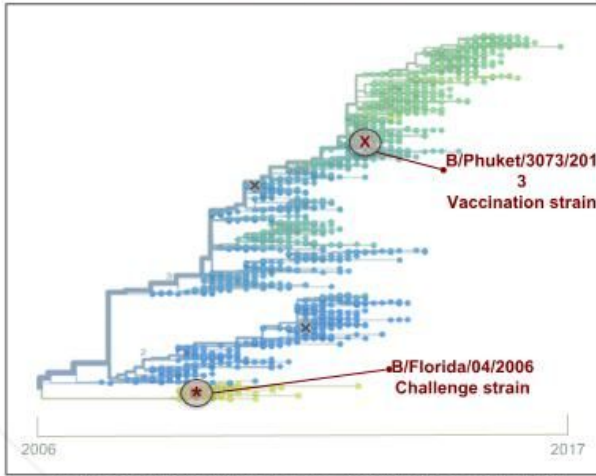
- Adults 65 years of age and older
- Immunocompromised due to a disease or medications (autoimmune, cancer, etc.)
- Patients with respiratory, cardiovascular, kidney, metabolic, neurological disorders
- Pre- and post-exposure prophylaxis of high-risk patients and critical services personnel
  - High-risk patients in nursing homes/assisted living
  - Hospitalized
  - First responders/military/medical providers
  - Critical infrastructure operators
- Administration Routes
  - Intravenous
  - Subcutaneous and Intramuscular administration in development

# Efficacy Against Mutational Drift

*Adaptive & Cross Reactive to Mutating Strains*

## Highly-Mutational Influenza Virus

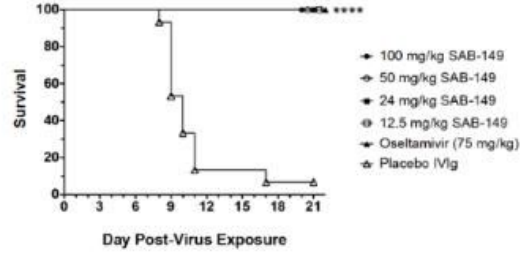
BYAM PHYLOGENIC TREE



SOURCE: NEXTFLU AT [HTTPS://NEXTFLU.ORG/VIC/12Y/](https://nextflu.org/vic/12y/)

## 100% Protection at All Dose Levels in Influenza Mouse Challenge

Antibodies produced to B/Phuket/3073/2013 –like virus protected against B/Florida/04/2006



# Highly-Potent: Exceeds Titers of Human Hyperimmune IVIg by up to 128X



## SAB-176 protects against seasonal and pandemic influenza vaccine strains past & future non-vaccine strains

Sample Started at 5mg/ml	H1N1				H3N2			B-Vic			B Yam	
	A/California/4/2009 (Pandemic Strain)	A/Michigan/45/2015	A/Brisbane/02/2018	A/Guangdong-g-maonan/2019	A/Singapore/IN16/2016	A/Kansas/14/2017	A/Hong Kong/45/2019	B/Maryland/15/2016	B/Colorado/06/2017	B/Washington/02/2019	B/Phuket/3073/2013	B/California/12/2015
Anti-Influenza (Tc Bovine-derived quadrivalent hyperimmune)	<b>SAB-176</b>	1:1,024	1:512	1:512	1:512	1:512	1:256	1:256	1:256	1:128	1:256	1:128
		32X	16X	16-32X	16-32X	8-32X	16-128X	16-32X	16-32X	16-32X	32X	16-32X
Anti-Influenza hIVIg (human-derived)	2018	1:32	1:32	1:32	1:32	1:64	1:16	1:16	1:16	1:8	1:8	1:8
	2017	1:32	1:32	1:16	1:16	1:64	1:16	1:16	1:16	1:8	1:8	1:8
	2013	1:32	1:32	1:32	1:16	1:16	1:4	1:8	1:8	1:4	1:8	1:4
Negative Control Antibody		<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1

Vaccine strain (season): 18-19 19-20 20-21 18-21

SAB-176 purified from TcB plasma vaccinated with 18-21 vaccine strain

HUBER LAB, USD, JUL  
2021

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## Trial Design and Methods

- **Trial design:** Randomized, Double-Blind, Placebo-Controlled Influenza Challenge Study
- **Study sample size:** 60 Healthy volunteers, 18-45 years of age
- **Study flow:**
  - Participants were admitted into the hVIVO facility 2 days prior inoculation and were quarantined for up to 11 days (Day -2 to 8) with Influenza challenge occurring on day 0 and SAB-176/placebo infusion on day 1. Participants were discharged on day 8. Participants returned for 1 outpatient visit on day 28.
  - Subjects were randomized 1:1 prior to receive SAB-176 or matching placebo 20-24 hours after influenza challenge.
- **Challenge virus:** A previously utilized Influenza **pandemic H1N1 A/California/2009**-like challenge virus was produced by Meridian Life Sciences under Good Manufacturing Practices (Watson et al., 2015; Leibowitz et al., 2020)
- **Investigational treatment:** Participants received 25 mg/kg of SAB-176 diluted in normal saline at a concentration of 20 mg/ml or an equivalent volume of normal saline (placebo) in a single IV infusion.

## Primary and Selected Secondary Outcome Measures

### **Primary Outcome Measure:**

- Area under the viral load-time curve (VL-AUC) of Influenza A/California/2009 H1N1 virus as determined by qRT-PCR on nasal samples of SAB-176 when compared to placebo. [Time Frame: 8 Days ]

### **Selected Secondary Outcome Measures:**

- Area under the curve over time of total clinical symptoms score (TSS-AUC) as measured by graded symptom scoring system (categorical and visual analogue scales) to evaluate the effect of SAB-176 in reducing symptoms due to Influenza A/California/2009 H1N1 virus compared to placebo. [Time Frame: 8 Days ]
- Duration of influenza quantifiable by cell culture measurement to evaluate the effect of SAB-176 in reducing viral loads in cell culture due to Influenza A/California/2009 H1N1 virus, compared to placebo.
- Safety

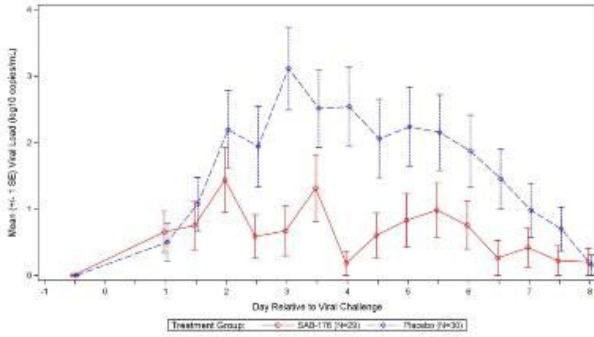


## Emerging Safety Profile

- Overall, the challenge virus inoculation and subsequent single IV infusion of SAB-176 were safe and well tolerated. There were no SAEs in this study, no AEs leading to early withdrawal from the study, and none of the AEs were of grade 3 or higher in severity.
- **The incidence of AEs was similar between the treatment groups:** 18 (60.0%) participants in the SAB-176 group reported 27 AEs and 16 (53.3%) participants in the placebo group reported 23 AEs from viral challenge (Day 0) onwards.
  - Most TEAEs were reported in the SOC general disorders and administration site conditions (8 TEAEs in 5 [16.7%] participants in the SAB-176 group, and 1 TEAE in 1 [3.3%] participant in the placebo group). **Almost all TEAEs were mild in intensity.** One TEAE of neutrophil count decreased in the SAB-176 group and 4 TEAEs (ALT increased [n=1], lymphocyte count decreased [n=2], and rash [n=1]) in the placebo group were moderate in intensity.
  - **TEAEs that were at least possibly related to the study treatment** were reported by **2 (6.7%) participants in the SAB-176 group** (1 TEAE of blood pressure systolic decreased and 1 TEAE of paraesthesia) and **by 4 (13.3%) participants in the placebo group** (1 TEAE of rhinorrhoea, 1 TEAE of ALT increased, 1 TEAE of pain in extremity, and 1 TEAE of procedural hypotension).

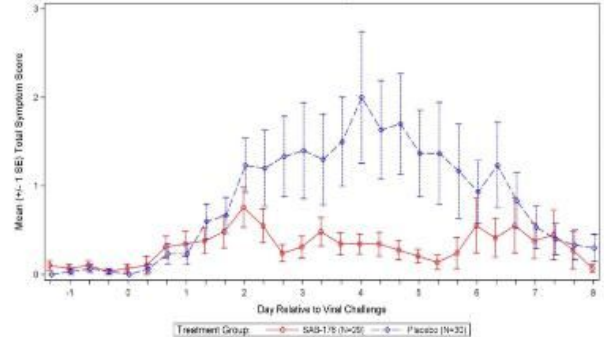
# SAB-176 Met the Primary Endpoint of Viral Load and Secondary Endpoint of Symptom Reduction

**Achieved Statistically Significant ( $p = 0.026$ ) Reduction in Viral Load**



**Mean Viral Load by Nasal Samples qRT-qPCR by Day Relative to Viral Challenge**

**SAB-176 Achieved Statistically Significant ( $p = 0.013$ ) Improvement in Symptomology at Day 4**

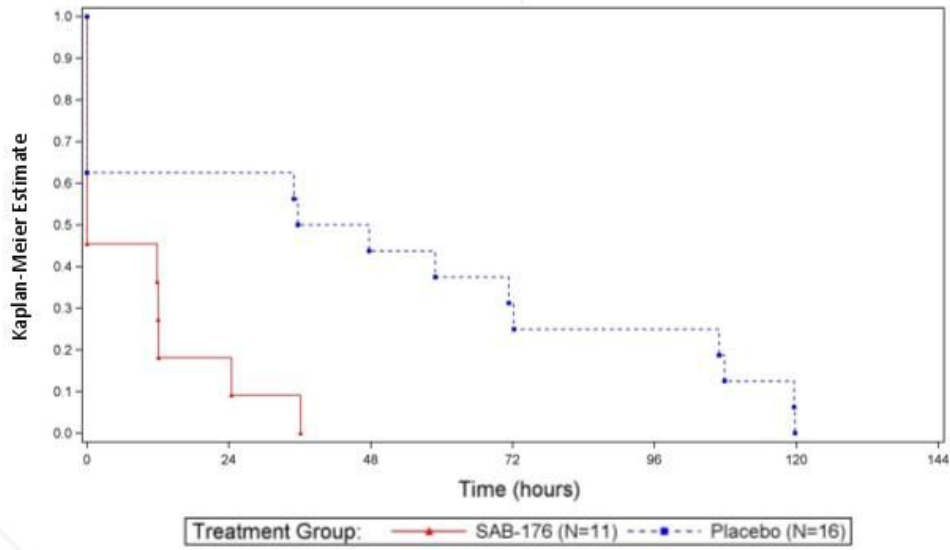


**Mean Total Symptom Score by Day Relative to Viral Challenge**

# Kaplan-Meier Time to Resolution of Positive Viral Cultures Following First Positive Culture Starting 2 Days After Intranasal Viral Challenge



Shortened time of viral shedding, as measured by lack of culturable virus



## Conclusions

### **SAB-176: A novel pan influenza polyclonal immunotherapeutic**

- Demonstrates significant HAI titers to multiple Type A and B and pandemic influenza strains
- In response to pandemic H1N1 viral challenge met primary endpoint of reducing nasopharyngeal viral load as determined by qRT-PCR
- Met secondary endpoint of reducing symptoms
- Shortened the time of infectious viral shedding, as measured by inability to culture virus in vitro
- IV infusion of SAB-176 appeared to be safe and well tolerated. The incidence of AEs was similar between SAB-176 and placebo.
- Next step is conducting a Phase 2b dose-range finding study in influenza patients at high risk of developing severe influenza complications

## **SAB Biotherapeutics Presents Overview of DiversitAb™ Platform and Data Showing Benefits of Fully-Human Polyclonal Antibodies Derived from Cows vs. Human-Derived Plasma, at 2022 Plasma Product Biotechnology Conference**

***SAB highlights data on SAB-176 for seasonal and pandemic influenza and SAB-185 for COVID-19, showing broad efficacy against highly mutating viruses associated with respiratory disease***

SIOUX FALLS, S.D., November 3, 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 that the Company presented an overview of its DiversitAb™ polyclonal platform and data on SAB-176 and SAB-185 showing the benefits of fully-human polyclonal antibodies derived from SAB's Transchromosomal (Tc) Bovine™ over plasma derived antibodies from humans, at the 2022 Plasma Product Biotechnology Conference in Limassol, Cyprus, which concluded on Nov. 3.

SAB's Chief Operating Officer Christoph Bausch, Ph.D., led two presentations at the conference on Tuesday, Nov. 1.

In a presentation titled, "*Plasma fractionation and downstream processing of human polyclonal antibodies from the DiversitAb platform*," Dr. Bausch presented an overview of SAB's novel immunotherapy platform utilizing a specialized manufacturing process to enable a scalable and reliable production of targeted, higher-potency neutralizing antibody products than has been previously possible. The platform can reliably and rapidly produce large quantities of fully-human immunoglobulins against a variety of disease targets, such as viruses, bacteria, toxins, and cancers, without the need for convalescent plasma from human donors with a significantly simplified and controlled process. Tc Bovine, SAB's genetically engineered cows, mount the same immune response as humans, only with a much higher concentration of targeted neutralizing antibodies. In addition, by eliminating the need to identify, screen, and draw blood from recovering volunteers, SAB's approach opens the door to polyclonal antibody therapeutics that are potentially more potent, safer, and longer-lasting than current antibody therapies.

"SAB's platform is a major advancement in plasma science and allows for a large supply of neutralizing, fully-human antibodies that can be targeted to treat a number of challenging diseases," Dr. Bausch said. "Our novel approach to creating high-potency, high-avidity antibodies that naturally activate cellular immunity using our transchromosomal cows has the potential to profoundly change how we approach and treat a wide range of diseases."

Titled "*Phase 2 efficacy and safety of two novel SAB immunotherapies against respiratory disease indications associated with highly mutating viruses*," Dr. Bausch's second presentation outlined

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data on SAB-185 for COVID-19 and SAB-176 for seasonal and pandemic influenza. The data show that SAB-185 and SAB-176 are highly effective against variants of several highly mutating viruses associated with the diseases, a major challenge in currently available treatments for COVID-19 and influenza.

Data from 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 variants and a variant isolated from an immunocompromised patient (D144-146) and retained neutralization of the Delta variant AY.1 and multiple Omicron variants from BA.1 through 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.

Also outlined was a Phase 2a, Randomized, Double-Blind Trial in H1N1 Challenged Adults, which showed 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 4 and shortened the timeframe of the ability to culture virus *in vitro*, suggesting reduced viral shedding, and was safe and well tolerated. Further, while SAB-176 was developed against recent seasonal influenza A and B strains, it also 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 data on SAB-176 and SAB-185 validated that our platform delivers on its promise and can create fully-human antibodies that offer much broader efficacy in highly mutating pathogens,” Dr. Bausch said. “The data show the antibodies cross react to mutating strains, preventing additional mutations, and shorten the time of infectious viral shedding to reduce the spread of disease. These components are critical in developing effective innovative future treatments.”

#### **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 Transchromosomal (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

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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-176, SAB-185, and 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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