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

Thomas C. Luke, MD.
Senior Vice President, Research and Development
SAB Biotherapeutics, Inc.
*As an employee, Dr. Luke has a potential financial conflict of interest.

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 unless required by law. 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. The forward-looking statements contained or implied in this presentation are subject to other risks and uncertainties, including those discussed under the heading "Risk Factors" in SAB’s most recent Annual Report on Form 10-K with the Securities and Exchange Commission (the “SEC”) and in other filings that SAB makes with the SEC.

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

The SAB logo and other trademarks of SAB appearing in this presentation are the property of SAB. All other trademarks, services marks, and trade names in this presentation are the property of their respective owners.

Targeted Product Profile and Administration Routes

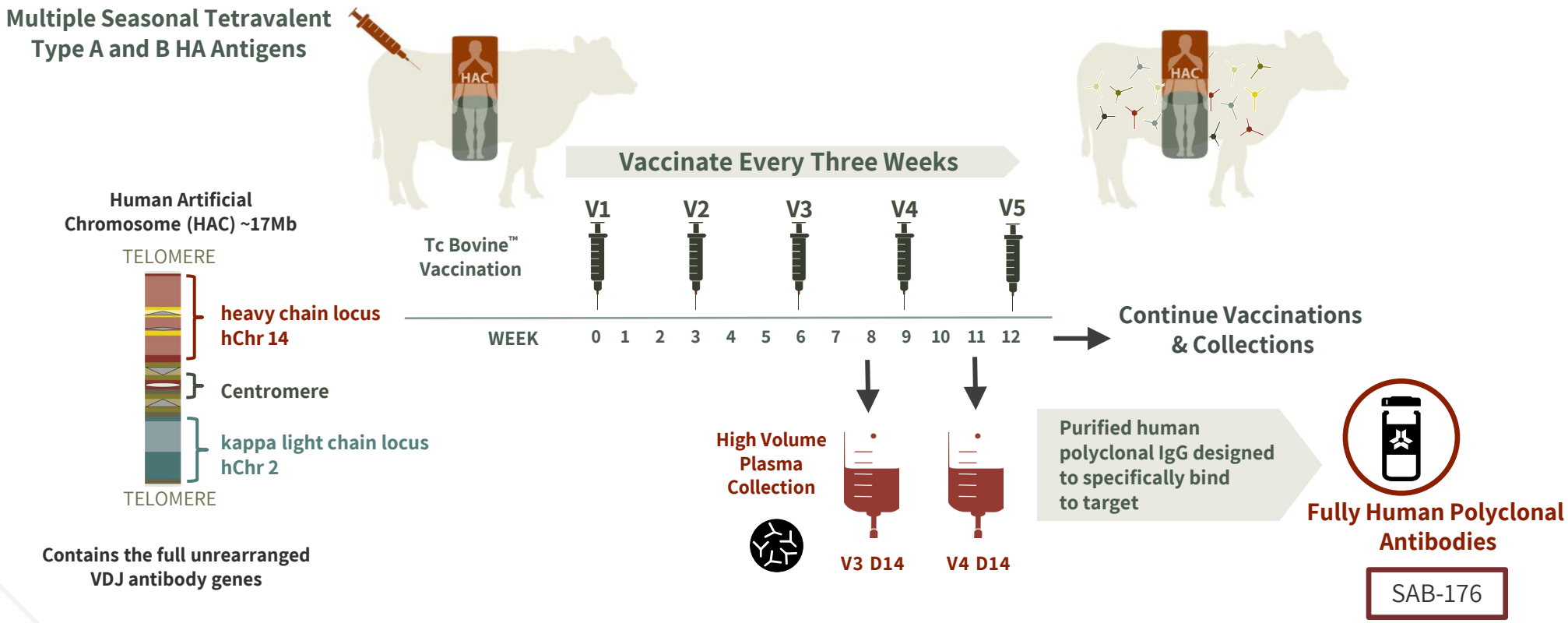
Treat high-risk influenza adult patients prior to the development of severe disease:

- 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

DiversitAb™ Development Process for SAB-176



SAB-176 had Higher HAI Titers than Anti-Flu hIVIGs Against Multiple Influenza Vaccine Strains and Non-Vaccine Strains

	H1N1							H3N2				B-Vic			B-Yam		
Sample **Started at 5mg/ml**	**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/257 0/2019 (2021-22)**	**A/Singapore/INI FMH-16-0019/2016**	**A/Kansas/14/ 2017**	**A/Hong Kong/2671/20 19 (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**	**G4HA**
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 hIVIG 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 hIVIG 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 hIVIG 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

Trial Design and Methods

- The trial was sponsored by SAB Biotherapeutics and designed with hVIVO Services Limited. The study was conducted at hVIVO Services Limited screening and quarantine facilities in London, England. (EudraCT reference number 2021-001254-56 and registered with ClinicalTrials.gov number NCT04850898).

- Healthy volunteers aged between 18 and 45 years were enrolled between 23 June and 20 Sept 2020. They were screened per protocol to be nonsmokers, healthy, with a body mass index ≥18 and ≤35, no vaccine received within 30 days of infusion, and a A/California/2009/H1N1 serum hemagglutination inhibition (HAI) antibody titer of ≤1:10 within 90 days prior to enrollment.

- 60 Participants were randomized prior to challenge 1:1, double-blinded, to receive SAB-176 or placebo 20-24 hours after influenza challenge. 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.

- 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.

- A previously utilized Influenza 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)

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]

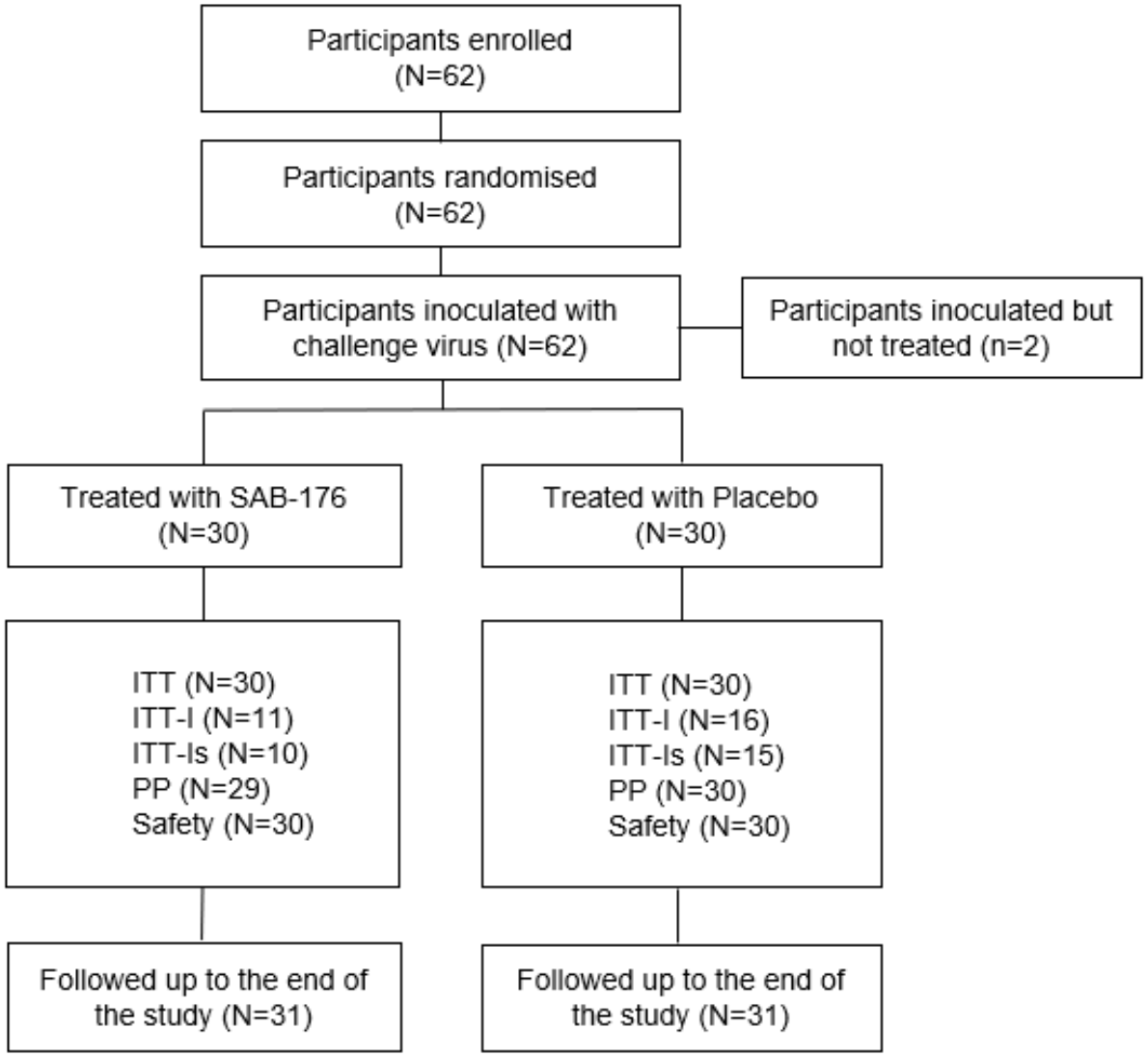
Selected Secondary Outcome Measures:

- 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.

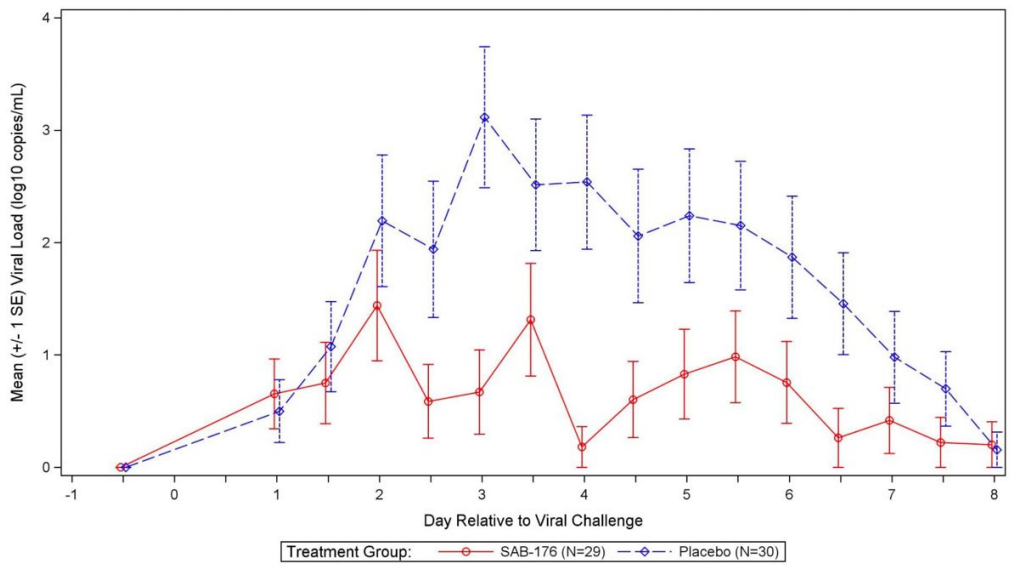
- Safety

Disposition of Participants



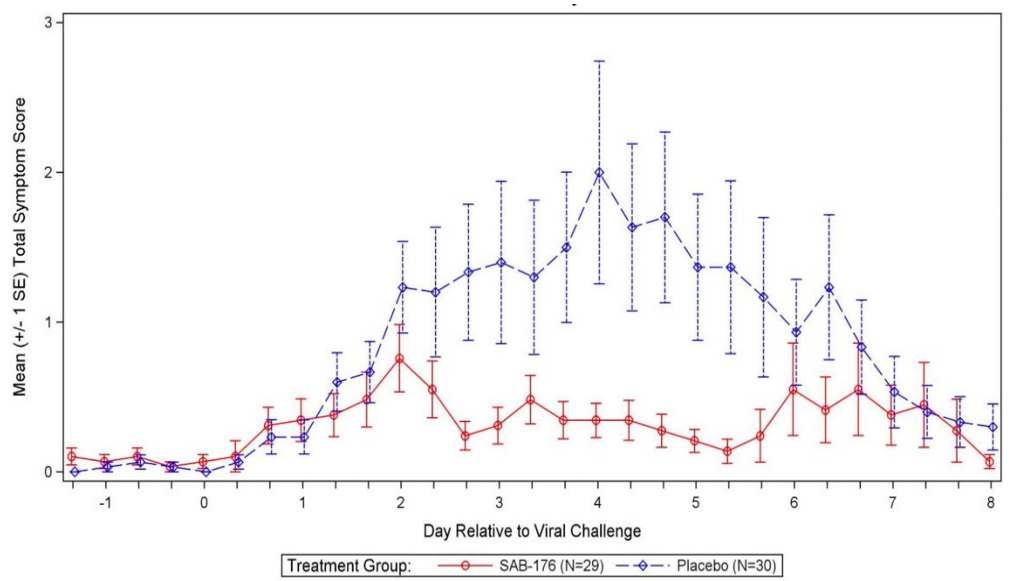
SAB-176 Met the Primary Endpoint of Viral Load and Secondary Endpoint of Symptom Reduction

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



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

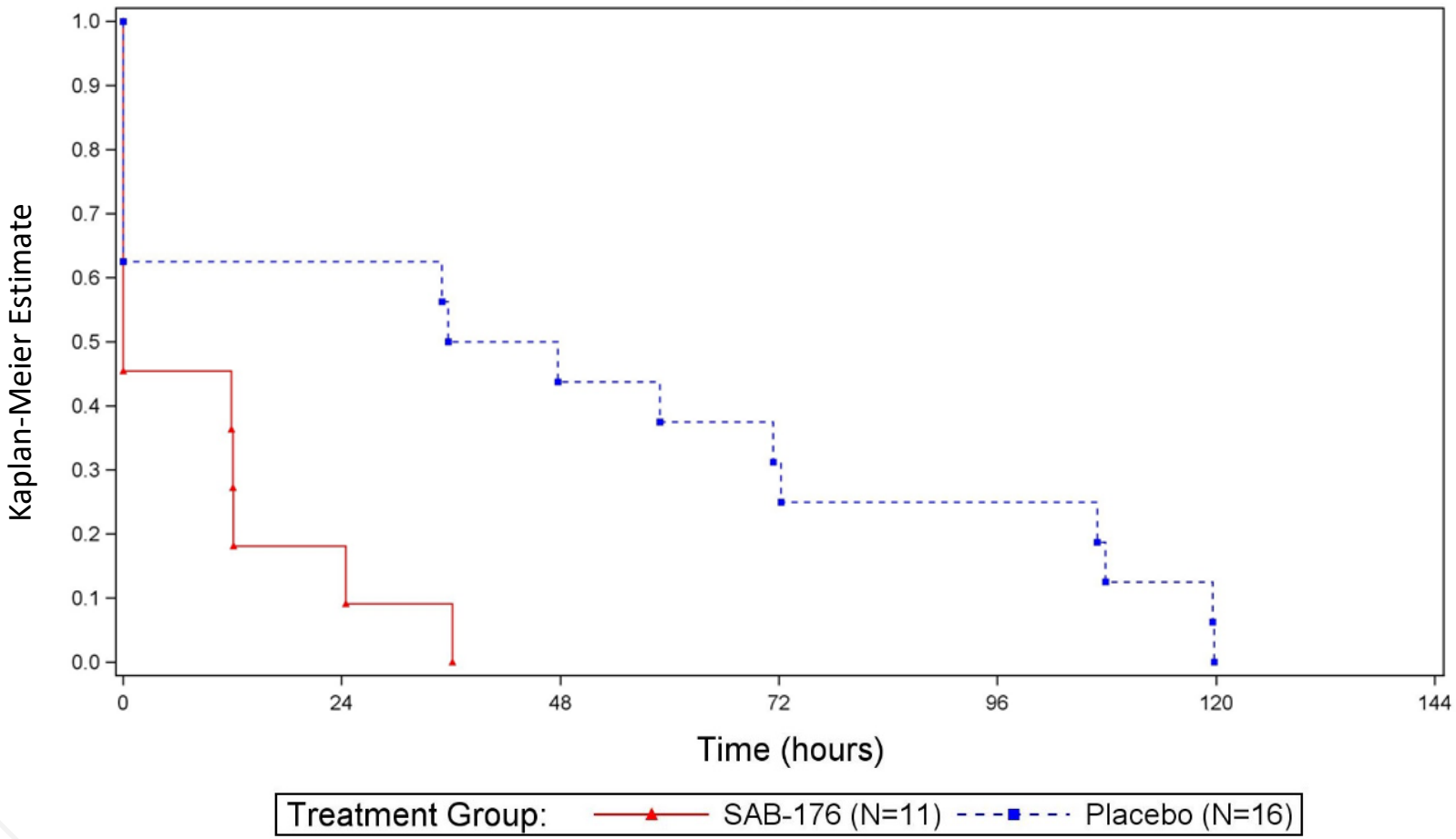
SAB-176 Achieved Statistically Significant (p = 0.013) Improvement in Symptomology at Day 4



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 anti-Type A and B influenza polyclonal immunotherapeutic

- Demonstrates significant HAI titers to multiple Type A and B influenza strains
- 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
- Demonstrated safety and tolerability
- Future studies in high-risk patients should be conducted

Acknowledgements

SAB Biotherapeutics, Inc., would like to acknowledge the support of Dr. Victor Huber, University of South Dakota, for HAI assessment of influenza strains.

SAB Biotherapeutics, Inc., would like to acknowledge Dr. Alex Mann, Dr. Victoria Parker, Mr. Kingsley Eze and Ms. Madhuri Patel, among others, at hVIVO, PLC., for their work on this clinical trial.