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): June 24, 2022

Blue Water Vaccines Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-41294**	**83-2262816**
(State or other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

201 E. Fifth Street, Suite 1900 Cincinnati, Ohio	**45202**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: **(513) 620-4101**

(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, par value $0.00001 per share	BWV	The Nasdaq Stock Market LLC

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 8.01. Other Events.

Due to delays caused by manufacturing, disruptions relating to suppliers, and those caused by the global COVID-19 pandemic, the Companyhas adjusted the estimated timeline previously reported in its public filings with respect to the development of its vaccine candidates, BWV-102 and BWV-302 to account for additional time needed to optimize vaccine platform approach and perform sufficient preclinical studies. An updated summary of the Company's pipeline for all vaccine candidates is provided as follows:

The FDA regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our vaccine candidates. Our vaccine candidates are in early stages of development and may fail in development or suffer delays that materially and adversely affect their commercial viability. We may be unable to complete development of or commercialize our vaccine candidates or experience significant delays in doing so due to regulatory or other uncertainties.

Additional details regarding the Company and its vaccine candidates are available in the Company's updated corporate presentation, which is attached hereto as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Blue Water Vaccines Inc. Corporate Presentation, as of June 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

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

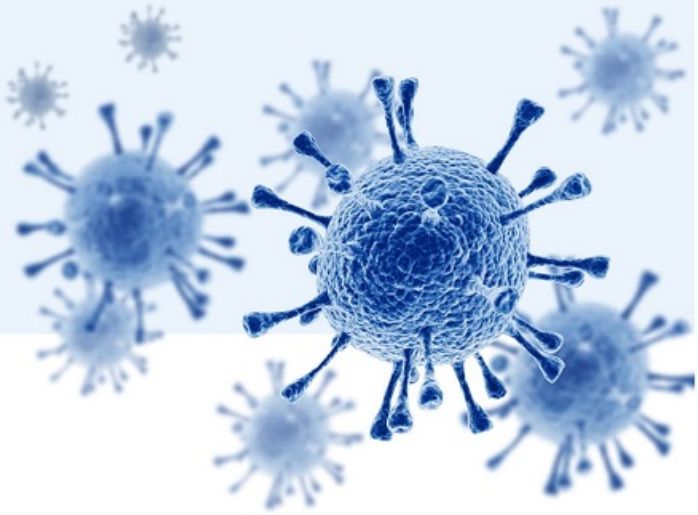
Blue Water Vaccines Inc.

Date: June 24, 2022

By: /s/ Joseph Hernandez
Joseph Hernandez
Chief Executive Officer

Exhibit 99.1

blue water™
vaccines



June 2022

Corporate Presentation

NASDAQ: BWV

The Presentation (the "Presentation") has been prepared by Blue Water Vaccines, Inc. (the "Company"). Certain information contained herein has been derived from sources prepared by third parties. While such information is believed to be reliable for the purposes used herein, the Company makes no representation or warranty with respect to the accuracy of such information.

This Presentation does not constitute an offer to sell, or the solicitation of an offer to buy, any securities of the Company in any jurisdiction, domestic of foreign, where the offer, solicitation or sale is not permitted or would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

FORWARD LOOKING STATEMENTS:

Certain statements in this presentation (the "Presentation") has been prepared by Blue Water Vaccines, Inc. (the "Company"). This presentation contains forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate," "expect," and "intend," among others. These forward-looking statements are based on BWV's current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, risks related to the development of BWV's vaccine candidates, including, but not limited to BWV-301; the failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; delays and uncertainties caused by the global COVID-19 pandemic; risks related to the timing and progress of clinical development of our product candidates; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payor reimbursement; limited research and development efforts and dependence upon third parties; and substantial competition. As with any vaccine under development, there are significant risks in the development, regulatory approval and commercialization of new products. BWV does not undertake an obligation to update or revise any forward-looking statement. Investors should read the risk factors set forth in BWV's Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the Securities and Exchange Commission (the "SEC") on March 31, 2022, and periodic reports filed with the SEC on or after the date thereof. All of BWV's forward-looking statements are expressly qualified by all such risk factors and other cautionary statements. The information set forth herein speaks only as of the date thereof.

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BWV Highlights

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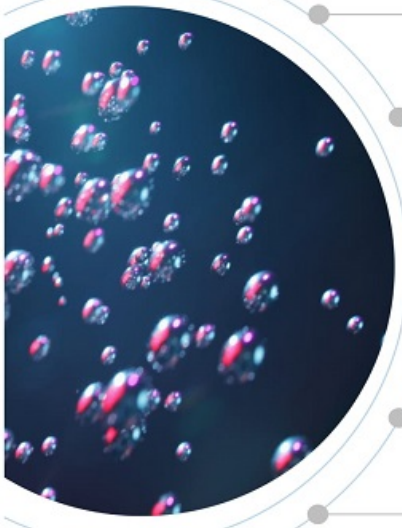
Overview



- **Broad and diverse vaccine pipeline:** Novel preclinical vaccine candidates
- **Proprietary Versatile Vaccine Platform:** POC, multi-valent, scalable, and flexible discovery engine with broad therapeutic capabilities
- **Lead Vaccine Candidates:** Targeting Universal and H1 Influenza utilizing proprietary influenza epitopes of limited variability (ELV) that remain present through viral mutation
- **AOM Prevention Candidate:** Targeting *S. pneumoniae* utilizing a proprietary live-attenuated strain with intranasal delivery
- **Esteemed Collaborators:** University of Oxford, Cincinnati Children's, St. Jude's Children's
- **Opportunistic Business model:** Exclusive licenses of assets and platforms, broad business development, opportunistic growth and expansion

AOM: acute otitis media

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Accomplished Management Team and Board of Directors

Led by experienced entrepreneurs who bring sustained records of successfully leading innovation and commercialization

Joseph Hernandez

Founder, Chairman & Chief Executive Officer

- Founder, Blue Water Acquisition Corporation, SPAC, (now Clarus, CRXT); Founder, Chairman Noachis Terra, Inc. (Oragenics, Inc)
- M.Sc. Candidate, Chronic Disease Epidemiology, Yale; MBA , University of Florida

Andrew Skibo

Head Biologic Operations

- Biological Manufacturing expertise
- Former, EVP, Operations, AstraZeneca/ MedImmune
- M.S., Chemical Engineering, Massachusetts Institute of Technology

Ronald Cobb, Ph.D.

Head of Science and Discovery

- Vaccine development expertise
- Former CSO, Ology Bioservices
- Ph.D, Biochemistry, Medical College of Georgia

Erin Henderson

Chief Business Officer

- Administrative, corporate and stakeholder relations expertise
- Former Managing Principal, The Aetos Group
- B.S., Chemical Engineering, Auburn University

Jon Garfield

Chief Financial Officer

- Financial and M&A expertise
- Prior big four accounting firm experience
- B.B.A, Accounting, University of Texas at Austin

Board of Directors

Kimberly Murphy

CEO and Director at Oragenics, Inc. (NYSE: OGEN), Board of Directors at Clarus (NASDAQ: CRXT)

James Sapirstein

President & CEO, First Wave Biopharma (NASDAQ: FWBI)

Allan Shaw

CFO, Portage Biotech Inc. (NASDAQ: PRTG)

Michael Venerable

CEO, CincyTech

Partnered with Renowned Research Leaders

Sunetra Gupta, Ph.D.

Co-Inventor, Universal Influenza vaccine
Department of Zoology, University of Oxford

Xi Jason Jiang, Ph.D.

Co-Inventor, S & P Particle VLP Platform, Norovirus-Rotavirus vaccine
Professor, University of Cincinnati, Department of Pediatrics

Ming Tan, Ph.D.

Co-Inventor, S & P Particle VLP Platform, Norovirus-Rotavirus vaccine
Assistant Professor, University of Cincinnati, Department of Pediatrics

Jason Rosch, Ph.D.

Inventor, *S. pneumoniae* vaccine
Associate Member, St. Jude Faculty

UNIVERSITY OF OXFORD

Cincinnati Children's

St. Jude Children's Research Hospital

Scientific Advisory Board

Sunetra Gupta, Ph.D.
Professor, University of Oxford

C. David Zarley, Ph.D.
Vaccine Development, Vice President., (Retired), Pfizer, Inc.

John Rice, Ph.D.
Life Sciences Managing Director, CincyTech

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Novel Vaccine Pipeline

Infectious Disease Program	Candidate	Preclinical	Phase 1	Collaborator
Universal Flu	BWV-101			UNIVERSITY OF OXFORD
H1 pre-pandemic	BWV-102			
S. pneumo induced AOM (intranasal)	BWV-201			St. Jude Children's Research Hospital
Norovirus / Rotavirus	BWV-301			Cincinnati Children's
Norovirus / Malaria	BWV-302			

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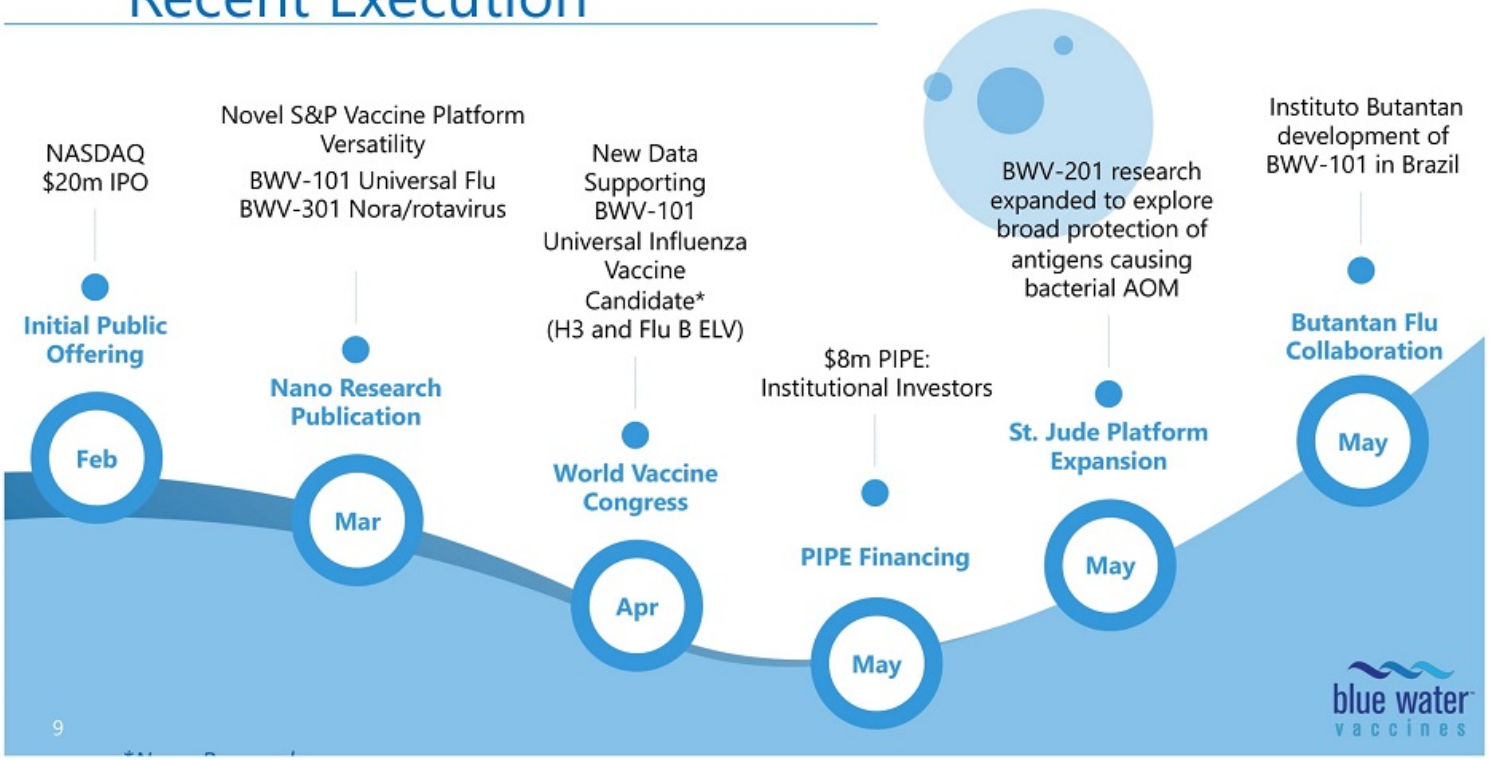
Recent Execution



Our Vaccine Candidates

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BWV-101: Universal Flu
BWV-102: H1

Aiming to eradicate the flu, universally, with a smart vaccine that targets frequently occurring virulent epitopes.

Influenza BWV-101 BWV-102

Need for broad protection flu vaccine

- Current annual flu vaccine effectiveness is up to 50%
- 1 billion influenza infections each year, 3 – 5 million of which are considered severe
- Influenza A&B cause most of human illness and the flu season

Differentiated Approach

- Mathematical model for epitope identification
- Global license with University of Oxford
- Epitopes of limited variability (ELV's) naturally immunogenic and cross-protective
- ELV's are ideal vaccine targets for broad long-term protection

Current Status

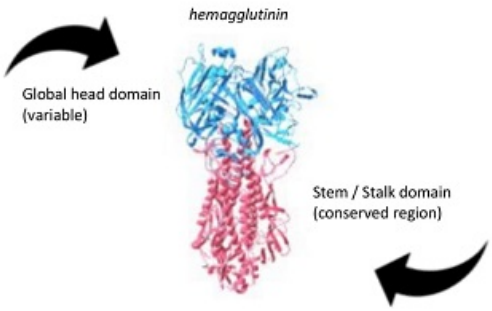
- BWV-101: Universal flu (H1, H3, Flu B), BWV-102: H1 pre-pandemic flu
- POC data for H1N1
- New H3, and flu B data presented at the World Vaccine Congress
- Provisional patents have been filed for additional ELV's in H3N2 and flu B

Our Approach

Current influenza vaccine can be divided into two groups:

Target regions that are highly immunogenic of high variability or evolve frequently.

These vaccines need to be updated regularly and administered annually.



Target regions that are conserved with low immunogenicity.

There is less need for updating these vaccines, but they provide a poor immune response.

Our vaccine overcomes such issues by targeting regions, or epitopes, of the virus which are of limited variability. These epitopes remain present through the virus mutations.

By identifying multiple epitopes of limited variability, it is possible to produce vaccines or a single vaccine to protect against all previous and future H1 flu strains.

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Proprietary Epitopes of Limited Variability (ELVs)*

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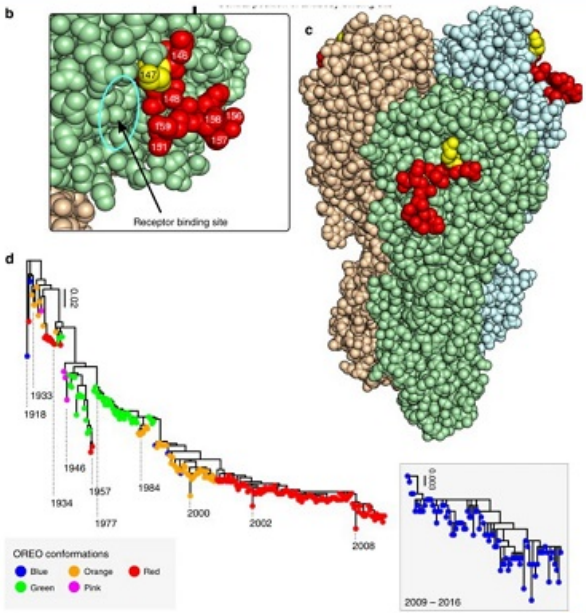
- Antigen/epitope evolution is limited in certain regions of the influenza virus
- ELVs are naturally immunogenic
  - Drive antigenic evolution which could result in a pandemic
  - Cycle between limited number of different conformations
- We licensed IP for cross-protective epitopes for our vaccine candidates:
  - Developed at the University of Oxford by Dr. Sunetra Gupta
  - Mathematical research has pinpointed ELVs that provide immunity to multiple strains
  - Identified ELVs in historical H1, H3 influenza and influenza B strains



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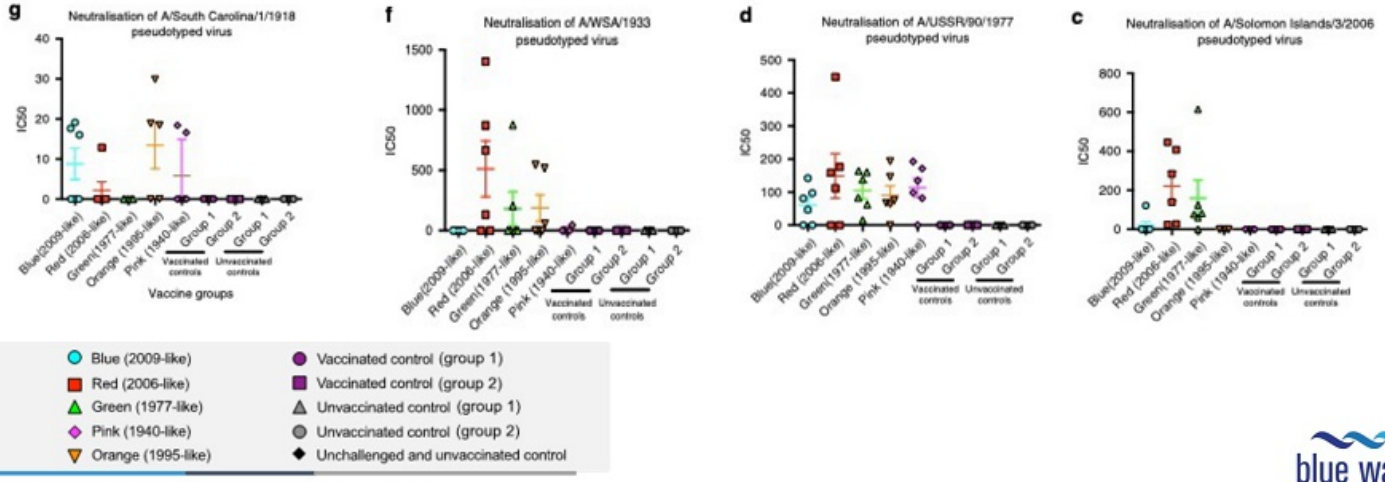
*Thompson et al. Nature Communications. 2018. 9:385

ELV vaccine Proof-of-concept*

Vaccination of mice with epitopes from H1N1 influenza viruses circulating in 2006 and 1977 provided protection against a strain that last circulated in 1934

Data demonstrate H1N1 ELVs provide cross-reactive immune response in historical influenza strains



* Thompson et al. Nature Communications. 2018. 9:385

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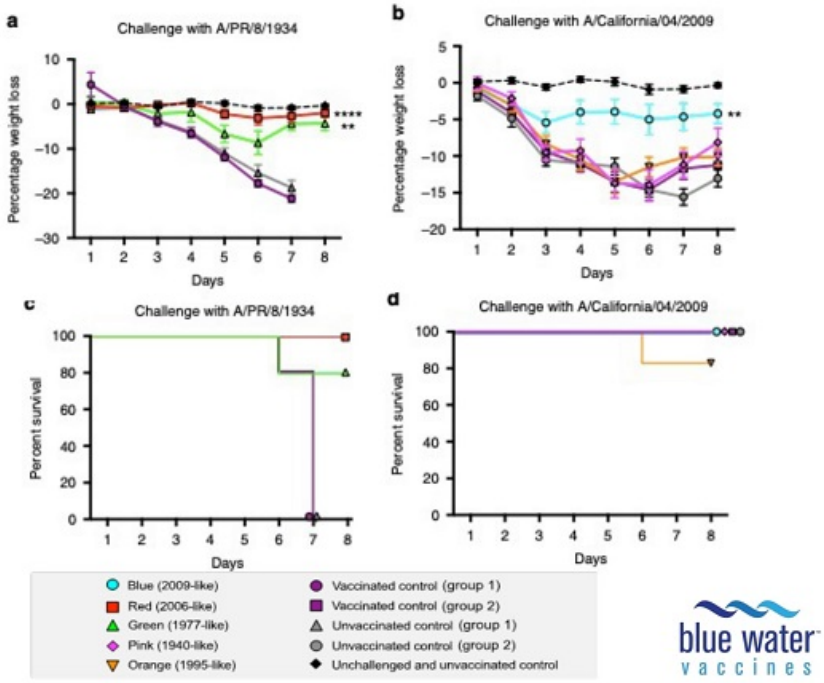
ELV vaccine Proof-of-concept*

Influenza challenge

- Data in mice models demonstrated that vaccinated mice did not have as severe of a reduction in weight loss compared to the control groups

- Survival curves demonstrated that vaccinated mice were able to produce antibodies to protect against historical flu strains



*Thompson et al. Nature Communications. 2018. 9:385

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BWV's ELV Vaccine Targets

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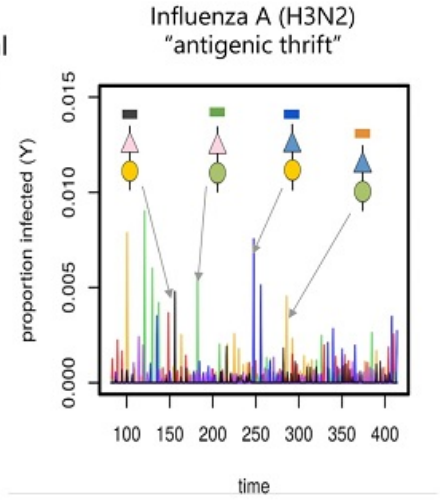
Candidates

Influenza A H1N1:
"Oreo"

Influenza A H3N2:
"INDY"
"MAIZ"

Influenza B
(Yamagata & Victoria):
"TATI"

- Mice data demonstrated cross-reactive immune response in historical influenza strains such as H10N3 (bird flu), and H5NX, H7NX, and H9NX
- Two epitopes with either 4 or 6 variants. Currently generating additional neutralization data
- One epitope in 7 variants to cover the variability seen across these two lineages.



St. Jude Children's Research Hospital®

BWV-201: *S. Pneumoniae* induced acute otitis media (AOM)

Blue Water Vaccines is committed to alleviating pain in children who suffer from S. pneumoniae induced middle ear infections.

Bacterial Induced-AOM BWV-201

Need for broad protection vaccine

- 5 million cases of AOM in the United States annually
- Estimated $4.3 billion USD is spent on AOM treatment each year in the United States alone
- Complications from AOM include sensorineural hearing loss (SNHL)

Differentiated Approach

- Global license with St. Jude Children's Research Hospital
- BWV-201 is a live attenuated serotype-independent vaccine
- Intranasal delivery
- Production of vaccine is straightforward; utilizes the entire bacterium

Current Status

- Research funded by BWV to evaluate the viability of this vaccine platform to potentially provide protection against multiple pathogens including, non-typeable *Haemophilus* influenzae (NTHi)
- License expansion, Provisional patented filed

BWV-201 Proof of Concept*

Deletion of ftsY, a central component of the signal recognition particle (SRP) pathway show heightened sensitivity to environmental stress and have greatly diminished virulence.

Deletion of caxP, a calcium/magnesium transporter, renders host physiological conditions in blood and mucosa toxic to the bacterium.

Vaccines in Study	Serotypes
D39DftsY	2
D39DcaxP	2
BHN97DftsY	19F
BHN97DcaxP	19F
PCV7	4, 6B, 9V, 14, 18C, 19A, 19F & 23 F
PCV13	1, 3, 4, 5, 6B, 7F, 9V, 14, 18C, 19A, 19F & 23 F
PPV23	1, 3, 4,5, 6B, 7F, 8, 9V, 10A, 11A,12F, 14, 15, 17A 18C, 19A, 19F, 20, 22F, 23F & 33 F
Mock	None

*Rosch, Jason W et al. "A live-attenuated pneumococcal vaccine elicits CD4+ T-cell dependent class switching and provides serotype independent protection against acute otitis media." *EMBO molecular medicine* vol. 6,1 (2014): 141-54. doi:10.1002/emmm.201202150

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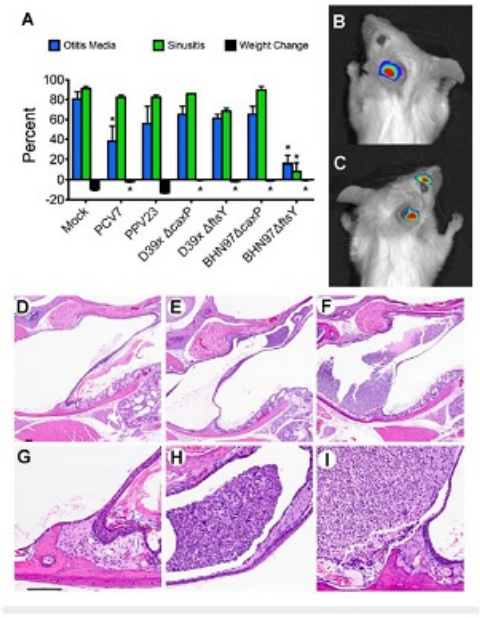
Pre-Clinical Data: Mouse Model*



Vaccine Protection against AOM and sinusitis

- 25-31 per group, performed at least twice
- Vaccinated with either Mock or live attenuated with deletions on either type 2 or 19 F background.
- Challenged with bioluminescent BMH97X (type 19F), imaged twice daily for AOM and sinusitis

A. The proportion of mice developing infection of ear or sinus by Xenogen imaging PPV23 was used as a negative control

B.,C. Representative pictures from bioluminescent imaging with (B) AOM and (C) both AOM and sinusitis.

D-I. Representative histopathology at 4x (top row) and 40x (bottom row) of (D,G) normal ear, (E,H) mouse with mild AOM and (F,I) marked AOM

* Rosch, Jason W et al. "A live-attenuated pneumococcal vaccine elicits CD4+ T-cell dependent class switching and provides serotype independent protection against acute otitis media." *EMBO molecular medicine* vol. 6,1 (2014): 141-54. doi:10.1002/emmm.201202150

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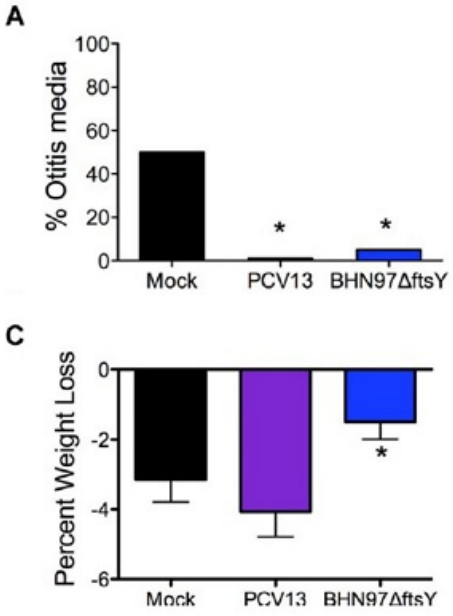
Pre-Clinical Data: Mouse Model*



Vaccine protection against heterologous challenge

- Mice were mock-vaccinated with PBS (Mock) or vaccinated with PCV13 or a live attenuated vaccine deleted for FtsY on a type 19F background (BNH97ΔftsY).

A. Mice were challenged with a bioluminescent version of *S. pneumoniae* strain BNH54 (type 7F) and assessed by imaging for development of otitis media over 72 h (24 h time point is pictured).

C. Weight loss observed in the animals further supported the observed protection. PCV13 contains type 7F antigen, so this was a homologous challenge for the PCV13 group but a heterologous challenge for the BNH97ΔftsY group.

*Rosch, Jason W et al. "A live-attenuated pneumococcal vaccine elicits CD4+ T-cell dependent class switching and provides serotype independent protection against acute otitis media." *EMBO molecular medicine* vol. 6,1 (2014): 141-54. doi:10.1002/emmm.201202150

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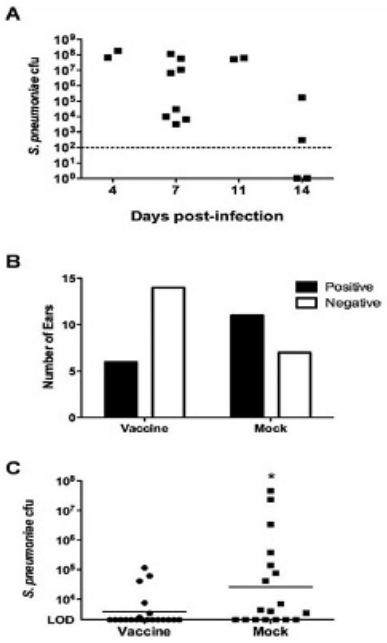
Pre-Clinical Data: Chinchilla Model*



Vaccine protection in chinchilla model of AOM

A. The BHN97 strain is capable of causing AOM in chinchillas via intranasal administration as observed by recoverable bacterial colony forming units (CFUs) from the middle ear (A) following challenge.

B.,C. Following vaccination, a reduction in the number of culture positive ears in vaccinated group compared to the mock animals was observed (B) as well as significant reduction in recoverable CFUs from middle ear 7 days post challenge (C).

*Rosch, Jason W et al. "A live-attenuated pneumococcal vaccine elicits CD4+ T-cell dependent class switching and provides serotype independent protection against acute otitis media." *EMBO molecular medicine* vol. 6,1 (2014): 141-54. doi:10.1002/emmm.201202150

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Cincinnati Children's

S&P Nanoparticle VLP

BWV 301: Norovirus-Rotavirus

We aim to mitigate the global abundance of pathogen mediated digestive tract infections via our novel norovirus/rotavirus chimeric vaccine.

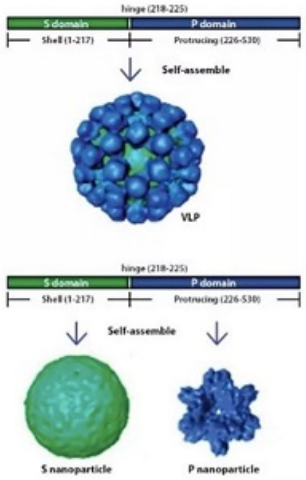
Versatile Nanoparticle VLP Vaccine Platform

Our novel Shell and Protrusion (S&P) norovirus platform combines 2 or more immunogenic components: a norovirus antigen + at least one additional antigen = novel vaccines

Discovery Engine: potentially stable, flexible, cost-effective nanoparticles

POC: animal models showed strong enhanced immunogenicity

Broad therapeutic capabilities & Partnering opportunities



Cincinnati Children's

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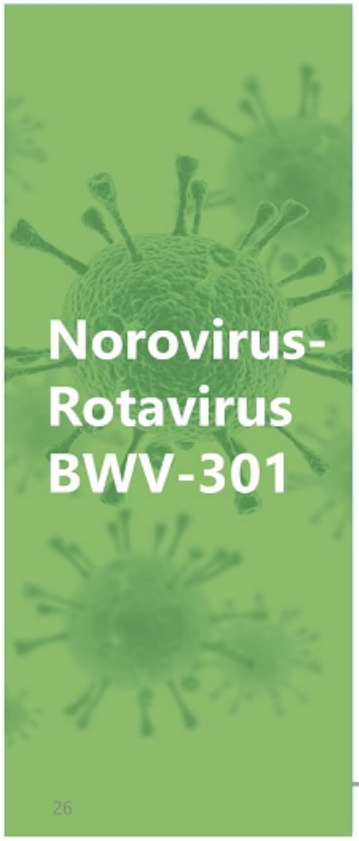


Norovirus-Rotavirus BWV-301

Impact / Need

- Norovirus is the most common cause of acute gastroenteritis, 700 million global annual cases
- Rotavirus causes an estimated 111 million annual episodes of diarrhea
- Rotavirus is the most common cause of diarrheal disease among infants and young children
- No norovirus vaccine is available to date

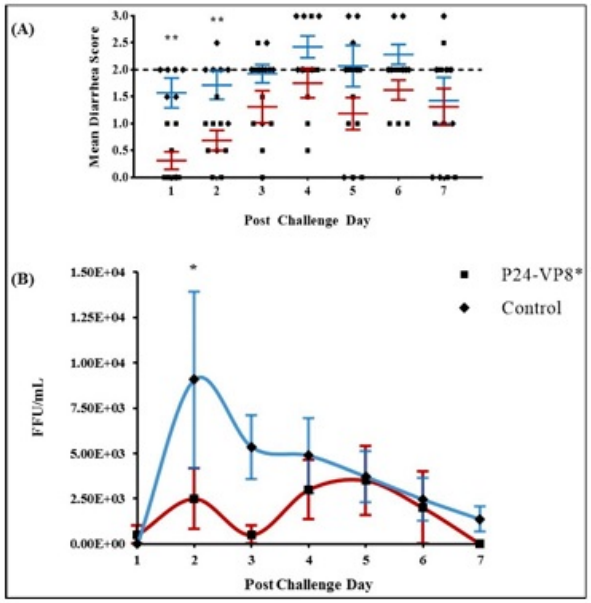
BWV's Differentiated Approach

- Our S&P platform was co-invented by Xi Jason Jiang, Ph.D., and Ming Tan, Ph.D., of the Division of Infectious Disease at the Cincinnati Children's
- ELV's are ideal vaccine targets for broad long-term protection

Current Status

- Preclinical data from gnotobiotic pig studies showed BWV-301 prevented severe gastroenteritis and reduces viral shedding.
- Identification of S_{60} - VP8 (rotavirus spike protein)
- Preclinical mouse sera after immunization with the S_{60}-VP8* nanoparticle exhibited higher neutralizing activity

Pre-clinical Data: Gnotobiotic Pig Model*



P_{24}-VP8* vaccine protected against VirHRV diarrhea and reduced overall viral shedding.

* Ramesh et al. *Vaccines* 2019, 7, 777

VirHRV = virulent human rotavirus

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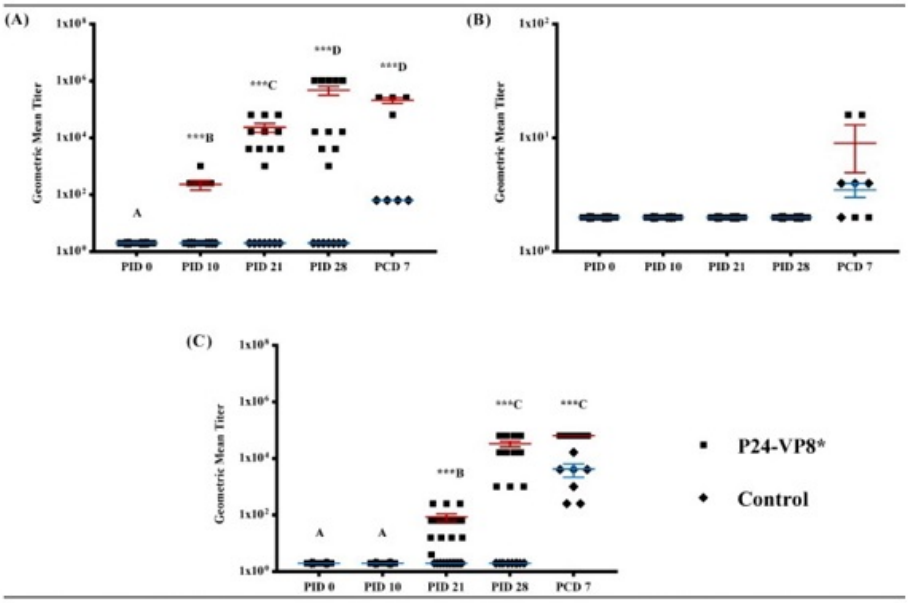
Pre-clinical Data: Gnotobiotic Pig Model*



Vaccine provided neutralizing antibodies in serum collected from gnotobiotic pigs

*Ramesh et al. *Vaccines* 2019, 7, 777

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Pre-clinical Data: Mouse Model*

- Vaccination of mice with vaccine candidate P_{24} particle presenting the small domain of the CS protein (3D7-PP) and two controls. Mice were immunized three times with the chimeric nanoparticle using aluminum hydroxide as an adjuvant. Sera was collected and evaluated.
- Data demonstrate vaccine candidate produces a higher titer

Antibody titer after 2nd immunization

	3D7-PP	3D7-His	3D7-GST
Mouse-1	**25600**	800	400
Mouse-2	**51200**	<100	400
Mouse-3	**25600**	400	400
Mouse-4	**25600**	<100	800

Antibody titer after 3nd immunization

	3D7-PP	3D7-His	3D7-GST
Mouse-1	**201400**	25600	12800
Mouse-2	**402800**	12800	12800
Mouse-3	**201400**	25600	12800
Mouse-4	**402800**	12800	12800

* BWV Presentation

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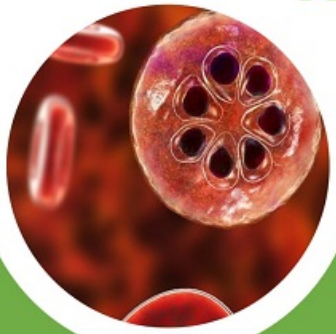
BWV 302: Norovirus-Malaria



We aim to mitigate the global abundance of pathogen mediated digestive tract infections via our novel norovirus/malaria chimeric vaccine.

Norovirus-Malaria

Overview

Worldwide estimates each year:
Caused by protozoan parasites from the Plasmodium family:

- About 219 million cases were reported in 2019 leading to an estimated 409,000 deaths globally.*
- Approximately 67% of the deaths can be attributed to children.*

Current Treatment limitations*,***, ****

- One vaccine currently available for treatment with limited authorization by the EMA in high transmission regions, outside of the of the European Union.
- The two most common treatments are Chloroquine phosphate and Artemisinin-based combination (ACT) therapies

Economic Impact

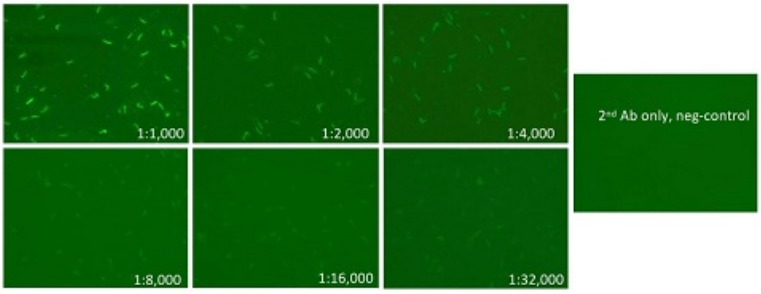
- Direct cost of $12 billion worldwide each year**

There is growing concern about resistance to mosquito control pesticides and existing malaria treatment*, *

* WHO, https://www.who.int/news-room/fact-sheets/detail/malaria ** https://www.cdc.gov/malaria/malaria_worldwide/impact.html
. . (https://www.ema.europa.eu/en/news/first-malaria-vaccine-receives-positive-scientific-opinion-ema) *. https://www.nature.com/articles/s41591-020-1005-2.pdf

Pre-clinical Data: Mouse Model*

IFA of plasmodium sporozoites (3D7) stained with anti-P24 particle presenting the small domain of the CS protein mouse sera



- The antibodies were also shown to recognize the plasmodium falciparum 3D7 strain using immunofluorescence assays

* BWV Presentation.

VirHRV = virulent human rotavirus

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BWV: Highlights

1. **Developing a broad portfolio of vaccine candidate**
   Influenza, AOM induced s. pneumo, noro-rotavirus
2. **New ELV data for universal influenza**
   Presented at WVC
3. **Recent expansion of St. Jude Research for BWV-201**
   Potential to provide broad coverage of AOM causing antigens
4. **Secured Cash Runway to continue ongoing development**
   $20m IPO and $8m PIPE

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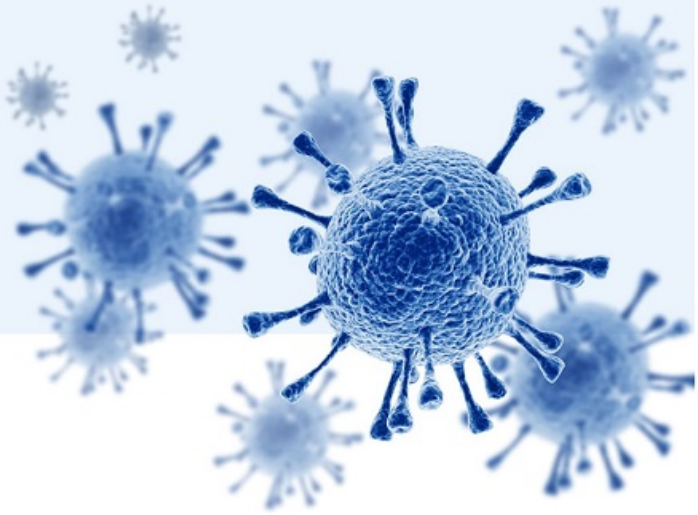
vaccines



Appendix

- Intellectual Property
- Influenza: background, data
- S. *pneumo* induced AOM: background/data
- S&P Nanoparticle VLP Platform
- Norovirus-Rotavirus
- Norovirus-Malaria

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Our U.S. IP Portfolio

S&P Platform[1]:

- US Patent 8,486,421: "Antigen-Norovirus P-Domain Monomers and Dimers, Antigen-Norovirus P-Particle Molecules, and Methods for Their Making and Use"
- US Patent 9,096,644: "Antigen-Norovirus P-Domain Monomers and Dimers, Antigen Norovirus P-Particle Molecules, and Methods for Their Making and Use"
- US Patent 9,562,077: "Protein Complex System For Increased Immunogenicity and Functionality, and Methods Making and Use"
- U. S. patent pending application no. 16/489,095: "Norovirus S Particle Based Vaccines and Methods of Making and Using Same"
- U.S. pending provisional application nos. 63/149,742 & 63/162,369: "S60-HA1 pseudovirus nanoparticles as a new influenza vaccine tactic and candidate"

Influenza[2]:

- US Patent 11,123,422: "Immunogenic composition"
- US patent application no. 17/458,712: "Immunogenic composition"

S. pneumonia[3]:

- US Patent 9,265,819: "Live, attenuated *Streptococcus pneumoniae* strain and vaccine for protection against pneumococcal disease"

In Process IP[4]:

- OUI project 16867 – Influenza A haemagglutinin antigen Group 2 (H3)
- OUI Project 16870 – Influenza Group B haemagglutinin antigen
- OUI Project 16872 – VLP delivery system for influenza vaccine

[1] Cincinnati Children's Hospital Medical Center exclusive license. [2] Oxford University Innovation Limited exclusive license. [3] St. Jude Children's Research Hospital, Inc. exclusive license. [4] Oxford University Innovation Limited exclusive license.

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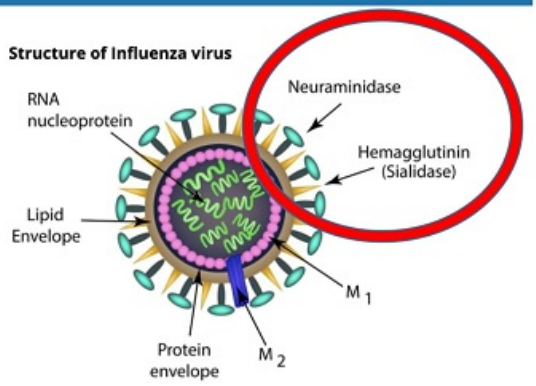
Influenza Viruses[6]

Influenza A: epidemic and pandemic → Subtypes based on two viral proteins:
H: hemagglutinin (HA)
N: neuraminidase

Influenza B: epidemic, slower mutations → Lineages
B: Victoria
B: Yamagata

Influenza C: mild, non-pandemic, vaccine not needed

Influenza D: animals only



Influenza A&B cause most of human illness and the flu season

18 different hemagglutinin subtypes (H1-H18)

11 different neuraminidase subtypes (N1-N11)

https://www.cdc.gov/flu/about/viruses/types.htm

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Influenza

Overview*

Worldwide estimates each year:

- **1 billion cases** of influenza infection
- **3-5 million severe cases**
- **290,000-650,000 deaths**

Current Treatment limitations***

- Target regions of the virus that is highly variable
- Annual flu vaccine effectiveness at preventing disease ranges between 20 and 60%
- Updated annually and reformulated 6-months prior to flu season and may not protect against subsequent strains

Economic Impact**

- **$4 billion** is spent annually on influenza vaccines worldwide
- **$87 billion** estimated lost productivity in the US alone

Our mission is grounded in the belief that vaccines are the best way to protect against the flu

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* https://www.who.int/influenza/Global ** https://www.reportlinker.com *** cdc.gov

S. pneumo induced AOM

Overview

Worldwide estimates each year:

- **709 million cases** per year, with 51% occurring in children under 5 years old*,10
- By 3 years of age, 80% of children are expected to have at least one episode*
- AOM due to *S. pneumoniae* is estimated to be 30-50%**

Impact

- **$4.3 billion USD** is spent on AOM treatment each year in the U.S. alone***

Current Treatment limitations

- Current treatment for AOM is by antibiotic prescription, with more than 80% of all consultations resulting in a prescription ***
- Even with introduction of the Prevnar13 in 2010, 26-36% of cases of AOM in U.S. were caused by *S. pneumoniae*[10]

Current treatments have limited effect on prevention of AOM due to S. pneumoniae*

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* Monsata 2012 2012; 7(4): e36226.
** Dagan et al. *The Journal of Infectious Diseases*, Volume 181, Issue 4, April 2000. *** Tong et al BMC Health Serv Res. 2018; 18: 318.

Our Approach

- In-licensed the novel attenuated *S. pneumoniae* strain from St. Jude Children's Research Hospital
- Our BWV-201 vaccine candidate is a live attenuated serotype-independent vaccine
- Long-term preventive intranasal vaccine for *S. pneumoniae* induced acute otitis media (AOM)
  - Potential short-term pain and/or long-term harmful side effects
  - Complications from AOM include sensorineural hearing loss (SNHL)
- Production of vaccine is straightforward
  - Utilizes the entire bacterium with purification and concentration steps only in the downstream process
  - Reduces the time and cost of production significantly compared to the commonly used vaccines

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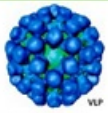
Versatile Vaccine Platform*,**

Cincinnati Children's

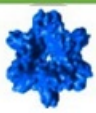
S-domain

- 60 freely exposed C-termini = S_{60} nanoparticle
- Foreign antigens fused to the end of the S domain via flexible linker
- Uniform 60-valent NoV VLPs via an expression system
  - never been produced before.
- S_{60} n nanoparticles maintained uniform complexity and size of vaccine particles



S&P Platform Characteristics

- Unique capsid dual-domain proprieties: S&P
- Stable, subviral nanoparticles
- Scalable, flexible discovery engine
- Multi-antigen and pathogen capabilities
- Broad therapeutical potential
- Cost-effective and Rapid Production of Novel Vaccines
- *E.coli* expression system



P-domain

- 24 valent P nanoparticles= P_{24}
- Three loops = multi-antigen potential
- Nanoparticles without adjuvant produce innate, humoral, and cellular immunity
- inter-P domain disulfide bonds significantly stabilizes P_{24}

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* TAN et al. REVIEW, Nanomedicine. 2012.

** Xia et al. *ACS Nano* **2018** *12* (11), 10665-10682.

NoV: NoraVirus. VLP: Vector-like-Particle(s)

Norovirus-Rotavirus

Overview

Worldwide estimates each year:
Norovirus is the most common cause of acute gastroenteritis, 700 million cases.*,***

- About 200 million cases are seen among children under 5 years old, leading to an estimated 50,000 child deaths every year.*

Rotavirus causes an estimated 111 million episodes of diarrhea*

- 2 million hospitalizations, and 352,000–592,000 deaths in children <5 years of age.*

Economic Impact

- **Norovirus:** $60.3 billion worldwide each year**

Current Treatment limitations*

- Norovirus: No vaccine is available
- Rotavirus: Current vaccines exist. Two vaccines are authorized for use in infants in the U.S. with a reported efficacy of 85-95%.****

Rotavirus is the most common cause of diarrheal disease among infants and young children*

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*. cdc.gov / Parashar et al. EID Journ May 2003 **. Bartsch et al. PLoS One 2016; 11:e0151219. ***. Shah et al. Infect Dis Clin North Am. 2018 Mar; 32(1): 103–118.
**** https://www.cdc.gov/vaccines/vpd/rotavirus/hcp/about-vaccine.html