

NOROVIRUS KOL EVENT

March 28, 2023

FORWARD-LOOKING STATEMENTS

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Vaxart's Oral Vaccine Platform

Sean Tucker, PhD

Vaxart Founder and Chief Scientific

Vaxart Solution: Intestinal Delivery + Targeted Immune Activation: Non-replicating Vector With A Molecular Adjuvant

- Key Issues we solve:
 - 1. Replicating oral vaccines don't work well in the developing world
 - 2. Protein delivered to the intestine is treated like food
 - 3. Pre-existing adenovirus immunity hinders injected adenovirus vaccines ^{1,2}



VAAST[™]: Vector-Adjuvant-Antigen Standardized Technology

Room-temperature stable enteric-coated tablets



1 Liebowitz, et al, *Lancet ID* 2015 2 Kim, et al, *JCI Insight*, 2018



Benefits of Vaxart Vaccine Platform



Distribution

- Temperature stable tablets
- Self administered
- Rapidly deployed in a pandemic or stockpiled

<u>Safety</u>

- Well-tolerated in studies to date
- No injection site pain

Immunogenicity

- Vaccine antigens delivered to a mucosal surface creating mucosal IgA
- Durable serum responses
- Enhances immune responses at the site of infection



The Importance of Mucosal IgA and IgA Antibody Secreting Cells

- Mucosal Immunity Important For Protection Against Norovirus
 - Correlates of protection from human challenge studies: rapid induction of mucosal IgA, serum IgA
- Correlate of protection in oral polio vaccine challenge
 - o a4b7 positive IgA antibody secreting cells
- IgA Better at Cross-reactivity and Neutralization
 - o IgA works by exclusion AND by neutralization
 - Head-to-head comparison between IgG, mIgA, dIgA suggests dIgA is a more potent neutralizing isotype
 - o IgA is much more cross-reactive isotype
- Injected vaccines and mucosal vaccines can have completely different correlates of protection
 - References:
 - Atmar, at al, CVI, 2015.
 - Ramani, et al, PlosPathogens 2016
 - Dey, et al, PLOSone, 2016
 - Sapparapu, et al, PlosPathogens 2016
 - Liebowitz, et al, Lancet ID, 2020



Oral Tablet Vaccine Protects As Well As An Injected Vaccine Against A Respiratory Pathogen

Oral Vaccine Candidate protected against influenza infection as well as market leading injected vaccine after influenza challenge

- Both vaccines protected against illness and infection
- Oral Vaccine had a different correlate of protection
 - Mucosal homing, antigen specific IgA B cells were found to be most important for protection
 - Very few were needed to get same level of protection as very high serum neutralizing antibody levels.

Reduced Infection Rates for both vaccines



Liebowitz, et al, Lancet ID, 2020



Working Model: Oral rAd5 Tablet Vaccine for the Norovirus Indication





VP1 Capsid Protein Is the Transgene Antigen in Vaxart's Oral Norovirus Vaccine

• VP1 mediates attachment to epithelial cells through interactions with carbohydrates





Vaxart Oral Norovirus G1.1 Vaccine Elicits Mucosal Homing B Cells That Are Enriched for IgA Production





Summary

Vaxart is developing an oral vaccine platform

- There are major logistical advantages of giving out pills for vaccines
- A key technical benefit of oral vaccination is the ability to make a mucosal response
- Oral vaccine platforms have been tricky to develop, but Vaxart has solved the major technical issues
- Oral vaccines can have different immune correlates of protection than injected vaccines
 - Mucosal homing, antigen specific IgA B cells were found to be most important for protection in a flu challenge study
- Vaxart is developing a norovirus vaccine that expresses the main norovirus surface protein (VP1) in intestinal cells





Norovirus Clinical Trials

James F. Cummings, MD

Vaxart Chief Medical Officer

Norovirus Clinical Trials - Completed

Trial ID	Phase/Design	# subjects	Age	Vaccine & Dose (IU)	# doses	Top line data	Completed
VXA-G11-101	Phase 1 double blinded Dose Ranging	66	18-49	GI.1 monovalent: 1.7x10 ¹⁰ 1x10 ¹¹ placebo	2	 Favorable safety and tolerability profile Higher immunogenicity responses observed in high dose group 	\checkmark
VXA-G11-102	Phase 1b open label Dose & Regimen Optimization	60	18-49	Gl.1 monovalent: 1.7x10 ¹⁰ (Days 1 & 8) 1.7x10 ¹⁰ (Days 1,3 & 5) 1.7x10 ¹⁰ (Days 1 & 29) 1.7x10 ¹⁰ (Days 1 & 29)	2 or 3	 Favorable safety and tolerability profile in all groups Confirmed findings of VXA-G11-101: single 1x10¹¹ IU dose is safe & immunogenic inducing both BT50 and ASC responses 	\checkmark
	Phase 1b double blinded R/O Bivalent Interference	80	18-49	GI.1 monovalent 5x10 ¹⁰ GII.4 monovalent 5x10 ¹⁰ GI.1/GII.4 bivalent 1x10 ¹¹ placebo	1	 Favorable safety and tolerability profile Statistically significant rises in Serum GI.1 BT₅₀ and ASC IgA in the GI.1, GII.4 and Bivalent group over placebo. Bivalent vaccine induced similar immune response to GI.1 and GII.4 as the respective monovalent vaccines. No significant differences between the Monovalent groups versus the Bivalent group, indicating lack of interference 	\checkmark
VXA-NVV-103	Duration of Response	23	18-49	No dosing (long term immuno)	N/A	GII.4 produces longer duration of serum immunogenicity after 16 months	\checkmark
	open label Boost Extension	12 bivalent or mono GI.1 (n=7) or placebo (n=5)	18-49	GI.1 monovalent 5x10 ¹⁰	1 (Boost)	 Equivalent immune response with GI.1 boost after 18 months in subjects who initially received bivalent or monovalent GI.1 vaccine compared to placebo 	\checkmark
VXA-NVV-104	Phase 1b double blinded Dose Ranging in Elderly	65	55-80	GI.1 monovalent: 1x10 ¹⁰ 3x10 ¹⁰ 1x10 ¹¹ placebo	2	 Favorable safety and tolerability profile Similar immunogenicity in older population compared with younger groups 	\checkmark
VXA-NVV-105	Phase 1b open label Boost Optimization at 4, 8 and 12 Weeks	30	18-55	GI.1 monovalent: 1x10 ¹⁰ (Days 1, 29) 1x10 ¹⁰ (Days 1, 57) 1x10 ¹⁰ (Days 1, 85)	2	 Favorable safety and tolerability profile Trend indicating an increase in immunogenicity with increasing interval between first and second dose leads to 	\checkmark
VXA-NVV-106	Phase 1 Open label Sub-Dose Administration	8	18-55	GI.1 monovalent $(2.2x10^9 \text{ IU per tablet; 45} \text{ tablets to deliver dose of } 1x10^{11} \text{ IU } \pm 0.5 \text{ log)}$ 15 tablets at T = 0 15 tablets at T = 2 hours 15 tablets at T = 4 hours	1	Favorable safety and tolerability profile Comparable immunogenicity to other GI.1 lots and administration	✓



VXA-NVV-101 Study

Phase 1 Double-Blinded Placebo Controlled

- GI.1, monovalent, two dose levels
- monovalent in 66 healthy adult volunteers

Vaccine Group	Designation	Dose (I.U.)	Subject number
Monovalent GI.1	VXA-G1.1-NN	1.7x10 ¹⁰	23
Monovalent GI.1	VXA-G1.1-NN	1x10 ¹¹	23
Placebo			20



Vaxart Oral Norovirus Vaccine: Dose Dependent Antigen-Specific IgG and IgA ASC Responses

- This study tested 1 tablet (1.7e10) vs 7 tablets (1e11) generating immune responses
- IgAASC have correlated to protection in other enteric pathogen studies





Vaxart Oral Norovirus Vaccine: Fecal IgA Responses Durable to 180 Days

No significant differences in fecal IgA responses between 1 tablet vs 7 tablets

Fecal IgA response 10000 Fold Increase in VP1 IgA D28 1000 D180 100 10 0.1 Placebo LowDose tighDose Group Kim et al. JCI, 2018 Fecal IgA measured by Marcela Pasetti, Clinical trial # NCT02868073 U Maryland, Baltimore



Immunophenotyping After G1.1 Viral Challenge Compared to rAd5 Vaccination



NVV-101 and Titration study



Plasmablast Responses Following Oral Immunization Is Comparable to GI.1 Infection

Plasmablasts (CD38+/CD27+)





VXA-NVV-103 Study

- Phase 1B Double-Blinded Placebo Controlled
 - GI.1, GII.4 or GI.1/GII.4
 - o monovalent or bivalent dosing in 80 healthy adult volunteers
 - Clinical trial # NCT03897309

Vaccine Group	Designation	Dose (I.U.)	Subject number
Monovalent GII.4	VXA-G2.4-NS	5x10 ¹⁰	5 sentinels + 15
Monovalent GI.1	VXA-G1.1-NN	5x10 ¹⁰	15
Bivalent	VXA-G2.4-NS + VXA-G1.1-NN	5x10 ¹⁰ / 5x10 ¹⁰	30
Placebo			15



Both Monovalent and Bivalent Norovirus Vaccine Generates Robust IgA ASC



Responder definition:

 3 standard deviations above the mean prevaccination count

IgA <u>> 23 spots/ 10⁶ PBMCs</u>

	Antigen			
Vaccine	G1.1	G11.4		
GI.1	85.70%	14.30%		
G11.4	68.40%	89.50%		
GI.1/ GII.4	77.80%	92.60%		



VXA-NVV-104 Study – Elderly Subjects

- Phase 1 Double-Blinded Placebo Controlled
 - GI.1, Low, medium and high doses in elderly subjects 55-80 years of age
 - Each dose cohort randomized with placebo
 - Two placebo subjects dropped out leaving 63 subjects to finish the trial

Group	Study Drug	Dose (IU)	No. of Doses	Dosing Schedule	No. of Subjects (Day1/Day29)
Cohort 1	VXA-GI.1-NN	1x10 ¹⁰	2	Day 1 & Day 29	16/16
(low dose)	Placebo	N/A	2	Day 1 & Day 29	8/7
Cohort 2	VXA-GI.1-NN	3 x10 ¹⁰	2	Day 1 & Day 29	16/16
(medium dose)	Placebo	N/A	2	Day 1 & Day 29	8/8
Cohort 3	VXA-GI.1-NN	1x10 ¹¹	2	Day 1 & Day 29	11/11
(high dose)	Placebo	N/A	2	Day 1 & Day 29	6/5
				Total	65/63



No Difference in ASC IgA Response Is Detected When Stratifying by Age or When Comparing to Previous G1.1 Monovalent Clinical Trials



Cut-off for responder (dotted line) is 23 spots



Sustained Serum IgA Antibody Responses After 200+ Days





Sustained Serum IgG Antibody Responses After 200+ Days





BT50 Is Maintained for >210 Days





Distal Mucosal IgA Is Detected in Subjects Given Norovirus Vaccine





Norovirus Clinical Trials – In Progress and Upcoming

Trial ID	Phase/Design	# subjects	Ages	Vaccine & Dose	# doses	Objectives	Completed
VXA-NVV-201	Phase 2 double blinded Infectious virus (GI.1) challenge	140 vaccinated 120 challenged	18-49	GI.1 monovalent: 1x10 ¹¹ placebo	1	 <u>Primary</u>: Clinical efficacy of VXA-G1.1 NN to protect against acute norovirus gastroenteritis following a single immunization with the VXA-G1.1 NN vaccine compared to placebo <u>Secondary</u>: Safety and immunogenicity of GI.1 vaccine Correlate immunogenicity parameters with clinical outcome 	Ongoing Topline expected Q3 2023
VXA-NVV-202	Phase 2 double blinded Dose Confirmation	125 + 10 sentinels	18-80	GI.1/GII.4 bivalent 1x10 ¹¹ 2x10 ¹¹ placebo	1	 <u>Primary</u>: Safety and immunogenicity of a bivalent dosing regimen of GI.1 and GII.4 Dose selection for Phase 3 <u>Secondary</u>: 	Ongoing Topline expected Q2 2023
VXA-NVV-108	Phase 1 double blinded Immunogenicity in lactating women (oral transfer of maternal noro IgA as evaluated in infant fecal sample)	76	18+	GI.1/GII.4 bivalent 1x10 ¹¹ 2x10 ¹¹ placebo	1	 <u>Primary</u>: Safety and tolerability of a bivalent dosing regimen in lactating women Short-term immunogenicity of the bivalent GI.1/GII.4 norovirus vaccine in healthy lactating female participants and its association with the immunogenicity response in breastmilk. 	Planned FPI Q3 2023



VXA-NVV-201 Study – Norovirus Challenge Study

- Phase 2 Double-Blinded Placebo Controlled Study
 - GI.1 or placebo, given to healthy subjects
 - Given norovirus infection 29+ days after vaccination
 - Determine infection and illness rates (AGE) in placebo and vaccinated subjects
 - Measure immune parameters; determine which ones are important at predicting protection





VXA-NVV-202: Bivalent NVV-GI.1-NN & NVV-GII.4 – In Progress

<u>Study Design</u>: Phase 2, multicenter, randomized, double-blind, placebo-controlled, single dose regimen, dose confirmation study <u>Population</u>: Healthy adults ages 55-80; 125 randomized + 10 open label high dose sentinels

Product: Bivalent GI.1 and GII.4 vaccines (VXA-G1.1-NN plus VXA-GII.4-NS):

- Arm 1: Bivalent GII.4/GI.1(VXA-GII.4-NS plus VXA-G1.1-NN) 5×10^{10} tablets; dose is 1×10^{11} IU/dose (n=50)
- Arm 2: Bivalent GII.4/GI.1 (VXA-GII.4-NS plus VXA-G1.1-NN) 1×10¹¹ tablets; dose is 2×10¹¹ IU/dose (n=50)
- Arm 3: Placebo tablets (n= 25)

Primary Objectives:

- Safety and immunogenicity of a bivalent dosing regimen of GI.1 and GII.4
- Select the dose level with which to safely proceed into Phase 3 development

Primary Endpoints (Safety):

- Frequency, duration, and severity of Solicited Symptoms of Reacto for 1wk post dose
- Frequency, duration, and severity of unsolicited adverse events (AEs) for 28D post dose

Primary Endpoints (Immunogenicity):

- Serum Anti-VP1 GI.1 IgA and Anti-VP1 GII.4 IgA (MSD) assay by dose level (D1,29)
- Serum Anti-VP1 GI.1 IgG and Anti-VP1 GII.4 IgG (MSD) assay by dose level (D1,29)
- Serum Antibody BT50 titers for both GI.1 and GII.4 by Histo-blood group antigen (HBGA) Assay

VXA-NVV-108 Study

- Phase 1 Double-Blinded Placebo Controlled
 - GI.1, G2.4 bivalent vaccine, two dose levels
 - 76 healthy breast-feeding volunteers

Vaccine Group	Designation	Dose (I.U.)	Subject number
Bivalent	VXA-G2.4-NS + VXA-G1.1-NN	5x10 ¹⁰ + 5x10 ¹⁰	25
Bivalent	VXA-G2.4-NS + VXA-G1.1-NN	1x10 ¹¹ + 1x10 ¹¹	25
Placebo			16





Vaxart Norovirus Vaccine Clinical Highlights

- Induces broad immune responses mucosal and serum
- Immune response rates above 90% for high dose
- Immune responses were durable, lasting over 200 days
- Vaccine responses can be boosted after a year
- Bivalent vaccine showed no interference between strains
- Immune responses induced in the elderly (55-80) were similar to those in young adults (18-49)
- Clean safety profile well tolerated in all clinical trials to date





Norovirus Market Opportunity and Disease Burden

Andrei Floroiu

Vaxart Chief Executive Officer

Norovirus Program: Addressing A Very Large Opportunity With Compelling Clinical Data Generated So Far

- Enterically delivered mucosal vaccine addressing enteric mucosal infection
- Compelling data based on completing 6 norovirus clinical trials enrolling almost 350 subjects immune responses have been:
 - Strong
 - Broad (mucosal and serum)
 - Long-lasting
 - Similar to natural infection
 - Similar in elderly as in younger adults
- \$10bn+ annual U.S. disease burden; \$60bn+ globally
- Significant unmet need no approved vaccine
- Ability to maximize value by optimizing pricing with different pediatric and adult formulations



Norovirus: \$10 billion+ Disease Burden

Presents significant threat to children and seniors

\$10.6 billion

U.S. market opportunity

21,000,000

illnesses/year caused by norovirus in the U.S.

15% of children under 5 catch norovirus

annually

7.5%

3,000,000 sets of parents need to take time from work (2.2 days) to

time from work (2.2 days) to care for these children

of age 65+ get sick, most hospitalizations in this group Economic burden of disease concentrated in these two groups





Source: Incidence of Norovirus and Other Viral Pathogens That Cause Acute Gastroenteritis (AGE) among Kaiser Permanente Member Populations in the United States, 2012–2013, Grytdal et al, PLOS 1, 2016

Source: CDC website (https://www.cdc.gov/norovirus/php/illness-outbreaks.html



U.S. Opportunity Is Driven By Pre-school Children and Seniors



Age	0-4	5 - 64	65+
Population US	20M	260M	55M
Price Target	\$500 ⁵	\$50 ¹	\$75 ⁵
Prospect of ACIP recommendation	High	Low	High
Percent vaccinated ²	70% ³	4%	65% ⁴
Market potential	\$7.0B+	\$0.5B	\$2.7B+

Source

* Grytdal et al, PLOS 1, 2016, Incidence of Norovirus and Other Viral Pathogens That Cause Acute Gastroenteritis (AGE) among Kaiser Permanente Member Populations in the United States, 2012–2013 1) US Disease burden, Bartsch S et al., Vaccine 2012 30(49):7097; 2) Assumes ACIP recommendation; 3) US Rotavirus complete series vaccination rate; 4) US Influenza Vaccine Age 65+ vaccination rate; 5) Potential Clinical and Economic Value of Norovirus Vaccination in the Community Setting, , Bartsch S et al., AJPM 2021- Cost Savings Price



Annual Delivery of Norovirus Vaccine Matches Flu

Seasonality: "Winter Vomiting Disease"

Acute gastroenteritis outbreaks in the U.S.A.



Hall AJ et al. Emerg Infect Dis 2012;18:1566-73.; Hall AJ et al. National Outbreak Reporting System (CDC/NORS) unpublished data.

Commercial Impact:

- The seasonality of disease allows for vaccination of norovirus vaccine at the same time people get flu vaccine
- Potential customers already getting flu vaccines: no additional effort needed to drive them to a clinic:
 - Adults Age 65+: 65%-75% per year
 - Children under age 5: 65-70% per year



ACIP Recommendation for A Norovirus Vaccine Would Insure Federal Government Coverage for Key Segments

Population	Size (M)	Payer
Pediatrics	20	VFC (~60%), Insurance
Elderly	55	CMS
First responders	2.7	Employer
Immunocompromised	7.4	Insurance
Military	1.4	
Childcare	1.8	
Health Care Workers	12.6	Employer
Food Handlers	13.3	Self Pay
Travel Industry	7.5	
Business Travelers	44	
Cruise Population	11	

Recommended	Permissive
Category A	Category B

ACIP recommendations likely for <5 year olds and ≥65 year olds

This means that the federal government would pays for most of the vaccine used in these populations and insurers must include on formulary

- Vaccine for Children (VFC) covers kids < 5 years
- Center for Medicaid and Medicare Services (CMS) covers people age 65+

Bartsch S et al., Vaccine 2012 30(49):7097-7104; Lopman B et al., CDC 2016; CDC; Long S et al. "Principles and Practice of Pediatric Infectious Diseases," Harpaz R et al., OFID 2016:1, ACIP-Advisory Committee on Immunization Practices, CMS-Center for Medicare and Medicaid Services, VFC – Vaccine for Children



Norovirus

Population	Size (M)	Payer
Pediatrics	20	VFC, Insurance
Elderly	55	CMS,
First responders	2.7	Employer,
Immunocompromised	7.4	insurance
Military	1.4	

Pneumococcal

Population	Size (M)	Payer
Pediatrics	4	VFC, Insurance
Elderly	55	CMS

Pneumococcal Vaccine (2022)

- \$6.3 Billion Global Sales
- \$4 Billion US Sales
- ACIP recommendation
 - \$600-800 per child
 - \$170-250 per adult

ACIP – Advisory Committee on Immunization Practices, CMS – Center for Medicare and Medicaid Services, VFC – Vaccine for Children



Bartsch S et al., Vaccine 2012 30(49):7097-7104; Lopman B et al., CDC 2016; CDC; Long S et al. "Principles and Practice of Pediatric Infectious Diseases," Harpaz R et al., OFID 2016:1, ACIP-Advisory Committee on Immunization Practices, CMS-Center for Medicare and Medicaid Services, VFC – Vaccine for Children

Norovirus

Population	Size (M)	Payer
Pediatrics	20	VFC, Insurance
Elderly	55	CMS,
First responders	2.7	Employer,
Immunocompromised	7.4	insurance
Military	1.4	

Rotavirus

Population	Size (M)	Payer
Pediatrics	4	VFC, Insurance

Rotavirus Vaccine 2022

- \$1.5 Billion global sales
- ~\$750 Million US sales*
- ACIP recommendation but only 1 birth cohort
 - \$225 per annual regiment

ACIP – Advisory Committee on Immunization Practices, CMS – Center for Medicare and Medicaid Services, VFC – Vaccine for Children



Bartsch S et al., Vaccine 2012 30(49):7097-7104; Lopman B et al., CDC 2016; CDC; Long S et al. "Principles and Practice of Pediatric Infectious Diseases," Harpaz R et al., OFID 2016:1, ACIP-Advisory Committee on Immunization Practices, CMS-Center for Medicare and Medicaid Services, VFC – Vaccine for Children

Norovirus

Population	Size (M)	Payer
Pediatrics	20	VFC, Insurance
Elderly	55	CMS,
First responders	2.7	Employer,
Immunocompromised	7.4	insurance
Military	1.4	

Zoster

Population	Size (M)	Payer
Elderly 65+	55	CMS, Insurance
Elderly 50 - 64	60	Insurance

Shingrix Vaccine 2022

- \$3.7 Billion Global Sales
- \$2.4 Billion US Sales
- ACIP recommendation
 - \$200-360 per adult

ACIP – Advisory Committee on Immunization Practices, CMS – Center for Medicare and Medicaid Services, VFC – Vaccine for Children



Bartsch S et al., Vaccine 2012 30(49):7097-7104; Lopman B et al., CDC 2016; CDC; Long S et al. "Principles and Practice of Pediatric Infectious Diseases," Harpaz R et al., OFID 2016:1, ACIP-Advisory Committee on Immunization Practices, CMS-Center for Medicare and Medicaid Services, VFC – Vaccine for Children

Addressing the Pediatric Population Through Breast Milk Antibodies and Minitablets

- Nursing infants (Gates Foundation co-funded study)
 - Utilize the current 250mg adult formulation to vaccinate lactating mothers
- ~7/8 to 18 year old population
 - Utilize the current 250mg adult formulation
- > 6/12 months to <7/8 year old population
 - Developing infant formulation that can be mixed with food





Vaxart's Different Formulations for the Pediatric and Adult Markets Enable Optimal Pricing for Each Segment

Cost-effective prices vary greatly between the pediatric and adult markets

US Norovirus Vaccine Market	Pediatric (6m – 5y)	Older Adults (≥65y)
Population Size (M)	20	56
Cost-Effective Price	\$500 per course	\$75 per course
VXRT Formulation	Micro Tabs (2-3mm)	Tablets 250mg



Additional Market Opportunity: ~90M People

Population	Size (M)	Payer
Pediatrics	20	VFC, Insurance
Elderly	55	CMS,
First responders	2.7	Employer,
Immunocompromised	7.4	insurance
Military	1.4	
Childcare	1.8	Employer,
Health Care Workers	12.6	Self Pay
Food Handlers	13.3	
Travel Industry	7.5	
Business Travelers	44	
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ACIP

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- \$10bn+ annual U.S. disease burden; \$60bn+ globally
- Significant unmet need no approved vaccine
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Questions

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