VAXART

Unlocking the Full Potential of Oral Vaccines

VXA-NVV-201

GI.1 Challenge Study

Topline Data Review

06 September 2023

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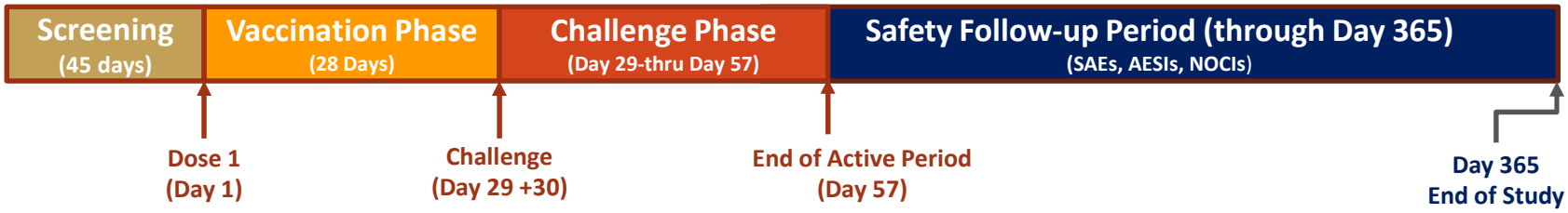
Protocol VXA-NVV-201 Study Design

Protocol Title: A Phase 2b Double-Blinded, Randomized, Placebo-Controlled, Human Norovirus GI.1 (Norwalk Virus Inoculum) Challenge Study Following Administration of an Oral, Single-dose Norovirus Vaccine expressing GI.1 VP1 and dsRNA adjuvant to Protect Against Norovirus Gastroenteritis (NVG) in Healthy Adult Volunteers



Product/Test Agent	No. of subjects
VXA-G1.1-NN oral vaccine tablets [1x1011 IU±0.5 log]	85
Placebo identical to NVV	85
Challenge Norwalk Virus Strain [Lot 001-09NV and Sublot 2 (1x106 GC)]	140

Objectives and Endpoints

Primary Objectives

- To determine the clinical efficacy of our monovalent norovirus vaccine candidate compared to placebo, to protect against norovirus acute gastroenteritis, or AGE, caused by the Norwalk strain challenge inoculum and
- To evaluate the VP1 specific IgA antigen secreting cells, or ASCs, HBGA blocking antibody, and VP1 specific serum IgG responses to the vaccine

Primary Endpoints

- Rate of norovirus Norwalk virus infection post vaccine and post challenge
- Rate of clinical norovirus AGE
- Induction of VP1-specific Immunoglobin A (IgA) antibody-secreting cells at Day 8 compared to placebo
- Histo-blood group antigen (HBGA) blocking antibodies by blockade titer (BT50) at Day 28 compared to placebo
- VP1-specific serum Immunoglobin G (IgG) at Day 28 compared to placebo
- VP1-specific serum Immunoglobin A (IgA) at Day 28 compared to placebo

Additional Pre-specified Endpoint

- Reduction in viral shedding

VXA-NVV-201 Topline Safety

- **No vaccine-related Serious Adverse Events (SAEs)**
- **No vaccine-related solicited Grade-3 Adverse Events (AEs)**
- **Benign safety and tolerability data profile consistent with safety of the platform in previous studies**

Analysis of Norovirus Infection Rate by Vaccination Group

Population	AGE Calculation	Vaccination Group	N*	n (%)	Relative Risk Reduction in Infection (%)	p-value[c]
Full Analysis	24-Hour Rolling Window	VXA	76	44 (57.9)	29	0.003
		Placebo	65	53 (81.5)		

Note: N = Number of subjects in the specified analysis population and vaccination group; N* = Number of subjects chall enged (N* is the denominator for percentages);
n = Number of subjects meeting the composite endpoint of Norovirus Infection.
[a] Difference is calculated as Placebo-VXA

[c] P-value calculated using a two-sided Chi-Squared Test.

Analysis of Norovirus Gastroenteritis (NVG) Rate by Vaccination Group Composite Score of AGE + NV Infection

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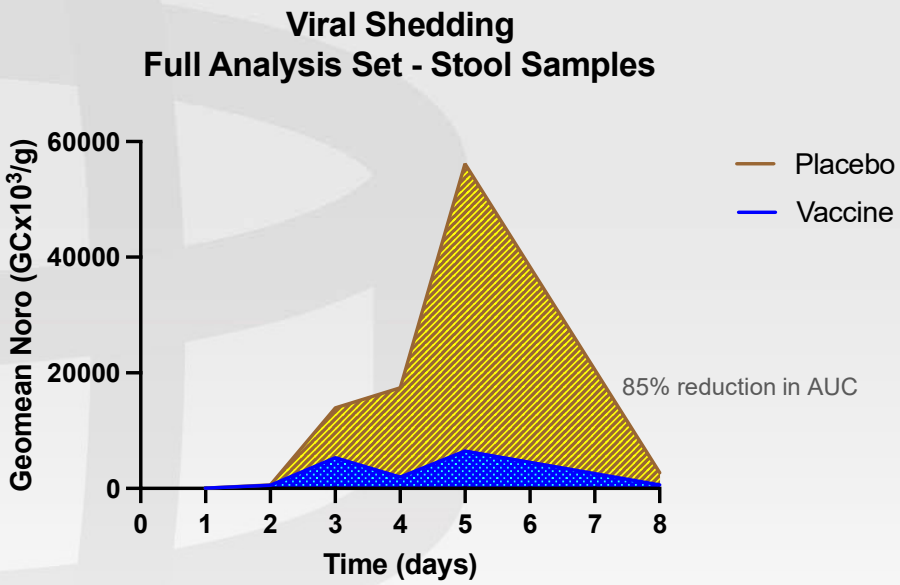
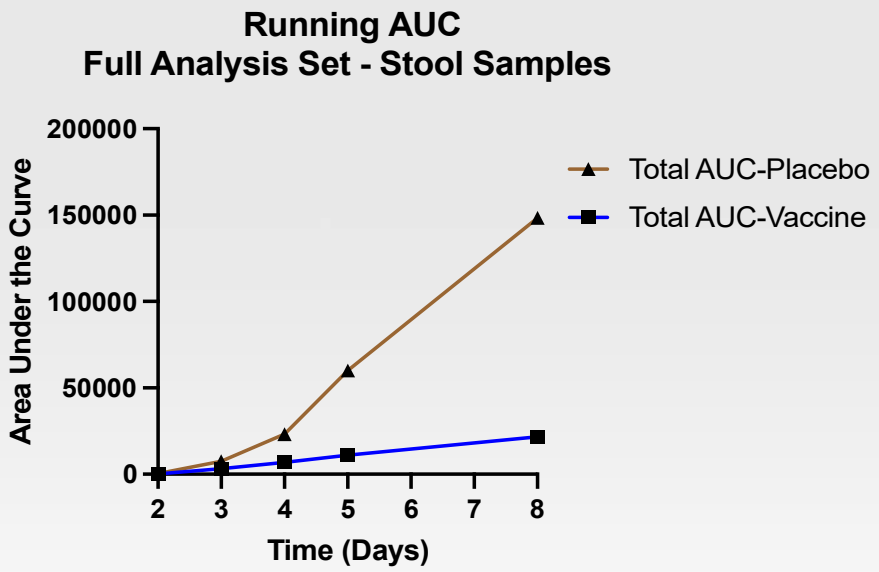
Population	AGE Calculation	Vaccination Group	N*	n (%)	Protective Efficacy (%)	Difference[a] (95% CI)	p-value[c]
Full Analysis	24-Hour Rolling Window	VXA (N=86)	76	34 (44.7)	21.4	12.2 [-4.3, 27.7]	0.149
		Placebo (N=79)	65	37 (56.9)			

Note: N = Number of subjects in the specified analysis population and vaccination group; N* = Number of subjects with evaluable Norovirus gastroenteritis (N* is the denominator for percentages);
n = Number of subjects meeting the composite endpoint of Norovirus Gastroenteritis (NVG).
[a] Difference is calculated as Placebo-VXA

[c] P-value calculated using a two-sided Chi-Squared Test.

85% Reduction in Viral shedding – Norovirus challenge results





LOD is 16 copies per reaction or 1186 copies per mL

Norovirus IgA ASC Response Results by Vaccination Group and Study Day - Immunogenicity Population

Study Day	Statistic	VXA (N = 86)	Placebo (N = 79)
Day 1 (Baseline)	n	81	79
	Mean (95% CI)[a]	0.4 (0.1, 0.6)	0.4 (0.1, 0.8)
	Median (Min, Max)	0.0 (0.0, 8.9)	0.0 (0.0, 12.2)
Day 8	n	81	79
	Mean (95% CI)[a]	374.8 (251.4, 498.1)	26.0 (-12.5, 64.4)
	Median (Min, Max)	188.7 (0.0, 3375.5)	0.0 (0.0, 1427.5)
	% Positive IgA ASC Response (95% CI)[b]	79.0 (68.5, 87.3)	2.5 (0.3, 8.8)
	p-value[c] for the mean spot count, Active vs Placebo	-	<0.001

N = Number of subjects in the immunogenicity population.; n = number of subjects with non-missing data
A positive VP1 specific IgA ASC response at Day 8 compared to Day 1 is defined as ≥ 23 mean spots/well/10^6 PBMC and at least 2 stan dard deviations higher than mean of Day 1 ASC counts.
[a] Confidence interval calculated based on the Student's t distribution.
[b] Exact binomial confidence interval calculated using the Clopper-Pearson methodology.
[c] p-value calculated from the Mann-Whitney test.

HBGA Blocking Antibodies Against Norovirus by Vaccination Group and Study Day – Immunogenicity Population

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Study Day	Statistic	VXA (N = 86)	Placebo (N = 79)
Day 1 (Baseline)	n	85	79
	GMT (95% CI)[a]	42.5 (35.7, 50.5)	43.6 (36.8, 51.7)
Day 28	n	82	71
	GMT (95% CI)[a]	133.9 (105.2, 170.3)	43.2 (36.3, 51.4)
	GMFR (95% CI)[a]	3.23 (2.70, 3.86)	1.00 (0.95, 1.06)
	p-value[b] for fold-rise, Active vs. Placebo	-	<0.001

Note: N = Number of subjects in the immunogenicity population.; n = number of subjects with non-missing data
GMT = Geometric mean titer. GMFR = Geometric mean fold rise in antibody compared to pre-dosing (Day 1).
[a] Confidence interval calculated based on the Student's t distribution.
[b] p-value calculated from the Mann-Whitney test.

Norovirus IgA Serum Response Results by Vaccination Group and Study Day – Immunogenicity Population

Study Day	Statistic	VXA (N = 86)	Placebo (N = 79)
Day 1 (Baseline)	n	86	79
	GMC (95% CI)[a]	790823.2 (545933.4, 1145563.5)	713161.3 (500564.8, 1016050.5)
Day 28	n	82	71
	GMC (95% CI)[a]	5698018.2 (3902409.7, 8319836.8)	717918.6 (497425.5, 1036149.4)
	GMFR (95% CI)[a]	7.14 (5.54, 9.22)	1.01 (0.98, 1.03)
	% 4 fold-rise (95% CI)[b]	65.9 (54.6, 76.0)	0.0 (0.0, 5.1)
	p-value[c] for fold-rise, Active vs. Placebo	-	<0.001

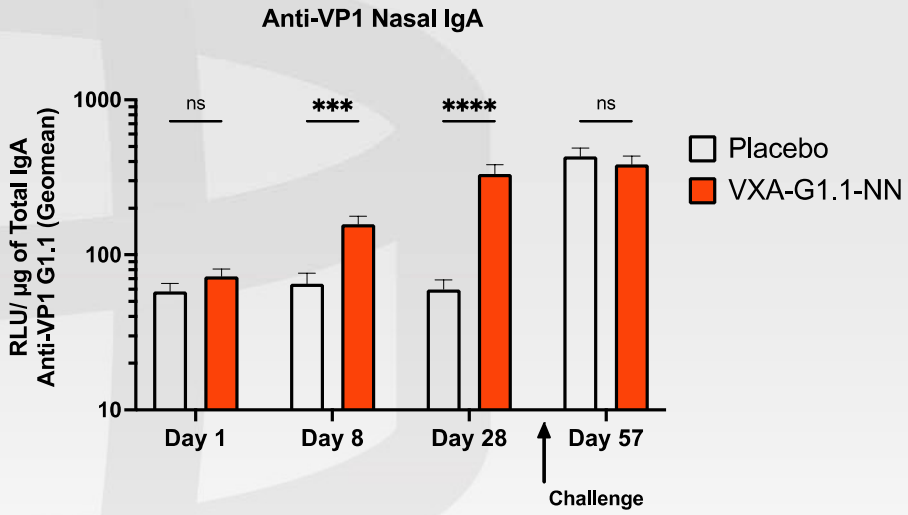
Note: N = Number of subjects in the immunogenicity population.; n = number of subjects with non-missing data
GMC = Geometric mean concentration. GMFR = Geometric mean fold rise in antibody compared to pre-dosing (Day 1).
4-Fold Rise represents the percentage of subjects with at least a 4-Fold Rise in antibody compared to pre- vaccination dosing (Day 1).
[a] Confidence interval calculated based on the Student's t distribution.
[b] Exact binomial confidence interval calculated using the Clopper-Pearson methodology.
[c] p-value calculated from the Mann-Whitney test.

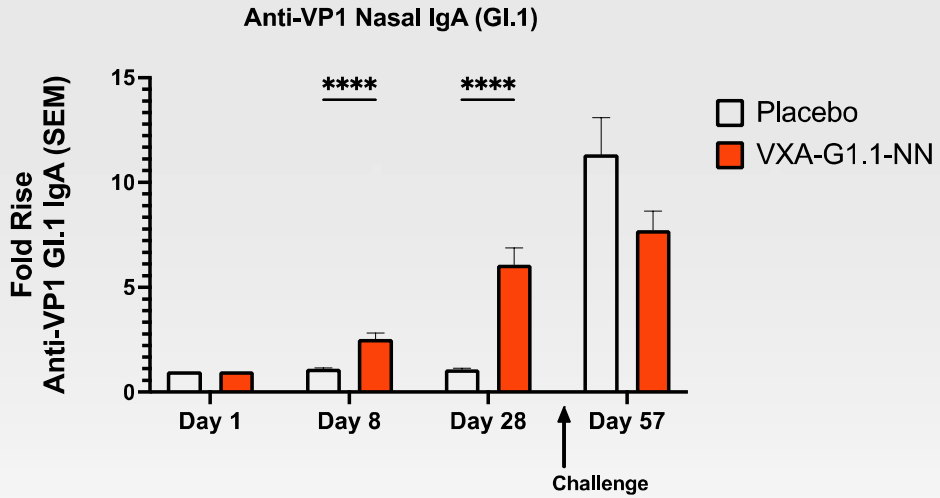
Norovirus IgG Serum Response Results by Vaccination Group and Study Day – Immunogenicity Population

Study Day	Statistic	VXA (N = 86)	Placebo (N = 79)
Day 1 (Baseline)	n	86	79
	GMC (95% CI)[a]	967454.6 (738896.0, 1266712.1)	808246.9 (613312.9, 1065138.3)
Day 28	n	82	71
	GMC (95% CI)[a]	4488823.4 (3280492.5, 6142228.9)	780088.5 (588889.2, 1033366.1)
	GMFR (95% CI)[a]	4.64 (3.83, 5.63)	0.99 (0.98, 1.01)
	% 4 fold-rise (95% CI)[b]	57.3 (45.9, 68.2)	0.0 (0.0, 5.1)
	p-value[c] for fold-rise, Active vs. Placebo	-	<0.001

Note: N = Number of subjects in the immunogenicity population.; n = number of subjects with non-missing data
GMC = Geometric mean concentration. GMFR = Geometric mean fold rise in antibody compared to pre-dosing (Day 1).
4-Fold Rise represents the percentage of subjects with at least a 4-Fold Rise in antibody compared to pre- vaccination dosing (Day 1).
[a] Confidence interval calculated based on the Student's t distribution.
[b] Exact binomial confidence interval calculated using the Clopper-Pearson methodology.
[c] p-value calculated from the Mann-Whitney test.

Mucosal Immune Responses after Norovirus Vaccination





n = 141

Mixed-Effects analysis

Key Takeaways / Next Steps

Key Takeaways

- GI.1 vaccine was safe and well tolerated
  - No vaccine-related SAEs or grade 3 AEs
- Robust immune response to vaccine consistent with what we have seen in past studies
- Vaccine efficacy for prevention of Noro-AGE (Full Analysis) was 21.4%
  - Two-sided Chi-square p value 0.149
  - While not statistically significant, we believe the numerical reduction is encouraging and believe that real-world may studies may show enhanced efficacy
- Vaccine norovirus relative risk reduction in infection (Full Analysis) was 29%
  - Two-sided Chi-square p-value of 0.003
- Virology (AUC, shedding endpoints) are promising
- Further analyses continuing
- Focus on bivalent candidate

Next Steps

- Conduct Phase 2b dose confirmation study of bivalent candidate
- Identify correlate of immunity, which could reduce the size and duration of a Phase 3 registration study

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Q&A