HILLEVAX

CORPORATE PRESENTATION

MAY 2024

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HilleVax May 2024

HILLEVAX

Norovirus has a high disease burden and unmet need

Multi-billion dollar commercial opportunity

Clinical PoC demonstrated in adults and near-term large Phase IIb infant readout in mid-2024

Strong capital position with $272.7M in cash as of March 31, 2024

Norovirus in the news…

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INNOVATION • HEALTHCARE

Over 230 Cases Of Suspected Gastroenteritis At Melbourne, Australia, Wedding Venue

Bruce Y. Lee Senior Contributor

I am a writer, journalist, professor, systems modeler, computational and digital health expert, avocado-eater, and entrepreneur, not always in that order.

Sep 30, 2023, 09:10am EDT

Listen to article 5 minutes

A total of at least 233 people have suffered ...
GETTY

When you think back to your wedding day, it's usually a bad sign when vomiting and diarrhea are among your first thoughts. Unfortunately, that may be the case for Rebecca and Brodey Fitz-Gerald after their September 16 wedding reception at The Park in Melbourne, Australia, turned out to be quite a sick affair. And it was sick in a bad way with at least 80 people—including the groom—from this wedding Down Under coming down with gastroenteritis. In fact, the latter half of September hasn't exactly been a walk in The Park for those attending events at that venue. A total of at least 233 people have suffered gastroenteritis over the course of five different events held there from September 13 through 24.

Forbes

FORBES > INNOVATION > HEALTHCARE

Norovirus Cruise Ship Outbreaks Already Reach 10-Year High In 2023

Bruce Y. Lee Senior Contributor

I am a writer, journalist, professor, systems modeler, computational and digital health expert, avocado-...

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Jul 14, 2023, 03:32pm EDT

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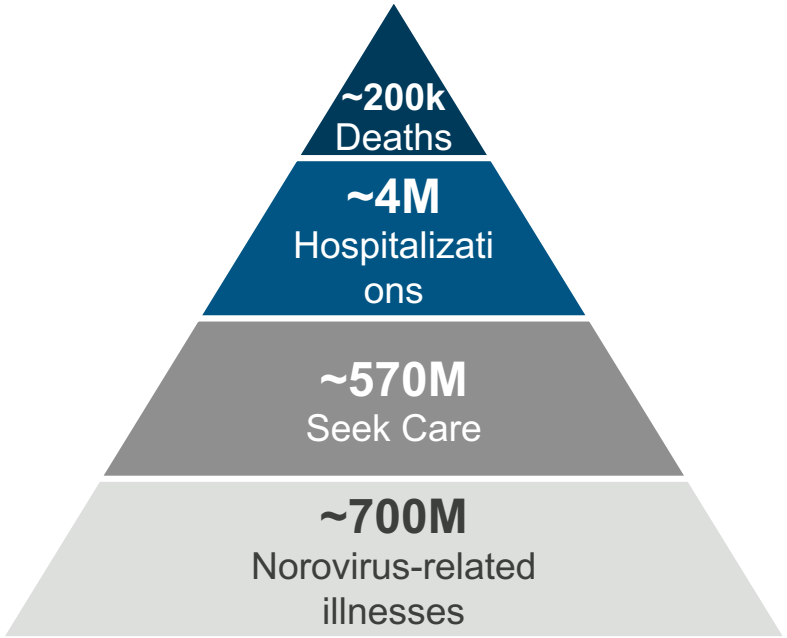
There have already been an unlucky 13 recorded norovirus outbreaks on cruise ships under U.S. ...
[+] GETTY IMAGES

Talk about being ship out of luck. There have already been an unlucky 13 recorded norovirus outbreaks on cruise ships under U.S. jurisdiction so far in 2023. That's the highest tally in 10-years, ever since 16 such outbreaks occurred in 2012, according to the Centers for Disease Control and Prevention (CDC) Vessel Sanitation Program. And with half of 2023 still to go, there's a good chance that the 2012 count will be surpassed sometime later this year.

"And these symptoms can be quite severe too. Norovirus often isn't just your typical I'm-feeling-a-little-sick-so-I-may-pass-on-shuffleboard type of gastroenteritis. No, a norovirus infection can consist of projectile vomiting and explosive diarrhea. Projecting your voice, feelings, or insecurities is one thing. Projecting your vomit is something completely different."

Bruce Y. Lee, Forbes 2023

Norovirus global annual burden is high…



… resulting in direct and indirect costs of ~$10b in US and ~$60b globally[1,2]

Costs

Direct

Medical

Clinical management, hospitalizations, infection control measures and cleaning, surveillance

Indirect

Health

Productivity losses: sick staff work days, resources not used while managing outbreak

Key vulnerable populations

Young children

Endemic, incidence of norovirus highest among young children[2]

Adults

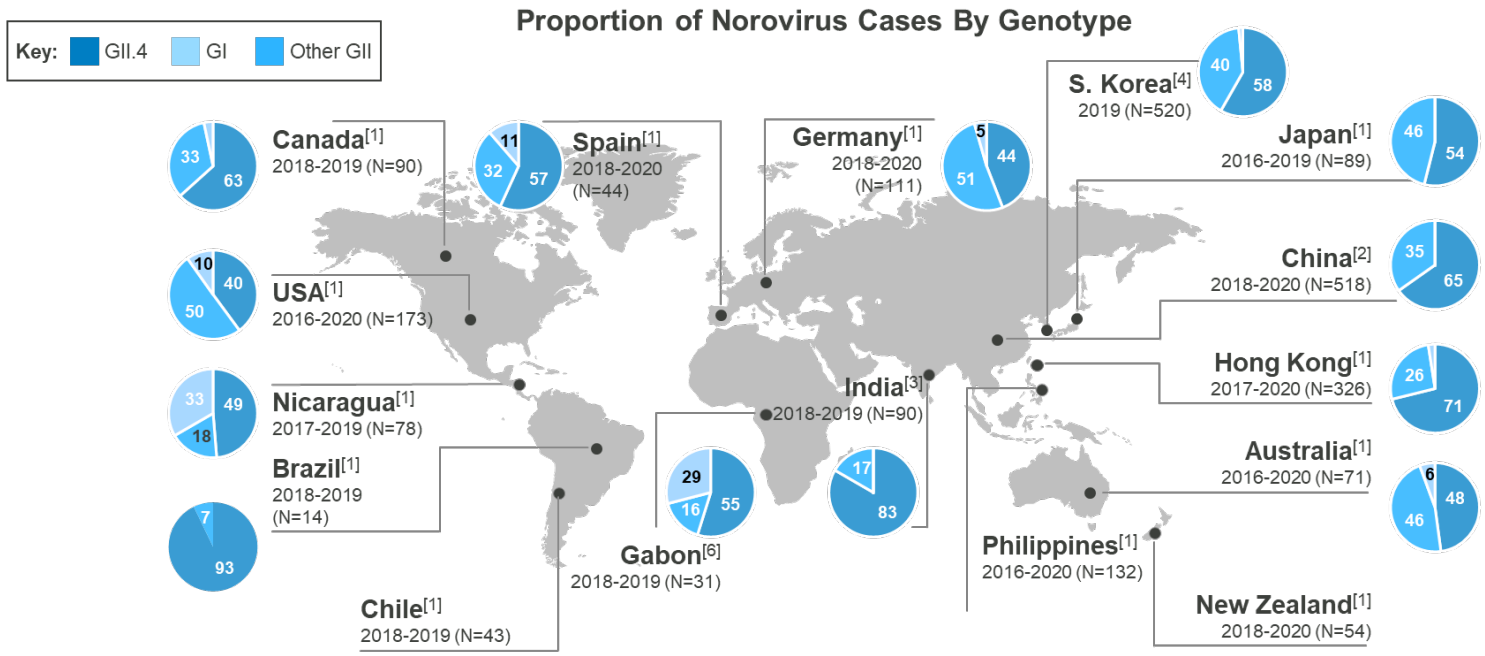
Outbreaks among HCPs, military, food handlers, travelers, other groups

Older adults

Outbreaks in nursing homes and hospitals, higher likelihood of hospitalization / death

1. Bartsch et al., 2016 2. Bartsch et al., 2020

GII.4 remains the dominant genotype associated with the majority of norovirus infections worldwide



- GII.4 infections in 2021-2022 represented approximately **60% of infections in children <5**[7]
- GII.4 infections resulted in **75% of hospitalizations and 82% of deaths** based on a meta analysis of 843 norovirus outbreaks[8]

[1] Cannon et al. Emerg Infect Dis. 2021.; [2] Fang et al. BMC Infect Dis. 2021.; [3] Lo et al. Arch Virol. 2021.; [4] Cho et al. J Med Virol. 2021.; [5] Rossouw et al. Viruses. 2021.; [6] Manouana et al. Viruses. 2021, [7] NoroSurv: A global network for norovirus strain surveillance – data retrieved on 17 Apr 2023; [8] Adapted from Desai et al. CID 2012.

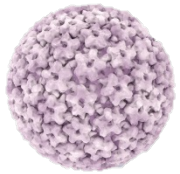
HIL-214 comprises VLPs for major genotypes GI.1 and GII.4

GI.1 selected based on its potential to promote a broad immune response to GI strains

GII.4 selected because it is estimated to be responsible for nearly two-thirds of norovirus illness[1]

1. Kumthip et al., 2019

1 Virus-Like Particles (VLPs)



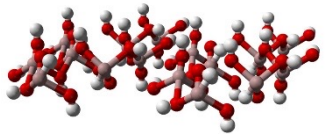
GI.1 VLP (Norwalk)

Consensus GII.4 VLP

Consensus Strategy

Presents epitopes from three different norovirus GII.4 strains on one VLP

2 Adjuvant



Aluminum hydroxide

3 Norovirus Vaccine

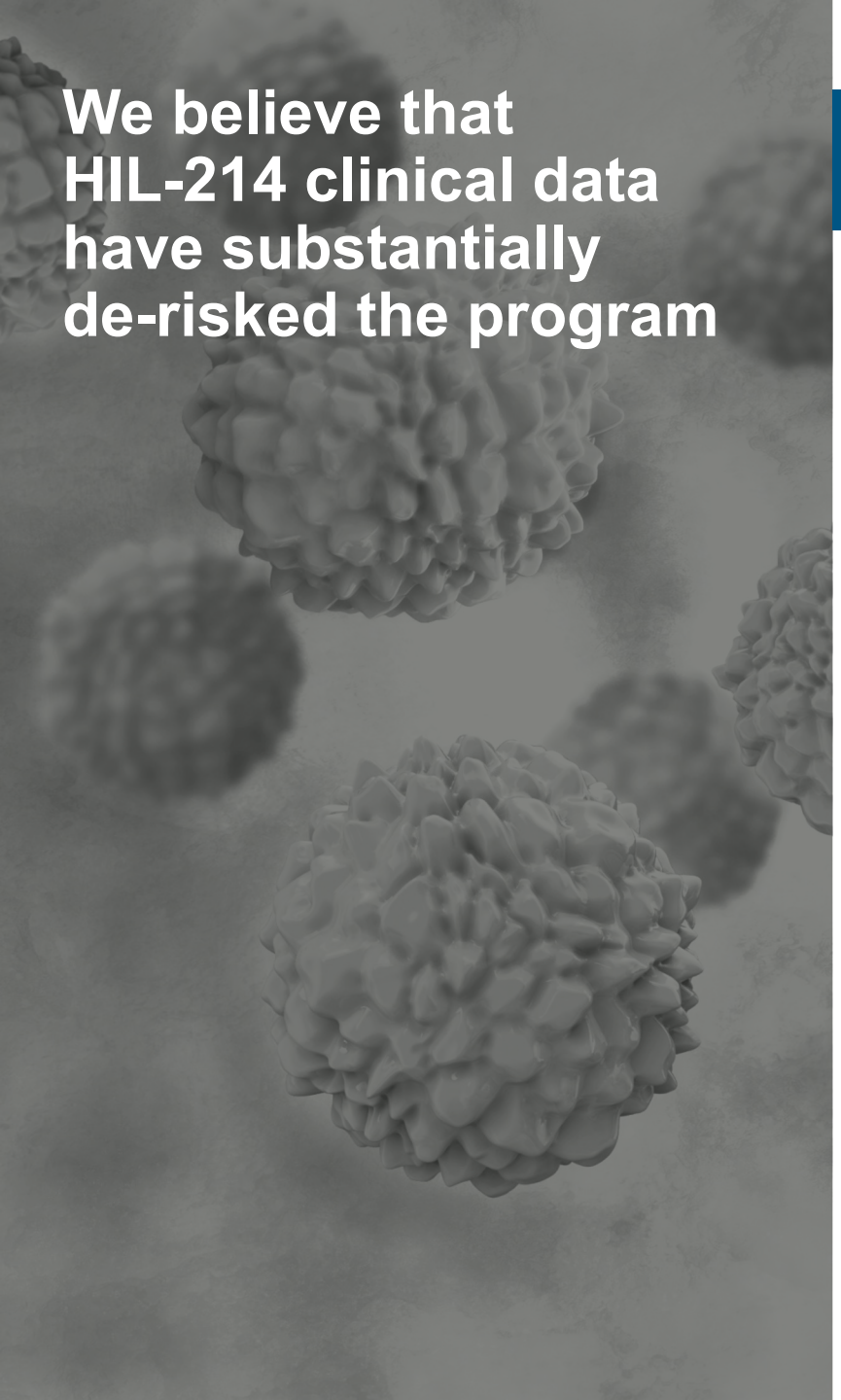
Prefilled Syringe (intramuscular)

Large clinical program demonstrates immunogenicity, efficacy, and safety/tolerability

Trial No.	Phase	Design	Study Population	HIL-214 safety, n=	HIL-214 immuno, n=
LV01-103	I/II	R, DB, Pbo, NoV challenge for **safety, immunogenicity, and efficacy**	18 - 50 years	N/A[1]	N/A[1]
LV03-104	I	R, DB, Pbo, dose/age-escalation for **safety and immunogenicity**	18 - 85 years	66	66
LV03-105	I/II	R, DB, Pbo, NoV challenge for **safety, immunogenicity, and efficacy**	18 - 50 years	67	67
NOR-210	II	Study to generate serum controls for **validation of serology assay**	18 - 49 years	50	50
NOR-107	II	R, DB, for **safety, immunogenicity, dose finding, and adjuvant justification**	18 - 64 years	418	418
NOR-201	II	RD, DB for **safety and immunogenicity**	18 - 49 years	425	425
NOR-204	II	R, DB for **safety, immunogenicity, dose finding and formulation selection**	18 - >85 years	311	311
NOR-211	IIb	R, DB, Pbo for **efficacy, safety, and immunogenicity**	18 - 49 years; military recruits	2,355	97
NOR-202	II	R, DB for **safety, immunogenicity, dose finding and adjuvant justification**	6wks - 9 years	839	839
NEST-IN1[2]	IIb	R, DB, Pbo for **efficacy, safety, and immunogenicity**	5 months	1,500	1,500
NOR-109[2]	**I**	R, DB, Pbo, **safety and immunogenicity**	5 months	14	14
NOR-206[2]	II	R, DB, Pbo, **safety and immunogenicity when HIL-214 is concomitantly administered** with routine infant vaccines	4 months	77	77
NOR-215[2]	II	SA, OL, **safety and immunogenicity**	18 – 49 years	185	185
TOTAL[2]				**6,307**	**4,049**

1. Intranasal formulation of vaccine, not included in HIL-214 safety and immunogenicity subject numbers
2. NEST-IN1, NOR-109, NOR-206, and NOR-215 clinical trials ongoing, final subject numbers still estimated for study completion

R: randomized. DB: double-blind. OL: open label. Pbo: placebo-controlled



We believe that HIL-214 clinical data have substantially de-risked the program

HIL-214 key clinical accomplishments

- ✓ Dose selection
- ✓ Adjuvant selection
- ✓ Immunogenicity in infants/children
- ✓ Immunogenicity in adults/older adults
- ✓ Efficacy proof-of-concept in adults
- ✓ Safety/tolerability profile across age groups
- ✓ 5-year safety and immunogenicity in adults

SAFETY

>6,000 subjects (2,430 pediatric subjects) received vaccine in clinical studies

In adults, local AEs all mild/moderate with systemic AEs similar to placebo

Infant AEs largely mild to moderate with short duration (<3-4 days)

NOR-202, NOR-211, NOR-204 studies, WHO, FDA prescribing information

These data are presented for informational purposes only, as the comparisons in the tables to the right are not based on head-to-head clinical studies and may not be comparable due to differences in vaccine design, disease under evaluation, trial designs and populations studied.

HIL-214 clinical AE profile comparable to commercial vaccines

Pediatric safety

Disease	Vaccine	Age	Local reactions	Systemic reactions	
			Pain, swelling or redness	Fever > 38°C	Irritability or fussiness
Norovirus	HIL-214	6 weeks – 6 months[5]	9 – 21%[1]	2 – 9%[1]	19 - 28%[1]
		6 months – 9 years[5]	21 – 33%[1]	7 – 8%[1]	10 - 20%[1]
Pneumococcal	Prevnar 13	2 – 15 months	20 – 42%[3,4]	24 – 37%[3]	80 - 86%[3]
Rotavirus	Rotarix	6 – 24 weeks	Oral – N/A	25 – 28%[1]	42 - 52%[1]
	RotaTeq	5 – 36 weeks		17 – 20%[2]	4 - 7%[2]
Pertussis	Daptacel (TDaP)	2 – 6 months	1 – 6%[2,4]	8 – 24%[2]	32 - 40%[2]
	Whole cell DTP	2 – 6 months	5 – 11%[2,4]	65 – 74%[2]	73 - 85%[2]
MMRV	M-M-R II & Varivax	12 – 23 months	10 – 16%[4]	15%	7%
	ProQuad	12 – 23 months	8 – 14%[4]	22%	7%
Polio	OPV	2 months – 6 years	Oral – N/A	< 1%	< 1%

1. After doses one or two. 2. After doses one, two, or three. 3. After doses one, two, three, or four. 4. Refers to redness or swelling only 5. Data from NOR-202.

Adult safety

Disease	Vaccine	Age	Local reactions	Systemic reactions	
			Pain at injection site	Fever > 38°C	Headache
Norovirus	HIL-214	18 to 49 years[4]	48%	6%	35%
		>60 years[5]	33%	<1%	8%
COVID-19	Comirnaty	16 to 55 years	78 - 84%[1]	4 - 16%[1]	44 - 54%[1]
	Moderna	18 to 64 years	87 - 90%[1]	1 - 17%[1]	35 - 63%[1]
HPV	Gardasil 9	16 to 26 years	71 - 74%[2]	2 - 3%[2]	15%
Influenza	Afluria	18 to 64 years	48%	1%	22%
	FluBlok	>50 years	19%	<1%	13%
Shingles	Shingrix	>50 years	69 - 88%[3]	14 - 28%[3]	29 - 51%[3]

1. After doses one or two. 2. After doses one, two, or three. 3. Range given for patients 50 - 59, 60 - 69, and >70 years of age 4. Data from NOR-211. 5. Data from NOR-204.

HIL-214
IMMUNOGENICITY

HBGA is an attachment factor on the surface of intestinal epithelia known to promote norovirus entry into host cells

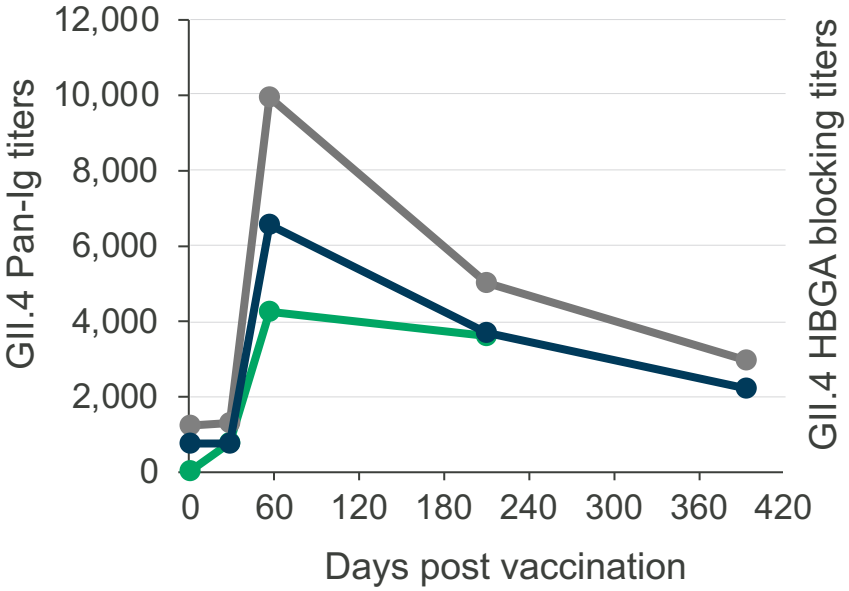
Measurement of HBGA-blocking antibodies is the primary method to assess vaccine immunogenicity against norovirus

Data from long-term immunogenicity study in adults (NOR-213) has shown titers to date **above baseline at year 5**

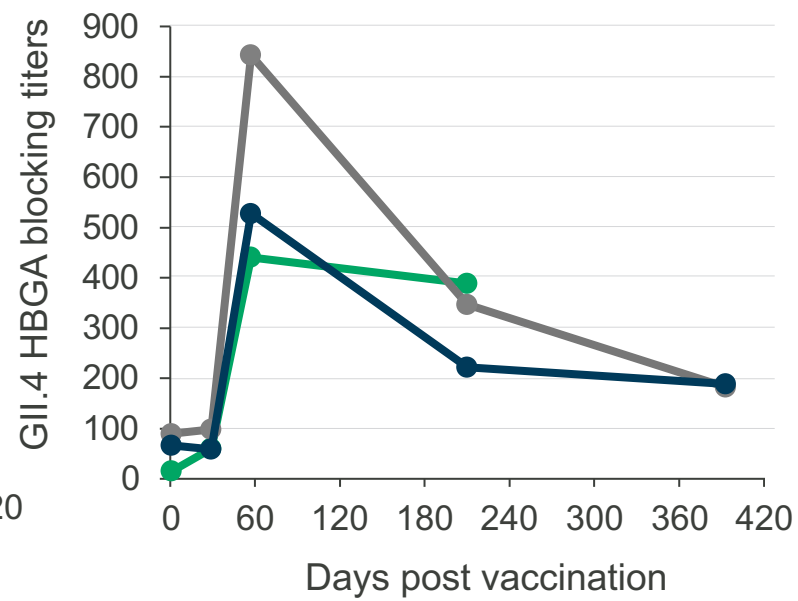
NOR-202, NOR-107, and NOR-204 studies

Functional and binding response following vaccination with HIL-214

GII.4 Pan-Ig titers
Note: cross study comparisons



GII.4 HBGA blocking titers
Note: cross study comparisons

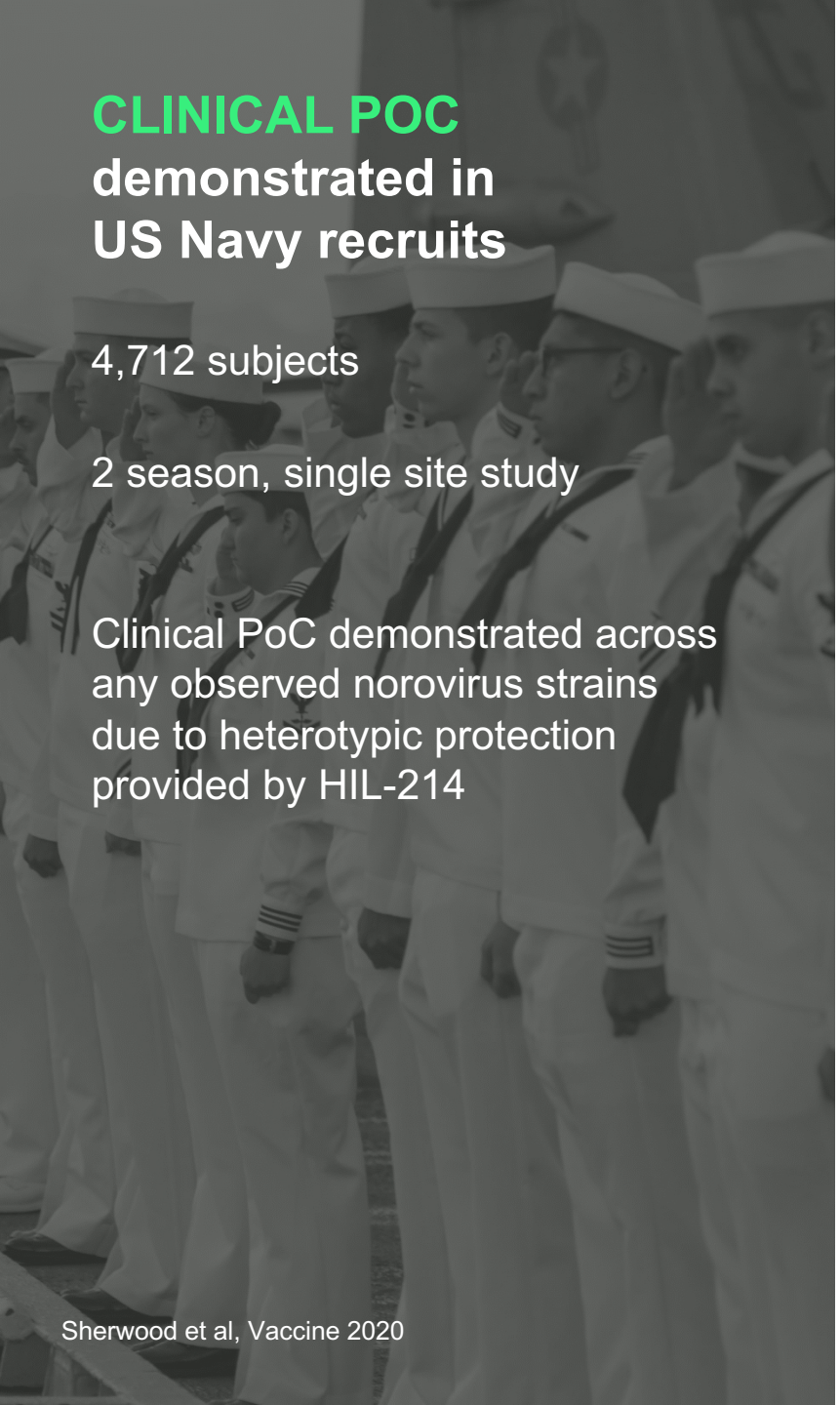


Infants (6 – 12 months)
50/150µg x 2 doses
(NOR-202)

Adults[1] (18 – 64 years)
15/50µg x 1 dose
(NOR-107)

Older adults (≥60 years)
15/50µg x 1 dose
(NOR-204)

1. Day 0 titers were collected 28 days prior to vaccination for adult study (NOR-107)



CLINICAL POC demonstrated in US Navy recruits

4,712 subjects

2 season, single site study

Clinical PoC demonstrated across any observed norovirus strains due to heterotypic protection provided by HIL-214

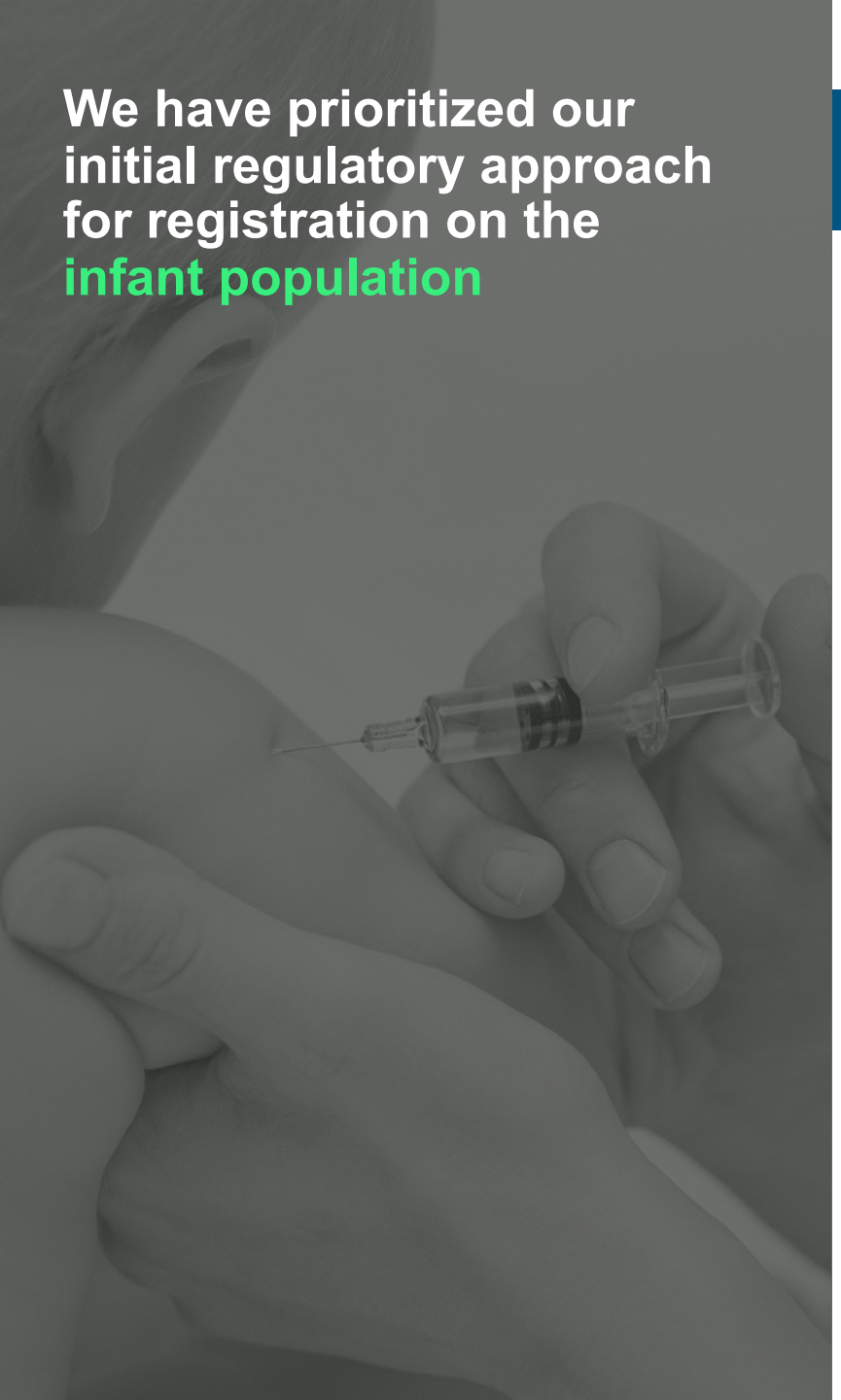
Sherwood et al, Vaccine 2020

Phase 2b in adults demonstrated **reduction in moderate-to-severe acute gastroenteritis**

	Cases of moderate-to-severe AGE			Viral efficacy	
	Pathogen	**Placebo** n = 2,357	**HIL-214** n = 2,355	**%**	**p value**
1°	HIL-214 vaccine strain only[1]	5 (0.2)	1 (<0.1)	80.0	p = 0.142
2°	Any NoV strain	26 (1.1)	10 (0.4)	61.8	p = 0.0097
Post-hoc	GII.2 strain	21	9	57.4	p = 0.0321

1. GI.1 or GII.4

We have prioritized our initial regulatory approach for registration on the **infant population**



Advantages of studying HIL-214 in infants

- ✓ Endemic pattern of infection
- ✓ Higher prevalence of GII.4
- ✓ Comparison to subjects without pre-existing immunity
- ✓ Regulatory and operational precedent of rotavirus vaccines

NEST-IN1 Phase 2b pediatric study ongoing

Healthy 5 mo. infants
(n = ~3,000)
Sites in the US and Latin America

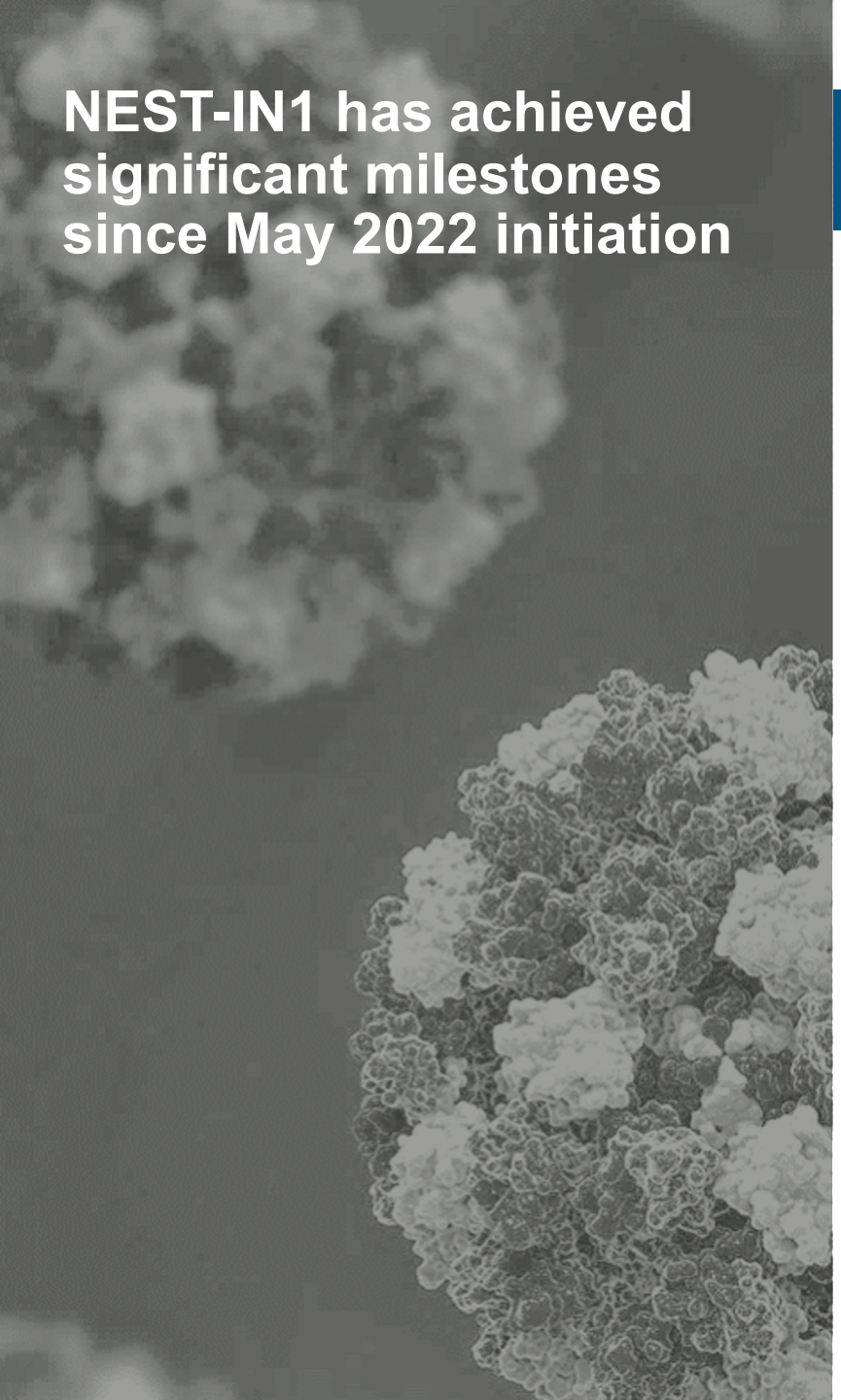
HIL-214[1]
(n = 1,500)

Placebo[1]
(n = 1,500)

Primary Endpoint
Reduction in moderate/severe acute gastroenteritis associated with norovirus GI.1 or GII.4
(co-pathogen negative)

Secondary Endpoints
Reduction in moderate/severe acute gastroenteritis associated with any norovirus strain
(+/- co-pathogen)

[1] Vaccinations at Day 1 and Day 29 - 57



NEST-IN1 has achieved significant milestones since May 2022 initiation

NEST-IN1 updates

Data Monitoring Committee completed **recommended study continuation** after safety review in August 2022

First 200 subjects **immune responses**[1] **were consistent** with prior infant studies of HIL-214 in November 2022

Enrollment completed with over 3,000 infants in April 2023

Topline data expected **mid-2024** – Clinical safety and clinical efficacy on all subjects

1. Pan-Ig antibody responses 28 days post second dose

Other ongoing supporting studies of HIL-214

Study #	Phase	Design	Subjects	Status	Purpose
NOR-109	I	R, DB, Pbo, safety and immunogenicity	5 months of age	Enrollment complete	Enable inclusion of Japanese infants in planned Phase III clinical trial of HIL-214
NOR-206	II	R, DB, Pbo, safety and immunogenicity when HIL-214 is concomitantly administered with routine infant vaccines	4 months of age	Enrollment complete	Generate data on concomitant administration with routine pediatric vaccines
NOR-215	II	SA, OL, safety and immunogenicity	18 – 49 years	Enrollment complete	Generate serum for immunological assays and reference material

R: randomized. SA: single arm. DB: double-blind. OL: open label. Pbo: placebo-controlled

Development and regulatory strategy

Initial clinical program focused on infant population

Followed by immuno-bridging and/or efficacy studies in older adults

Clinical program and concurrent epidemiology and pharmacoeconomic studies to support potential ACIP recommendations

1 Establish initial indication in infants

Phase 2b PoC study in infants
n ~ 3,000

→ **Phase 3 pivotal study in infants**

→ **Infant registration**

2 Develop in adults/older adults contemporaneously

Clinical PoC in young adults (NOR-211)[1]

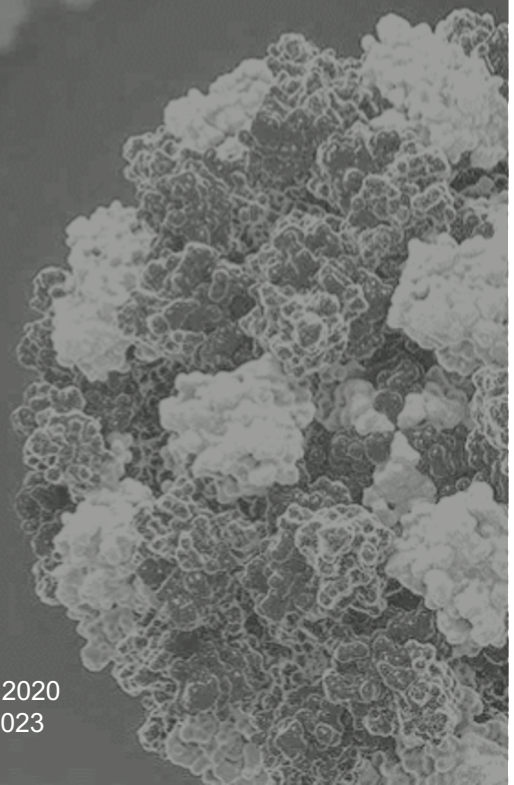
→ **Potential Immuno-bridging and/or efficacy studies**

→ **Adult/older adult registration**

1 – NOR-211 clinical trial already completed, refer to Sherwood et al, Vaccine 2020 for clinical trial results

ACIP recommendation will be sought for both the infant and older adult populations

Norovirus burden of disease compares favorably to other viruses which have vaccines that carry ACIP recommendations



Norovirus burden (today) is comparable to rotavirus, shingles, and RSV burden (pre-vaccines) in the United States

Disease	Age	US cases	US hospitalizations	US deaths	US economic burden (in 2020 dollars)
Norovirus	≤ 4 years	2.8 million	12,000	20	$1.2 billion
	5 – 64 years	15.7 million	34,000	70	$6.4 billion
	≥ 65 years	3.7 million	50,000	1,250	$3.2 billion
	All ages	22 million	96,000	1,350	$10.6 billion
Rotavirus (pre-vaccine)	≤ 5 years	2.7 million	70,000	60	$1.5 billion
Shingles (pre-vaccine)	≥ 50 years	1.0 million	46,000	80	$2.4 billion
RSV (pre-vaccine)	≥ 60 years	2.5 million	100,000	8,000	$7.4 billion

CDC and Bartsch et al., 2020
NIH and Carrico et al., 2023

Potential multi-billion dollar commercial opportunity

1 INFANTS/TODDLERS

ROTAVIRUS VACCINES AS A CASE STUDY

- Similar burden of disease between norovirus and rotavirus
- Two rotavirus vaccines were launched in 2006 and 2008 (RotaTeq and Rotarix)
- ACIP recommendation for routine infant use
- **$1.4B** global net sales in 2022
- $210-360 per rotavirus vaccine course (US)

2 OLDER ADULTS

RSV VACCINES AS A CASE STUDY

- Comparable burden of disease in older adults
- Arexvy and Abrysvo approved in 2023
- ACIP recommendation for adults over 60 following shared decision-making
- **$1.2B** global net sales in **Q3** of 2023
- $180-295 per single vaccine course (US)

+ OTHER ADULTS including HCPs, military, travelers, food handlers

HilleVax announces exclusive license with Kangh

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HilleVax and Kangh Announce Exclusive License Agreement for Hexavalent VLP Norovirus Vaccine Candidate Outside of China

Collaboration leverages HilleVax's leading norovirus vaccine development expertise and adds a Phase 1-ready next-generation program to HilleVax's pipeline

BOSTON and CHENGDU, China, Jan. 08, 2024 (GLOBE NEWSWIRE) -- HilleVax, Inc. (Nasdaq: HLVX), a clinical-stage biopharmaceutical company focused on developing and commercializing novel vaccines, and Chengdu Kanghua Biological Products Co., Ltd. (Kangh) (SHE: 300841), a biopharmaceutical company engaged in the research, development, production, and sale of bioproducts, today announced the entry into an exclusive license agreement for rights to Kangh's hexavalent virus-like particle (VLP) vaccine candidate for norovirus, referred to by HilleVax as HIL-216, outside of Greater China.

HIL-216 includes VLPs for six of the most common norovirus genotypes, including GI.1, GII.2, GII.3, GII.4, GII.6, and GII.17. The Investigational New Drug (IND) application for HIL-216 was cleared by the U.S. FDA in September 2023. As part of the exclusive license agreement, Kangh will supply HIL-216 for use in HilleVax's near-term clinical trials, including a Phase 1 trial that HilleVax expects to initiate in 2024.

Building towards a long-term norovirus vaccine leadership position

HIL-216 includes VLPs for **six of the most common norovirus genotypes**, including GI.1, GII.2, GII.3, GII.4, GII.6, and GII.17

Kangh to supply HIL-216 for use in **near-term clinical trials**

Addition of HIL-216 to portfolio through collaboration with Kangh

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KANGH

Follow-on hexavalent norovirus vaccine candidate

Selected genotypes cover approximately 90% of norovirus infections worldwide

IND cleared, Phase 1 ready vaccine candidate

Leverages HilleVax's VLP development capabilities

STRONG CAPITAL POSITION

As of March 31, 2024:

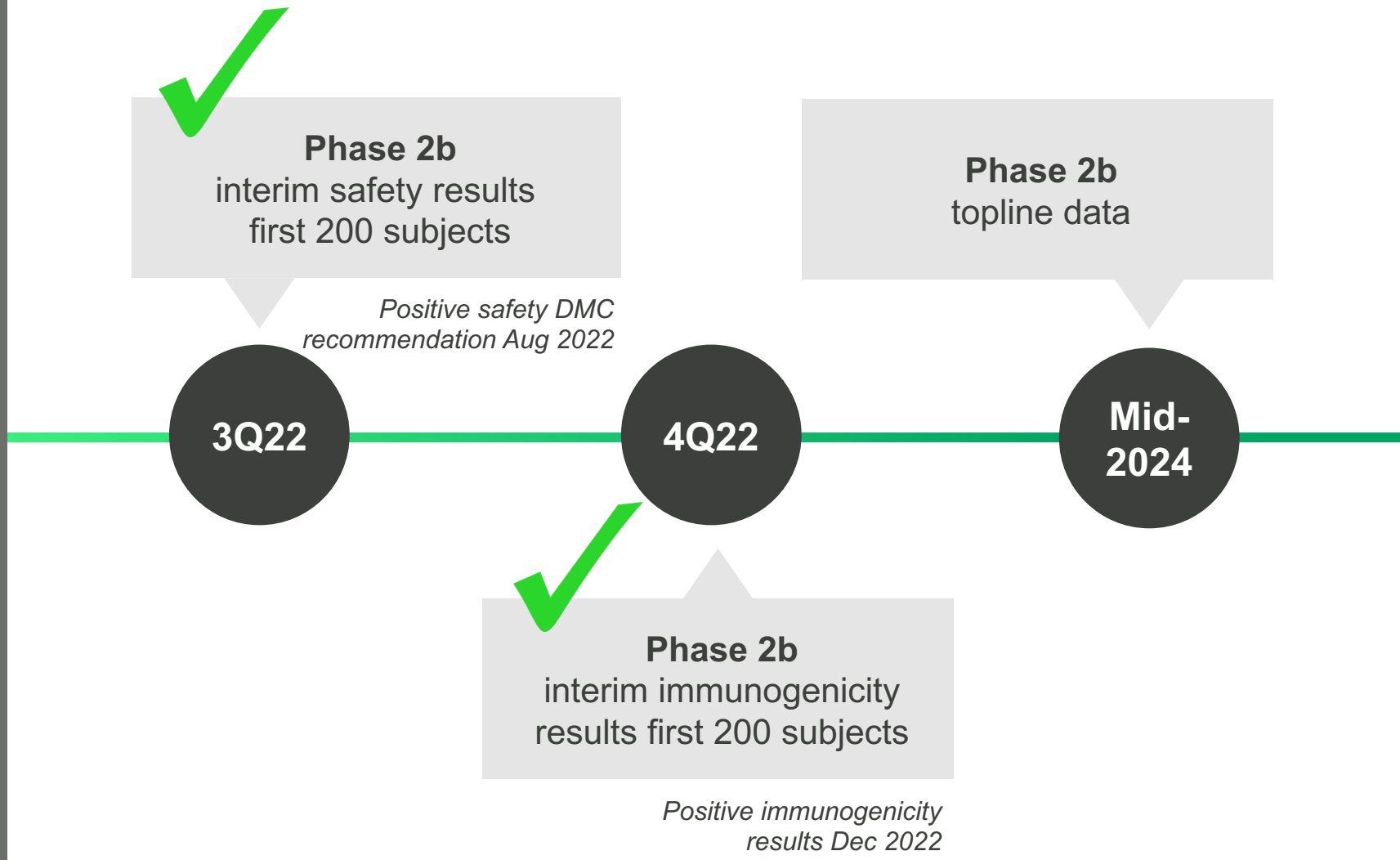
$272.7M cash, cash equivalents & marketable securities

$75M term loan[1]:

$25M drawn

[1] Full draw subject to certain milestones and conditions

Anticipated milestones



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NASDAQ: HLVX

- Most advanced norovirus vaccine candidate
- Clinical PoC demonstrated in adults
- Phase IIb study readout in mid-2024 on 3,000 infants
- Next gen hexavalent VLP vaccine candidate licensed
- Large potential commercial opportunity