

CORPORATE PRESENTATION

AUGUST 2023

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This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions, and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

Potential breakthrough

for the prevention of norovirus-related illness

HIL-214

Significant unmet medical need

Potential to be first vaccine approved for norovirus-related illness

9 Phase I & II studies completed in >4,500 subjects

Clinical PoC demonstrated in adult Phase IIb study

Phase IIb clinical trial ongoing with over 3,000 infants enrolled

Multi-billion dollar commercial potential



Senior Leadership



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Norovirus is the most common cause of acute gastroenteritis in US and worldwide¹

Highly contagious virus causing diarrhea, vomiting, stomach pain, fever, and headache

Complications from dehydration can be severe, including death

Easily transmitted via person-toperson contact, contaminated foods or surfaces



Key vulnerable populations

Young children

Endemic, incidence of norovirus highest among young children²

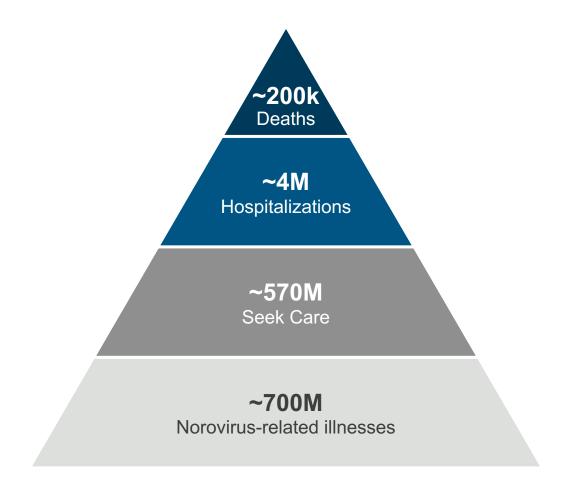
Adults

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

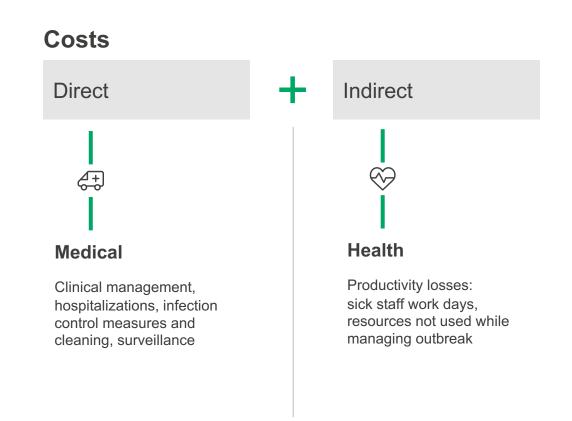
Older adults

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

Norovirus global annual burden is high...

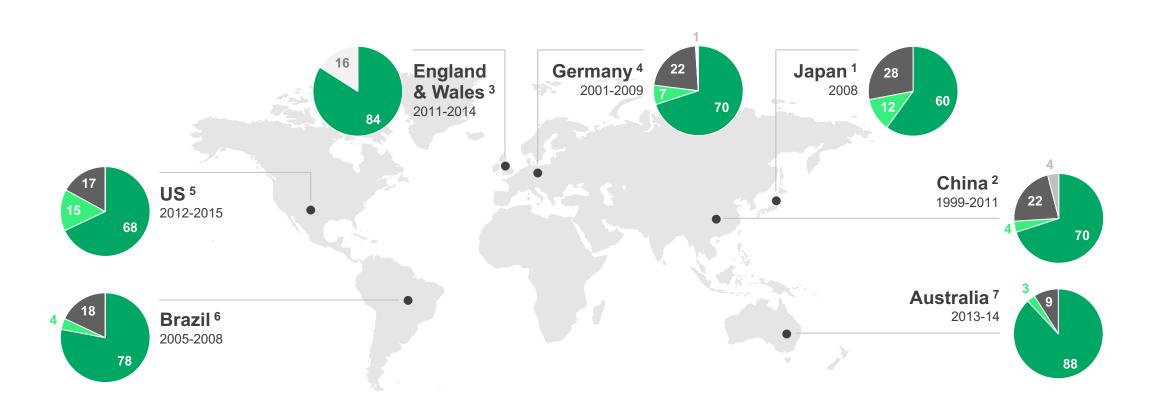


... resulting in direct and indirect costs of ~\$10b in US and ~\$60b globally^{1,2}



GI and GII.4 genotypes comprise the majority of norovirus infections worldwide

Norovirus incidence by strain % total incidence





^{2.} Yu Y Biomed Res Int. 2014; 2014 (ID 196169): 1-13

7. Lim KL, et al. PLoS One 2016



Other GII Mix

Other

^{3.} Public Health England. PHE National norovirus and rotavirus report. 10 Jul 2014

^{4.} Bernard H, et al. Epi infect 2014; 142(1): 63-74

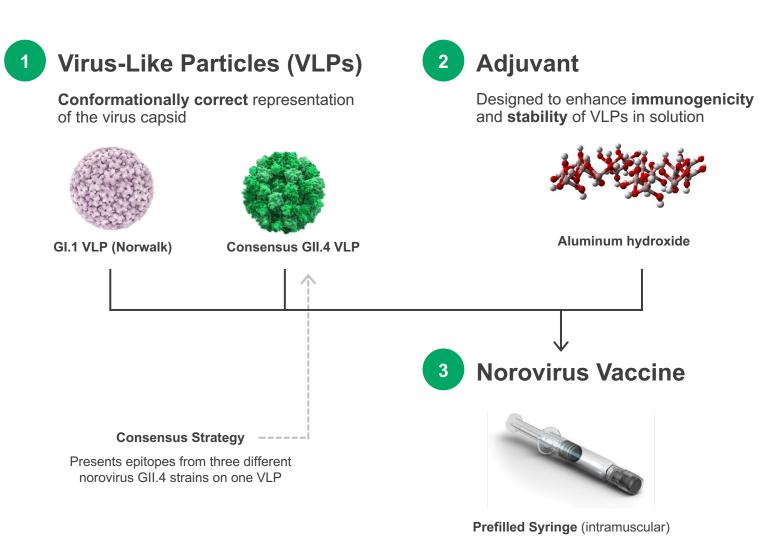
^{5.} Shah et al. CDC MMWR 2017

^{6.} Ferreira MS, et al. J Med Virol 2010

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 illness¹



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	1/11	R, DB, Pbo, NoV challenge for safety, immunogenicity, and efficacy	18 - 50 years	N/A ¹	N/A ¹
LV03-104	1	R, DB, Pbo, dose/age-escalation for safety and immunogenicity	18 - 85 years	66	66
LV03-105	1/11	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	Ilb	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
TOTAL				4,531	2,273



^{1.} Intranasal formulation of vaccine, not included in HIL-214 safety and immunogenicity subject numbers 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
- 5-year safety and immunogenicity

SAFETY

>4,500 subjects (839 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	Oval N/A	25 - 28%1	42 - 52%1	
	RotaTeq	5 – 36 weeks	Oral – N/A	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℃	Headache
Norovirus	1111 214	18 to 49 years⁴	48%	6%	35%
	HIL-214	>60 years⁵	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

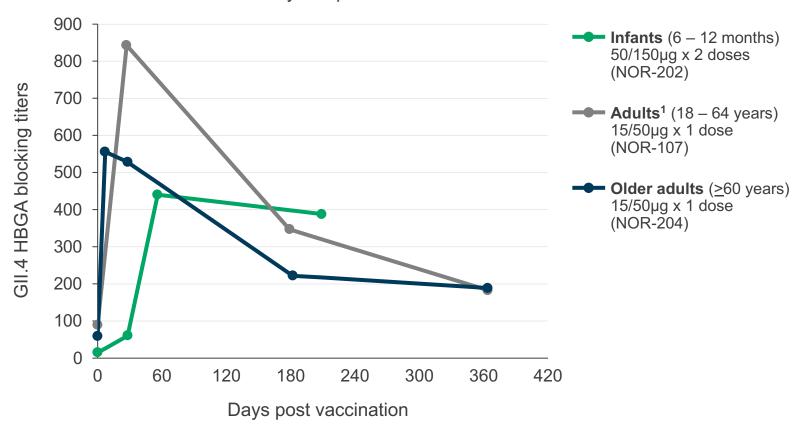
Measurement of HBGA-blocking antibodies is the primary method to assess vaccine immunogenicity against norovirus

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

HBGA blocking response following vaccination with HIL-214

GII.4 HBGA blocking titers over time

Note: cross study comparisons



CLINICAL POC

demonstrated in US Navy recruits

4,712 subjects

2 season, single site study had very few cases of HIL-214 vaccine strains of norovirus

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

Phase 2b demonstrated reduction in moderate-to-severe AGE

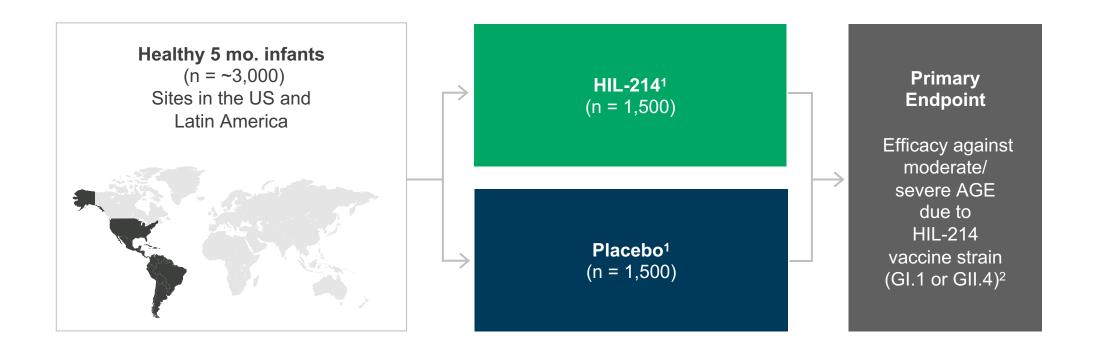
	Cases of moderate-to-severe AGE				
	Pathogen	Placebo n = 2,357	HIL-214 n = 2,355	%	p value
1°	HIL-214 vaccine strain only ¹	5 (0.2)	1 (<0.1)	80.0	p = 0.142
2 °	Any NoV strain	26 (1.1)	10 (0.4)	61.8	p = 0.0097
Post-hoc	GII.2 strain	21	9	57.4	p = 0.0321

We intend to focus our initial development primarily 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





¹ Vaccinations at Day 1 and Day 29 - 57

² Key secondary endpoints may include evaluation of efficacy against any GI or GII norovirus strain

NEST-IN1 has achieved significant milestones since 2Q22 initiation

NEST-IN1 updates

DMC completed Cohort 1 (203 subjects) safety review and recommended study continuation without modification

Cohort 1 immune responses¹ were consistent with prior infant studies of HIL-214

Enrollment completed with over 3,000 infants

Topline data expected mid-24

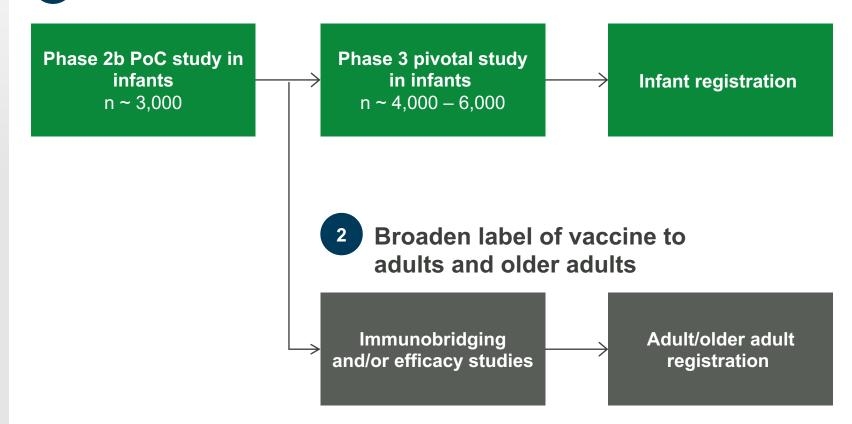
Development and regulatory strategy

Initial clinical program focused on infant population

Followed by immunobridging and/or efficacy studies in older adults

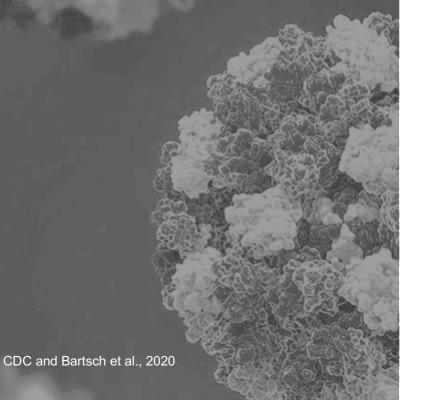
Clinical program and concurrent epidemiology and pharmacoeconomic studies to support potential ACIP recommendations

1 Establish initial indication in infants



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 and shingles burden (pre-vaccines) in the United States

Disease	Age	US cases	US hospitalizations	US deaths	US economic burden (in 2020 dollars)
	≤ 4 years	2.8 million	12,000	20	\$1.2 billion
Nanavima	5 – 64 years	15.7 million	34,000	70	\$6.4 billion
Norovirus	<u>></u> 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

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

SHINGLES VACCINES AS A CASE STUDY

CDC recommended vaccine for older adults

Zostavax approved in 2006; rapidly replaced by Shingrix approved Oct 2017

ACIP recommendation for adults over 50

\$3.6B global net sales of Shingrix in 2022

\$200-300 per shingles vaccine course (US)

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

STRONG CAPITAL POSITION

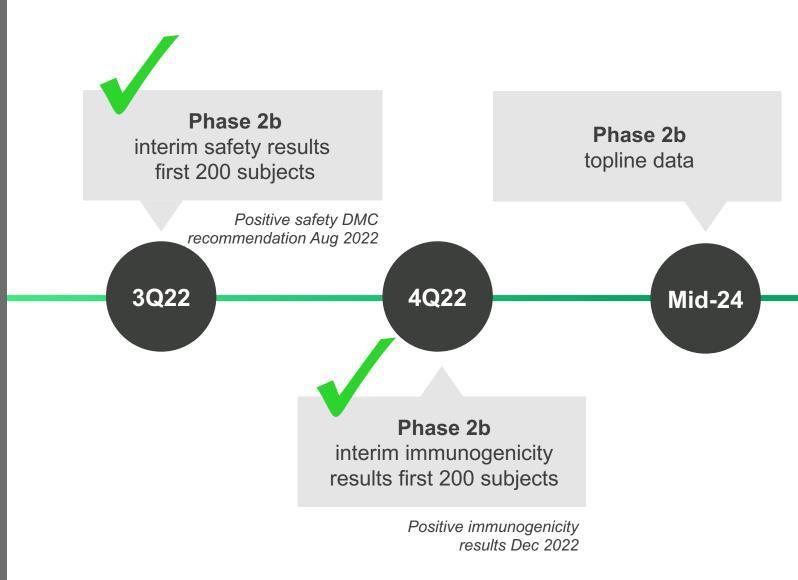
As of June 30, 2023:

\$244.1M cash & marketable securities

\$75M term loan¹:

\$25M drawn

Anticipated milestones





¹ Full draw subject to certain milestones and conditions

NASDAQ: HLVX*



- Most advanced norovirus vaccine candidate
- Clinical PoC demonstrated in adults
- Phase IIb study ongoing with over 3,000 infants enrolled
- Blockbuster potential commercial opportunity
- Highly experienced leadership team