

The Promise of Potent and Durable Immunity

October 2023

Gritstone bio, Inc.

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ABOUT GRITSTONE

Developing Next-Generation Vaccines for Oncology and Infectious Disease

Platforms Drive More Potent and Durable Immunity



Best-in-class antigen prediction



Proprietary, next-gen vectors drive response



Potential best-in-class neoantigen-based personalized cancer vaccine program (GRANITE) in randomized Phase 2/3 study for MSS-CRC

Self-amplifying mRNA (samRNA) candidate for COVID-19 in BARDAfunded, 10,000 subject Phase 2b randomized head-to-head study against currently-approved vaccine

Upcoming data readouts could de-risk clinical platforms and potentially enable expansion into additional disease types

Anticipated Upcoming Milestones

Additional data from COVID-19 Phase 1 studies (Oct 2023)

Preliminary data from Phase 2/3 GRANITE-1L study (1Q 2024)

Initiate Phase 2b head-to-head study in COVID-19 (1Q 2024)

Estimated Cash Runway into 4Q 2024*

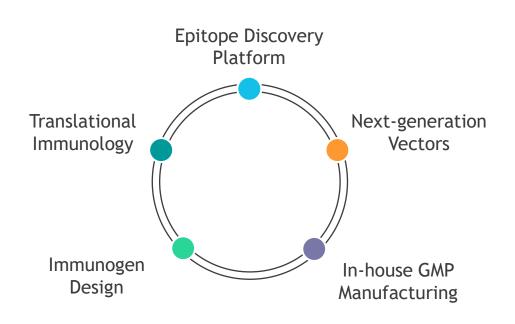
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OUR CAPABILITIES

Pursuing More Potent and Durable Immunity Through Vaccine Innovation

Capabilities uniquely designed to address current vaccine challenges





Proprietary artificial intelligence platform (EDGE™) to identify critical T cell targets



Next-gen vectors, ChAd and self-amplifying mRNA*, to drive potent and durable immune responses suited to the clinical context



In-house GMP manufacturing enables personalized and off-the-shelf products (clinical stage and scale-up)



Immunogen design is key component of novel vaccine formats - must be studied in clinical trials



Bench-to-bedside-to-bench: innovative product development pushes scientific boundaries



OUR VACCINE PIPELINE







Disease Area	Target/Approach	Indication	Preclinical	Phase 1	Phase 2	Milestones	Collaborator
	Individualized Neoantigens	First-line microsatellite-stable colorectal cancer (MSS-CRC)	6		GRANITE	1Q2024 Prelim Randomized Ph 2 Data	
Oncology	Shared Neoantigens	KRAS ^{mut} -driven tumor types	© 1	SLAT	Е	2024 Initiate Randomized Ph 2*	
	Shared Neoantigens	Solid tumor	© ∠ SLATE			Submit IND	

Disease Area	Target/Approach	Indication	Preclinical	Phase 1	Phase 2	Milestones	Collaborator
	Spike + T Cell Epitopes	SARS-CoV-2 (COVID-19)	© 0	CORA	L	1Q2024 Initiate Randomized Ph 2b	BARDA
ID Prophylaxis	Undisclosed	Multi-respiratory	© 0			Undisclosed	
	Undisclosed	Influenza	© 0			Undisclosed	

Disease Area	Target/Approach	Indication	Preclinical	Phase 1	Phase 2	Milestones	Collaborator
ID Therapeutic	HIV Eradication	HIV	4	HIV		TBD: Potential Opt-in Program	GILEAD
	HPV Eradication	HPV	©			Undisclosed	BILL&MELINDA GATES foundation

*Randomized trial in newly-diagnosed metastatic patients

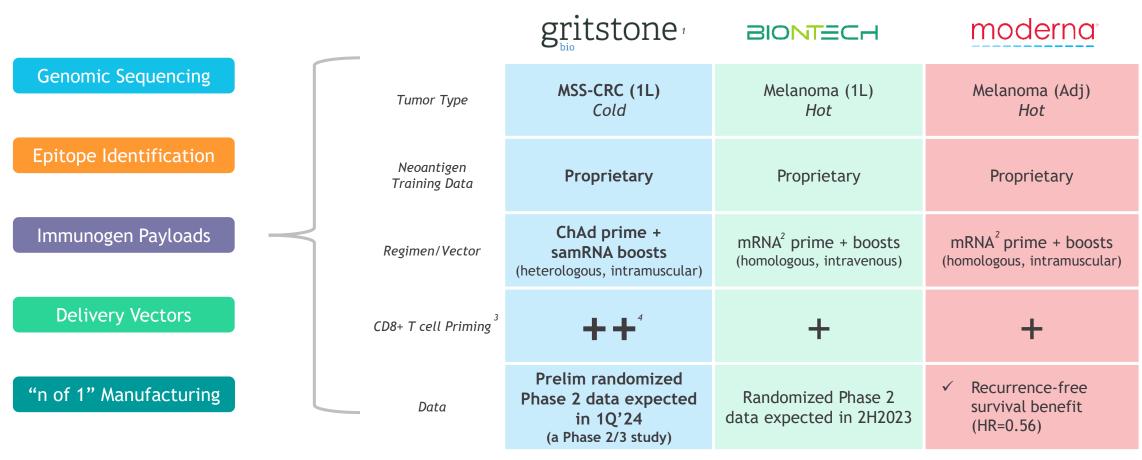






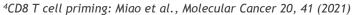
Personalized Cancer Vaccines are Ushering in a New Era of Immunotherapy

Potential proof-of-concept for novel modality is rapidly growing, with multiple randomized studies ongoing



¹GRTS vaccine candidates have not been studied head-to-head with those listed.

³Semi-quantitative assessment of strength and breadth of human T cell immune response to neoantigen vaccine based on cross-study comparisons of published data

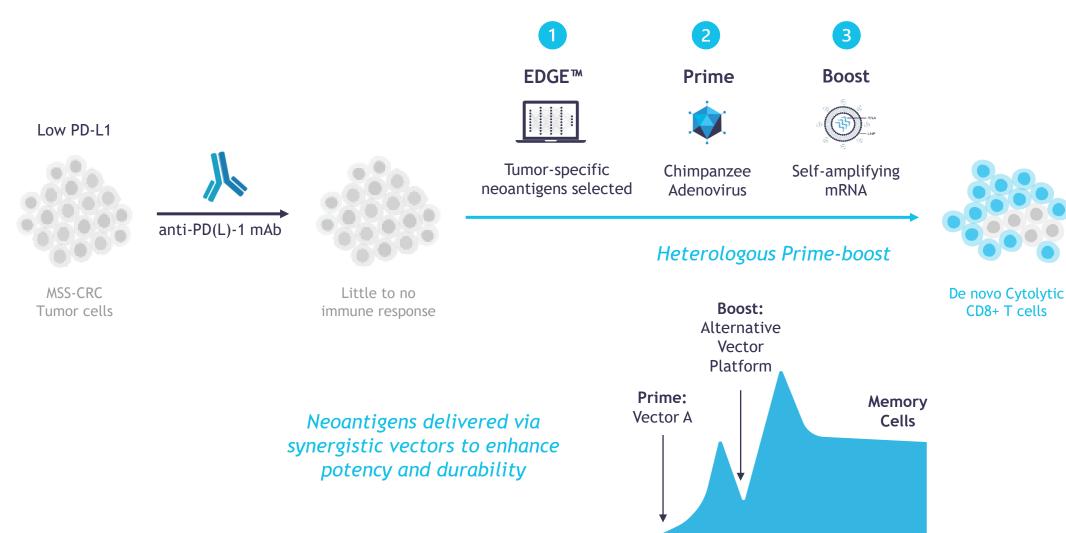




²BioNtech uses optimized Uridine mRNA. Moderna uses Modified Uridine mRNA.

Gritstone's Approach: Induce CD8+ T cells Against "Cold" Solid Tumors

Antigen selection + prime-boost regimen may be effective in tumors unresponsive to anti-PD(L)-1 therapy



GRANITE: Individualized Neoantigen Vaccine for Solid Tumors

Leveraging neoantigens to transform MSS-CRC* into an actionable target



Neoantigen Selection

20

patient-specific neoantigens identified by proprietary Al platform (EDGE™)



Heterologous Prime-Boost

ChAd + samRNA

delivery vectors synergize to enhance potency and durability of immunogen payload



Selected POC Indication

MSS-CRC

immunologically "cold" tumor with significant unmet need (2nd leading cause of cancer deaths**)

*MSS-CRC = metastatic, microsatellite stable colorectal cancer **American Cancer Society's Cancer Statistics Center and Colorectal Cancer Facts & Figures 2020-2022



GRANITE: Advanced to Randomized Phase 2/3 with Registrational Intent

Positive results in advanced solid tumors (Phase 1/2) provided basis for advancement to first-line MSS-CRC

Phase 1/2 Clinical Takeaways*

Indication: 3L advanced solid tumors (incl. MSS-CRC)

Regimen: GRANITE + nivolumab + ipilimumab

Patient Outcomes:

- Well-tolerated
- Extended survival (22+ months in molecular responders, mOS not reached yet)
- Robust, broad and persistent induction of CD8+ T cells against targeted neoantigens
- 55% (6/11) molecular response by ctDNA reduction with visible lesion shrinkage
- No dose-limiting toxicities (DLTs)

Randomized Phase 2/3 Study

Indication: 1L maintenance in MSS-CRC

Regimen: GRANITE + anti PD-L1+ Fluoropyrimidine +

bevacizumab

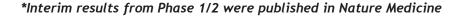
Endpoints: ctDNA (potential accelerated path) and/or overall survival

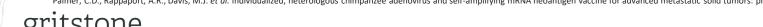
Clinical Strategy: Use MSS-CRC as POC to pursue multiple solid tumors

Milestones:

- Received fast-track designation in MSS-CRC (in 2018)
- Preliminary Phase 2 data expected in 1Q 2024







GRANITE: Phase 2 Primary Endpoint = Molecular Response (ctDNA)

Change in circulating tumor DNA (ctDNA) increasingly recognized as a clinically meaningful surrogate for survival

Researchers

nature. Genentech medicine

Overall, measuring ctDNA dynamics during treatment can improve patient risk stratification and may allow early differentiation between competing therapies during clinical trials



A longitudinal circulating tumor DNA-based model associated with survival in metastatic non-small-cell lung cancer (Nature Medicine, March 2023)

Developers

gritstone IMMUNOCORE *natera



















- ctDNA better surrogate of OS than RECIST
- KIMMTRAK (FDA-approved for uveal melanoma based on OS) showed significant correlation between ctDNA reduction and extended overall survival

Immunocore Corporate Presentation (November 2022)

Advocates









We observed strong associations between reductions in ctDNA levels from on-treatment liquid biopsies with improved overall survival and progression free survival

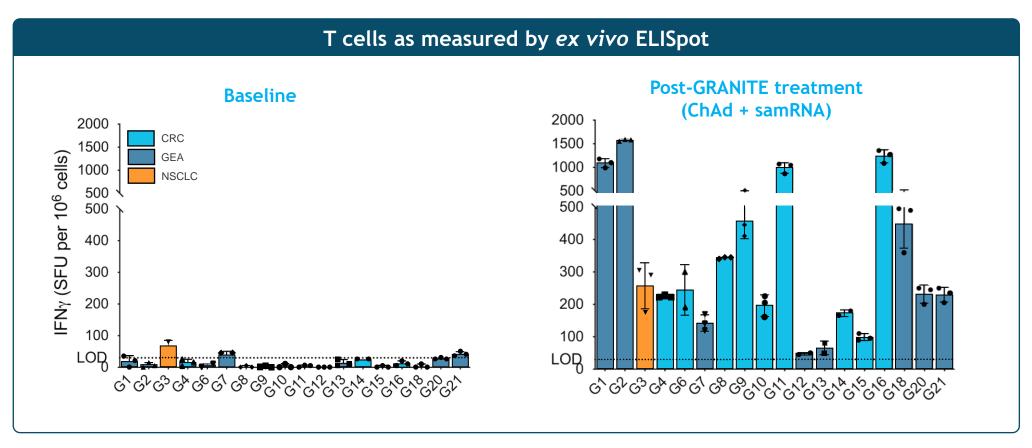


Changes in Circulating Tumor DNA Reflect Clinical Benefit Across Multiple Studies of Patients With Non-Small-Cell Lung Cancer Treated With Immune Checkpoint Inhibitors (JCO Oncology, August 2022)



Phase 1/2 Results: Consistent Induction of Neoantigen-specific T cells

Lack of T cells in patients prior to treatment reflective of poor intrinsic immunogenicity of tumors

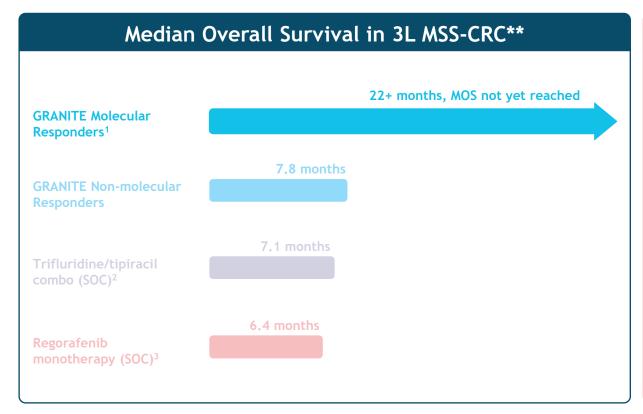


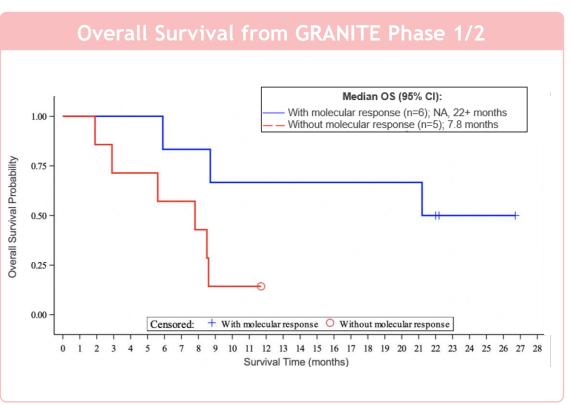
G5: no samples available (patient died); data represent peak responses post-GRANITE treatment



Phase 1/2 Results: Median Overall Survival in MR Exceeds 22 Months*

FDA has reviewed registrational Phase 2/3 study design with molecular response (MR) as Phase 2 primary endpoint; Phase 3 primary efficacy endpoint TBD





^{1 13} MSS-CRC patients treated; 2 did not have samples for analysis of ctDNA changes relative to baseline and included in without MR group; 6 of 11 were molecular responders; Molecular responders defined as patients with ≥30% reduction in ctDNA



² Mayer et al., The New England Journal of Medicine 372, 1909-1919 (2015)

³ Grothey et al., The Lancet 381, 303-312 (2013)

^{*}Data cut-off 31-Aug-2022

^{**}GRTS vaccine candidates have not been studied head-to-head with those listed.

GRANITE: Study Design for Randomized Phase 2/3 in 1L MSS-CRC

Study Population	Phase	Primary Endpoint	N
1L MSS-CRC	2	Molecular Response (change in ctDNA)	100 ¹
	3	TBD (to be determined following prelim Phase 2 data)	TBD

¹ Study expanded in May 2023 (from n = 80).



Induction Chemo All patients

Maintenace treatment stage begins

Control Arm

Continue 5-FU and bevacizumab only

~4-6 months

Oxaliplatin

(with or without irinotecan)

5-FU and bevacizumab

GRANITE

Continue 5-FU and bevacizumab + GRANITE + ipilimumab (x2 doses) + atezolizumab (monthly)

GRANITE = ChAd (Chimpanzee Adenovirus) + self-amplifying mRNA (samRNA)

Atezolizumab previously demonstrated to provide no additional benefit in this patient population (MODUL study²)

GRANITE regimen ~12 months



Positive Phase 2 Results Could Validate Platform and Support Phase 3 in MSS-CRC

Therapeutic Value Proposition

- Induce existing and de novo T cell response
- Make "cold" tumors actionable via neoantigens
- Personalize treatment to maximize efficacy



High Unmet Need in Colorectal Cancer*

2nd

leading cause of U.S. cancer deaths in men and women combined

~53,000

deaths expected to occur in 2023



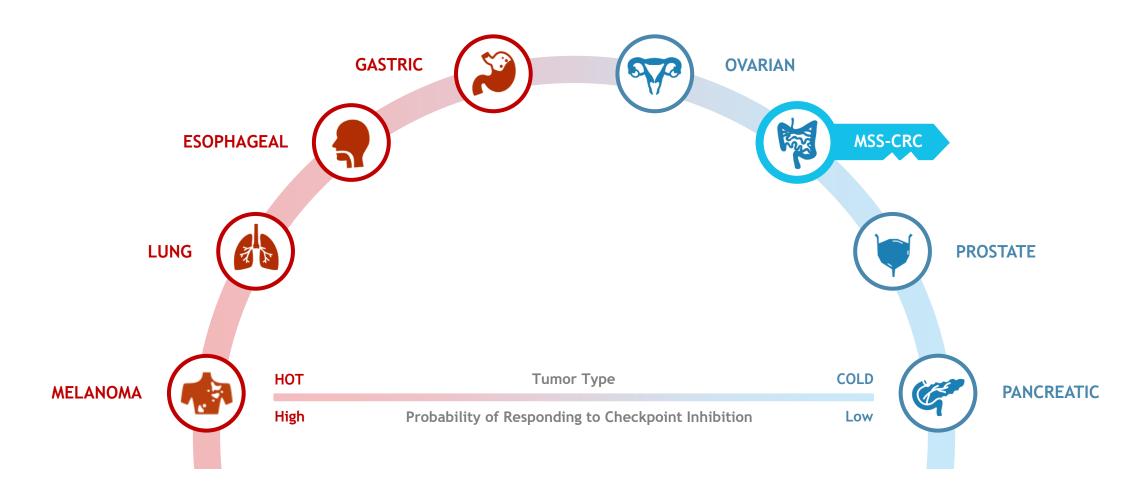
MSS-CRC is estimated to be 95%+ of all CRC*

*Colorectal cancer statistics per American Cancer Society 2023 Estimates



Positive Phase 2 Results Could Also Unlock Additional Tumor Types

Success in MSS-CRC could de-risk platform and support expansion to both "cold" and "hot" tumors





SLATE: Off-the-Shelf Neoantigen Vaccines for Solid Tumors

Shared neoantigen program utilizing same antigen selection and vectors as GRANITE



Neoantigen Selection

Relevant

Shared neoantigens identified by proprietary Al platform (EDGE™)



Heterologous Prime-Boost

ChAd + samRNA

delivery vectors synergize to enhance potency and durability of immunogen payload



Solid Tumor Application

Multiple

tumor types addressed via off-the-shelf cassette and streamlined manufacturing



Molecular Response Associated with Prolonged OS in MSS-CRC and NSCLC

Phase 1/2 Proof-of-Concept: Median Overall Survival in Late-line MSS-CRC and NSCLC¹

9.6 months*

SLATE Molecular Responders (KRAS)

4.5 months

SLATE Non-molecular Responders (KRAS)

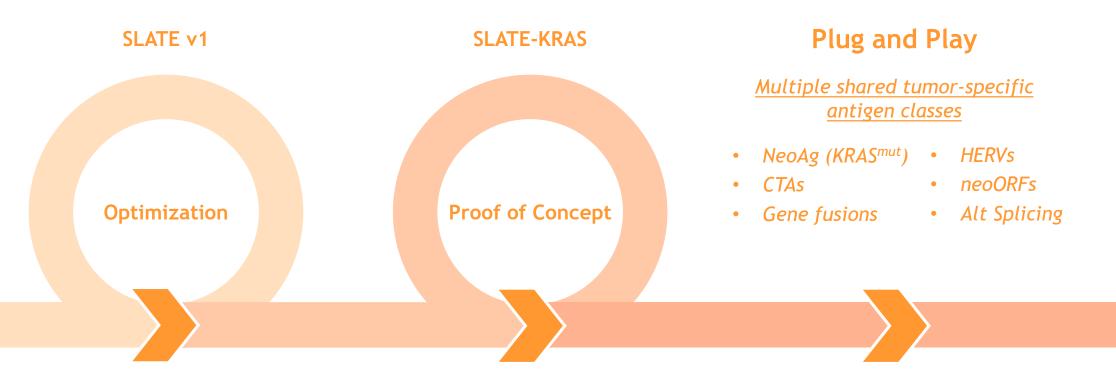
39% molecular response rate* and favorable safety profile of SLATE reinforces therapeutic potential of neoantigen approach

Phase 2 data further supports the correlation seen between molecular response and overall survival in late-line solid tumors

Phase 2 data in late-line patients supports moving KRAS-directed candidate into earlier lines of treatment



SLATE: Serving Solid Tumor Patients via Shared Neoantigen Immunotherapy



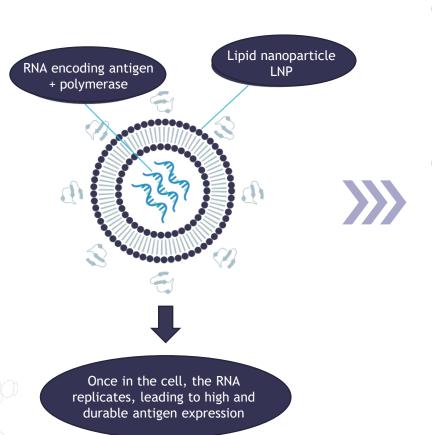
Refined payload of v1 cassette after initial studies indicated immunodominance of non-KRAS antigens KRAS-dedicated v2 cassette demonstrated Phase 2 proof of concept in MSS-CRC and NSCLC patients Optimized and validated SLATE cassette now ready for "plug and play" application across solid tumor indications





Self-amplifying mRNA: Addressing Current Vaccine Limitations for ID

Well-tolerated, scalable platform technology that offers potential advantages over first-generation mRNA



Durable antibody responses from extended antigen expression enable less frequent boosts

Broad T cell responses
provide second layer of protection
and may extend immunity

Dose-sparing regimens
induce equivalent nAb titers at
fractional doses of approved SOCs

samRNA Platform

Multiple Pathogens

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can be targeted, ranging from respiratory viruses like influenza to sexually transmitted infections such as HPV. Potential to combine into single product.



Gritstone's Differentiated Approach to COVID-19

Novel "Spike-plus" approach designed to drive durable and broad immunity

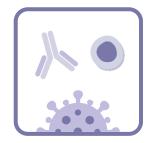
1st Generation mRNA (Spikevax, Comirnaty)

Gritstone self-amplifying mRNA (CORAL)

nAbs Against Spike Only That Wane After 4-6 Months







Durable nAbs Against Spike; T cells Against Conserved Viral Targets

Spike-specific Immunity Subject to Viral Mutation and Immune Evasion







Broad T cell Immunity May Enable Cross-Variant Protection

High-dose, Repeat Boosts





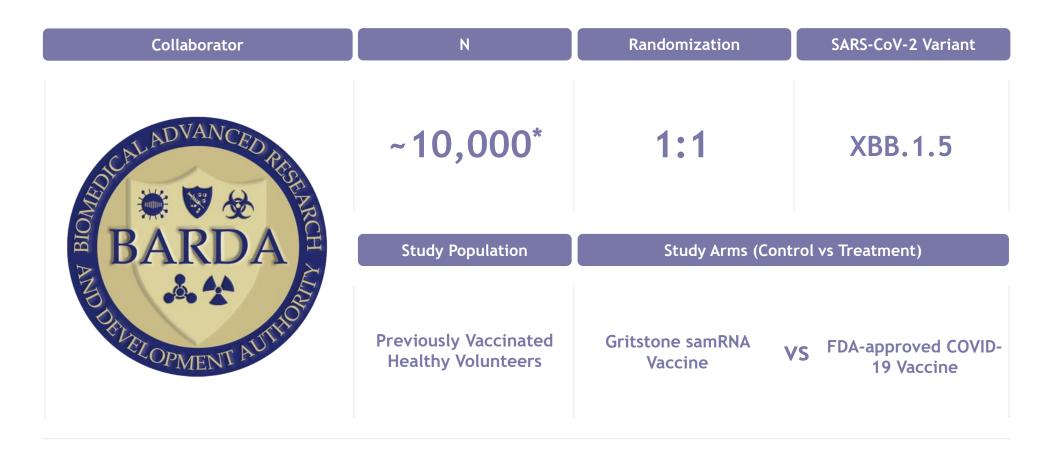


Low Dose, Durable Response



BARDA: Advancing CORAL to Phase 2b Head-to-Head Study in COVID-19

Contract valued at up to \$433 million enables randomized study evaluating Gritstone's samRNA vaccine with a currently-approved mRNA vaccine¹



^{*} Estimated study population size; US only



¹ Consists of funding for (1) a base period of \$10 million for performance of certain milestones such as preparation of protocol synopsis and submission of an investigational new drug application and (2) following successful completion of the base period, approximately \$423 million of additional BARDA funding for two stages gated at BARDA's discretion in support of the clinical trial execution and additional analyses for the clinical trial.

Phase 1 Studies Providing Proof-of-Concept for Wide Scale Use

Results to date demonstrate potential for broad applicability across patient populations and settings

Study	Population	Vaccine	n	Data to Date
CORAL - BOOST (United Kingdom)	Previously-vaccinated healthy volunteers (4 of 6 cohorts ≥60 years)	samRNA boost or samRNA/samRNA	40*	✓ Robust & durable nAbs✓ Dose sparing potential✓ T cell induction
CORAL - CEPI (S. Africa)	Unvaccinated (virus-naïve or convalescent) healthy volunteers, including people living with HIV	samRNA boost or samRNA/samRNA	342**	 ✓ Robust & durable nAbs ✓ Dose sparing potential ✓ T cell induction
CORAL - NIH (United States)	Previously-vaccinated healthy volunteers	ChAd/samRNA or samRNA/samRNA	150	Data to be presented at IDWeek 2023

^{**}Trial supported by funding from CEPI. Fully enrolled as of February 2023.

^{*}Original study included n = 20. Gritstone expanded study in January 2022.





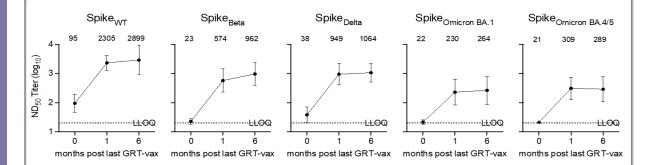
Phase 1 Results Highlight Differentiator: Long Lasting Antibody Response

High neutralizing antibody (nAb) levels sustained at 6 months across multiple populations and settings

CORAL-BOOST: Elderly UK Population, samRNA Following Adenoviral or mRNA Primary Series

High nAbs to Spike $_{D614G}$ and VOC Beta, Delta and Omicron BA1 & BA4/5 are maintained following single dose boost

**Post-adenoviral data below. See full poster for post-mRNA data.

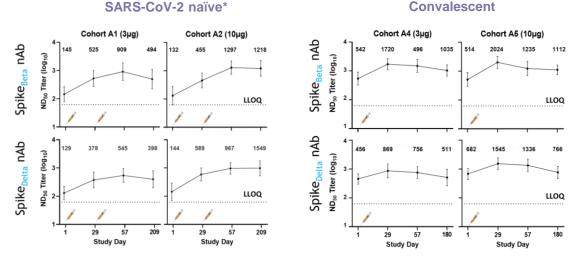


Spike-specific binding neutralizing (nAb) ND50 antibody levels are shown for cohort 1 and 2 subjects receiving a single or two doses of GRT-R910 at 10µg or 30µg. Data from treatment day D1 baseline, 1-month post most recent GRT-R910 dose, and 6-months post most recent GRT-R910 dose. Geomeans with 95% confidence intervals are shown. SARS-CoV-2 negative by PCR at screening.

CORAL-BOOST ECCMID 2023 Poster

CORAL-CEPI: Young, Unvaccinated S. African Population, samRNA as Single Dose or Homologous Prime Boost

High nAb levels to Spike Beta & Delta maintained in previously-unvaccinated subjects



Spike-specific neutralizing (nAb) ND₅₀ antibody levels are shown for naïve (A1 and A2) and convalescent (A4 and A5) subjects receiving one or two doses of GRT-R914 at 3µg or 10µg dose. Geomeans with 95% confidence intervals are shown. *SARS-CoV-2 anti-N IgG seronegative.

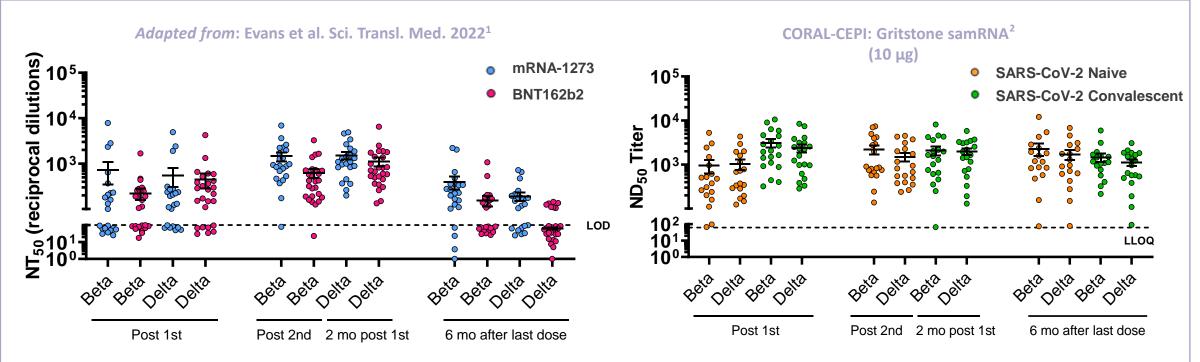
CORAL-CEPI ECCMID 2023 Poster



CORAL-CEPI: nAb Durability in Previously Unvaccinated Subjects (Beta and Delta VOCs)

Cross-study 6-month data vs. Moderna and Pfizer shown; vaccines not studied head-to-head directly

Gritstone's samRNA vaccine candidate elicits durable nAb responses against Beta and Delta variants, in contrast to FDA-approved Moderna and BioNtech/Pfizer mRNA vaccines

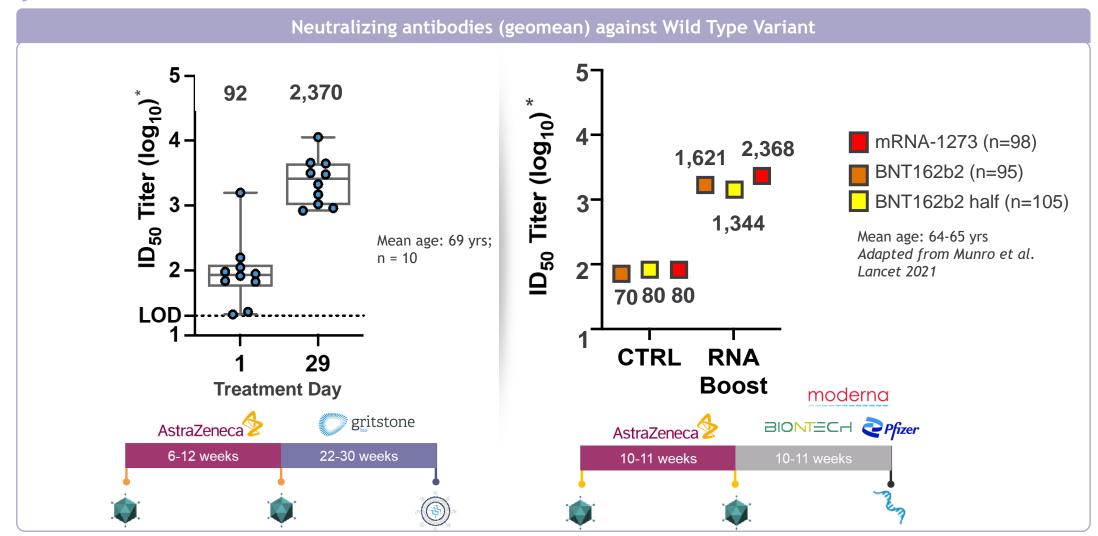


² SARS-CoV-2 naïve (orange): Participants received 2 doses with anti-N seronegative at baseline. nAb data were collected at Day 29 (Post 1st dose), Day 57 (Post 2nd dose), and Day 209 (6 month after last dose). SARS-CoV-2 convalescent (green): Participants received 1 dose with anti-N seropositive at baseline. nAb data were collected at Day 29 (Post 1st dose), Day 57 (2 months post 1st dose), and Day 180 (6 month after last dose). Error bars indicates means ± SEs; the dashed horizontal line indicates the limit of detection (NT50 < 100) for Evan et al. Sci. Transl. Med. 2022. and it is lower limit of quantification (ND₅₀ <62) for GO-012 data.

¹ Evans et al. Sci Transl Med. 2022 Mar

CORAL-BOOST: samRNA Boost Elicited Similar nAbs at up to 1/10th the Dose

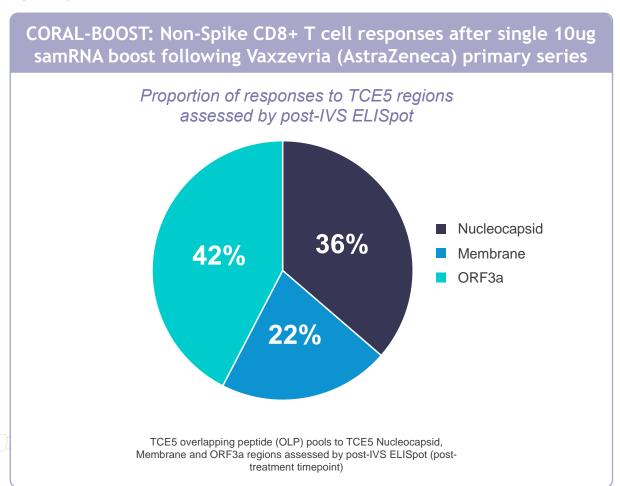
Cross-study comparison: 10µg of samRNA elicited similar nAbs as 100µg of Moderna (mRNA-1273) after AZ primary series*

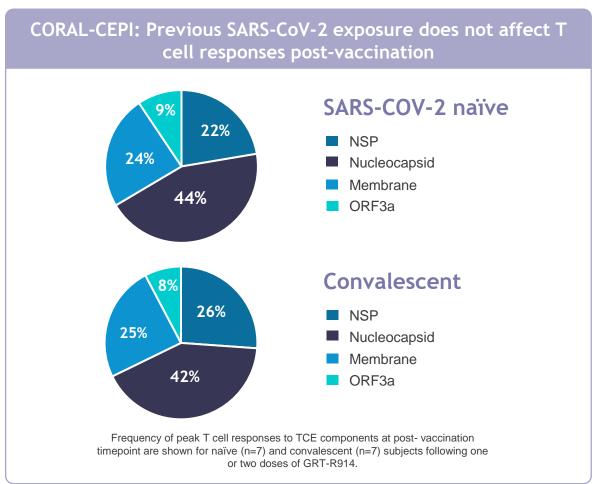




Phase 1 Results: Robust and Broad CD8+ T cell Induction

samRNA has driven potent cytotoxic cellular responses against both Spike and non-Spike SARS-CoV-2 viral epitopes







Next Steps: Initiating Phase 2b Head-to-Head Study in COVID-19

Randomized study to further establish differentiation and potential superiority over existing COVID-19 vaccines



Execute BARDA Contract (September 2023)

- Awarded contract to execute head-to-head Phase 2b study
- Contract valued at up to \$433 million



Study Planning and Preparation (In Process)

- Establish comparative vaccine and study design
- Submit and clear IND



Study Initiation (Expected 1Q 2024)

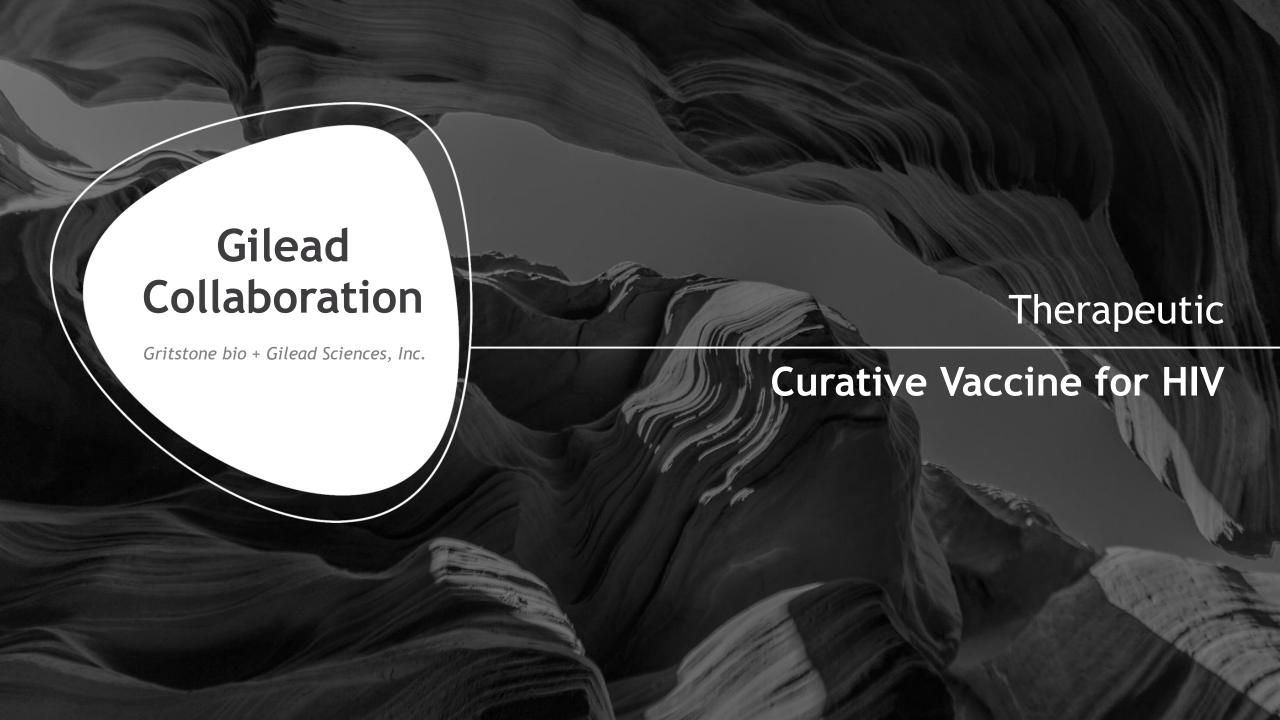
- Initiate 10,000 participant study, 1:1 randomization
- Enrollment expected to commence in 1Q 2024

Study to be executed in collaboration with:









Gilead HIV Cure Collaboration for Vaccine-based HIV Immunotherapy

Deal value of up to \$785 million plus royalties

- Leverages Gritstone's vaccine platform technologies (adenoviral and samRNA)
- Based on preclinical data demonstrating strong, durable and broad anti-SIV CD8+ T cell responses and T cell memory data
- Gilead is conducting a Phase 1 study and is responsible for all R&D
- \$40M milestone payment payable by Gilead for Phase 2 opt-in

Terms of Arrangement





\$60 million

Upfront payment

\$725 million

Clinical, regulatory, and commercial milestones

Mid single-digit to low double-digit tiered royalties on net sales upon commercialization



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Developing Next-Generation Vaccines for Oncology and Infectious Disease

Platforms Drive More Potent and Durable Immunity



Best-in-class antigen prediction



Proprietary, next-gen vectors drive response

Pleasanton, CA
Vaccine
Manufacturing

Boston, MA
GMP Sequencing
and Prediction

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