

On the call today



Joseph E. Payne, MSc
President & CEO



Pad Chivukula, Ph.D.
CSO & COO



Andrew Sassine, MBA
CFO



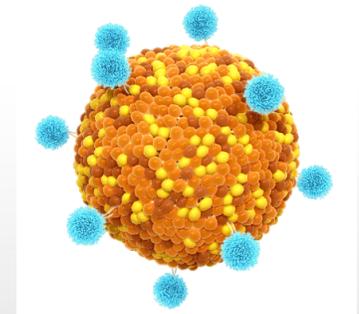
Steve Hughes, M.D.
Chief Development Officer



Ooi Eng Eong, BMBS, FRCPath, Ph.D.
*Professor of the Emerging Infectious Diseases
Programme at the Duke-NUS Medical School*



Thank you for joining us during the Holiday Season



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This presentation contains forward-looking statements. These statements relate to future events and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future performances or achievements expressed or implied by the forward-looking statements. Each of these statements is based only on current information, assumptions and expectations that are inherently subject to change and involve a number of risks and uncertainties. Forward-looking statements include, but are not limited to, statements about: the likelihood that preclinical or clinical results will be predictive of future clinical results or sufficient for regulatory approval; the likelihood of the Company to obtain clearance from regulatory authorities to proceed with planned clinical trials; the planned initiation, design or completion of clinical trials; the likelihood of success, or of the efficacy or safety, of the Company's COVID-19 vaccine candidate or other product candidates; potential treatment regimens of the Company's COVID-19 vaccine candidate; the ability to initiate or complete preclinical and clinical development programs, including as a result of the COVID-19 pandemic; the impact of commercialization of third-party COVID-19 vaccines on the design and enrollment in clinical trials; general market conditions that may prevent such achievements or performance; and any statements other than statements of historical fact, including those related to Arcturus' future cash, market or financial position.

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ARCT-021 Continues to Progress

Arcturus COVID-19 vaccine candidate continues to progress

Meaningfully different: utilizing STARR™ self-amplifying mRNA & LUNAR® delivery technology

Approved by the Singapore Health Sciences Authority (HSA) to proceed with a Phase 2 clinical study in 600 subjects

- Supported by comprehensive clinical and scientific data
- Phase 1/2 data & extensive preclinical studies

ARCT-021 may result in a highly effective vaccine with a differentiated product profile

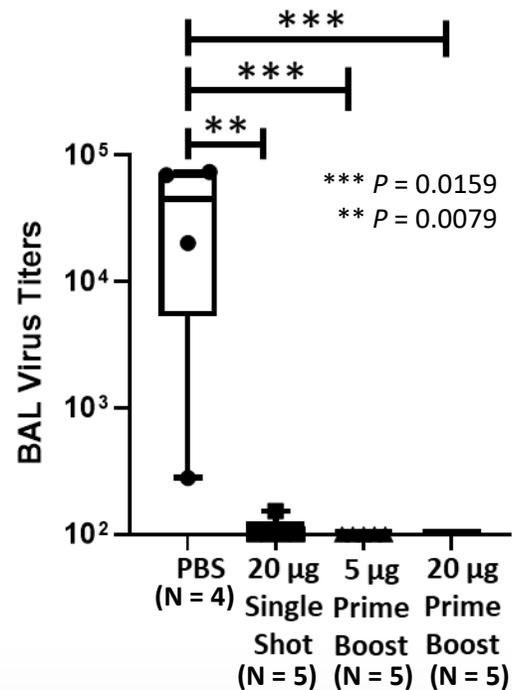
- may be effective as a low single dose mRNA vaccine
- compliance and logistical distribution benefits
- many areas of the world require a single dose regimen

Timeline

- Intend to start Phase 2 study soon
- IND application submitted to U.S. FDA; response anticipated soon
- Interim Phase 2 data in early 2021 to select a final dose and regimen for Phase 3 registrational study
- Targeting start of Phase 3 registrational study in Q2 2021

On today's call, Dr. Steve Hughes and Professor Ooi Eng Eong will provide a more detailed review of our data ...

ARCT-021 Vaccination Significantly Effective in Primate (Macaque) Challenge Model



7 Days After SARS-CoV-2 Virus Challenge –

- Geometric mean lung viral titers exceeded 1.31×10^4 in non-vaccinated primates (PBS)
- Lung viral titers are between 3.30 and 3.81 log **lower** in vaccinated primates

**Both single administration and prime-boost regimens of ARCT-021 are significantly effective
Vaccinated macaques show substantial reductions in lung viral titers (Geomean < 10)**

Interim Phase 1/2 Results

Steve Hughes, M.D.

Chief Development Officer

Study Overview

- Testing single doses and prime-boost regimens
- Younger (≤ 55 yr) and older (> 55 yr) adults
 - The single doses tested are 1, 5, 7.5 and 10 μg
 - 7.5 μg in older and younger adults
 - Two dose cohorts tested 3 μg and 5 μg in both older and younger adults
- Fully enrolled with 106 participants
 - All participants have now received all doses
 - 78 active vaccine; 48 received 2 doses.
 - No data yet available for 3 μg prime boost cohorts

Safety

Well tolerated at selected doses

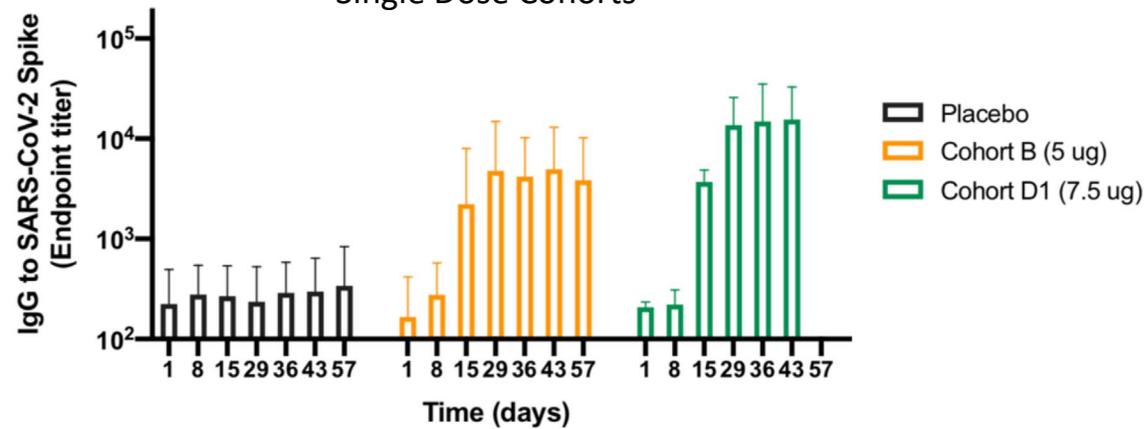
- No safety concerns identified
- No participants have withdrawn from the study; all participants completed all doses
- All adverse events except 2 were mild or moderate at doses selected for Phase 2
 - Transient Grade 3 fatigue and myalgia observed following second injection in one older adult.
 - Transient, asymptomatic Grade 3 lymphopenia seen in one participant.
 - Lymphopenia has been observed with other RNA vaccines.
- Only serious adverse event (SAE) was in a placebo participant

Immunogenicity

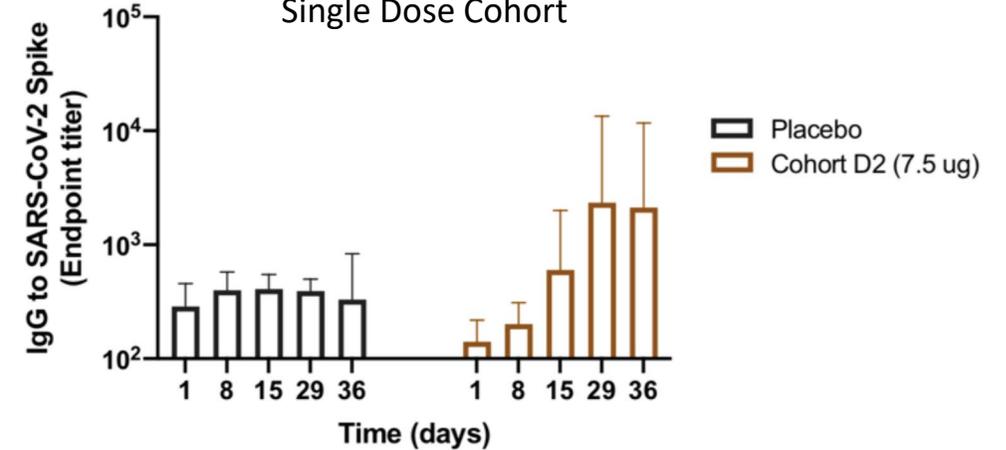
IgG Binding Antibodies

Luminex (GMT \pm SD)

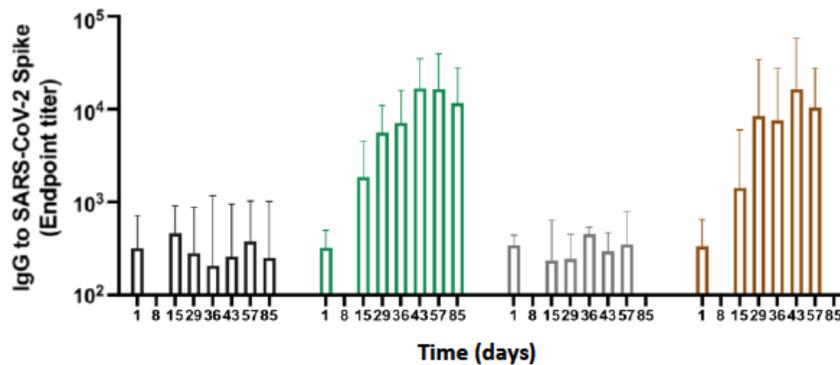
Younger Adult (≤ 55 yr) 5 μ g and 7.5 μ g
Single Dose Cohorts



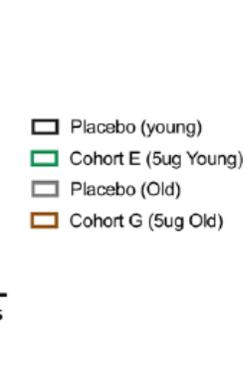
Older Adult (>55 yr) 7.5 μ g
Single Dose Cohort



Younger Adult 5 μ g
Prime-Boost Cohort



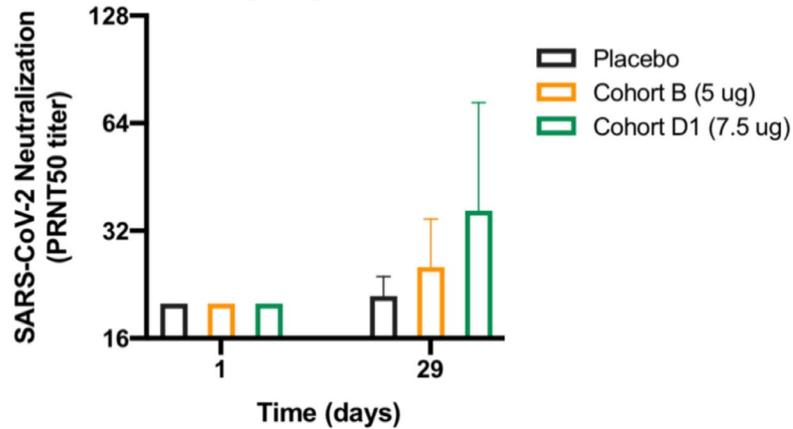
Older Adult 5 μ g
Prime-Boost Cohort



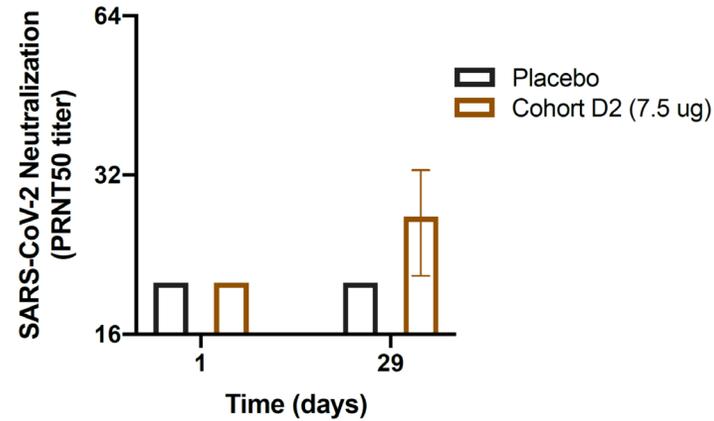
Neutralizing Antibodies

PRNT50 (GMT \pm SD)

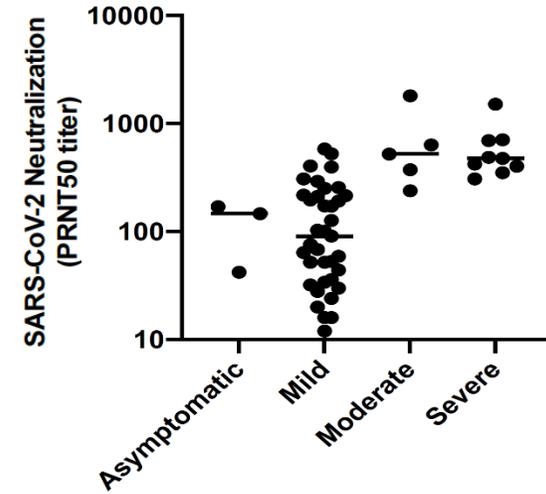
Younger Adult (≤ 55 yr) 5 μ g and 7.5 μ g Single Dose Cohorts



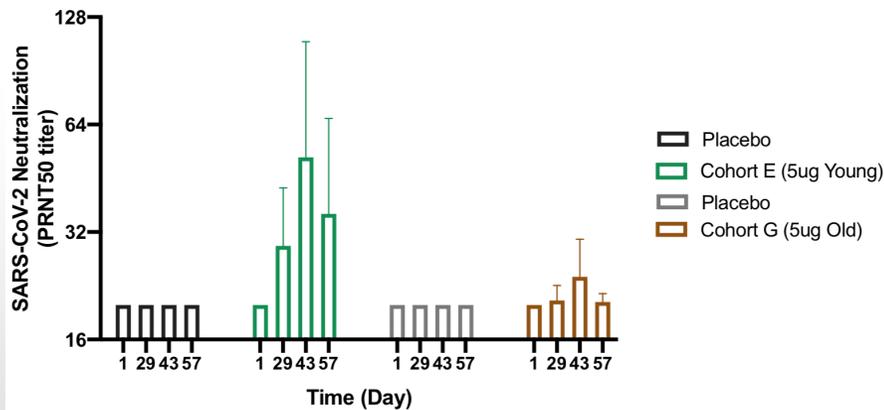
Older Adult (>55 yr) 7.5 μ g Single Dose Cohort



Convalescent COVID-19 Serum

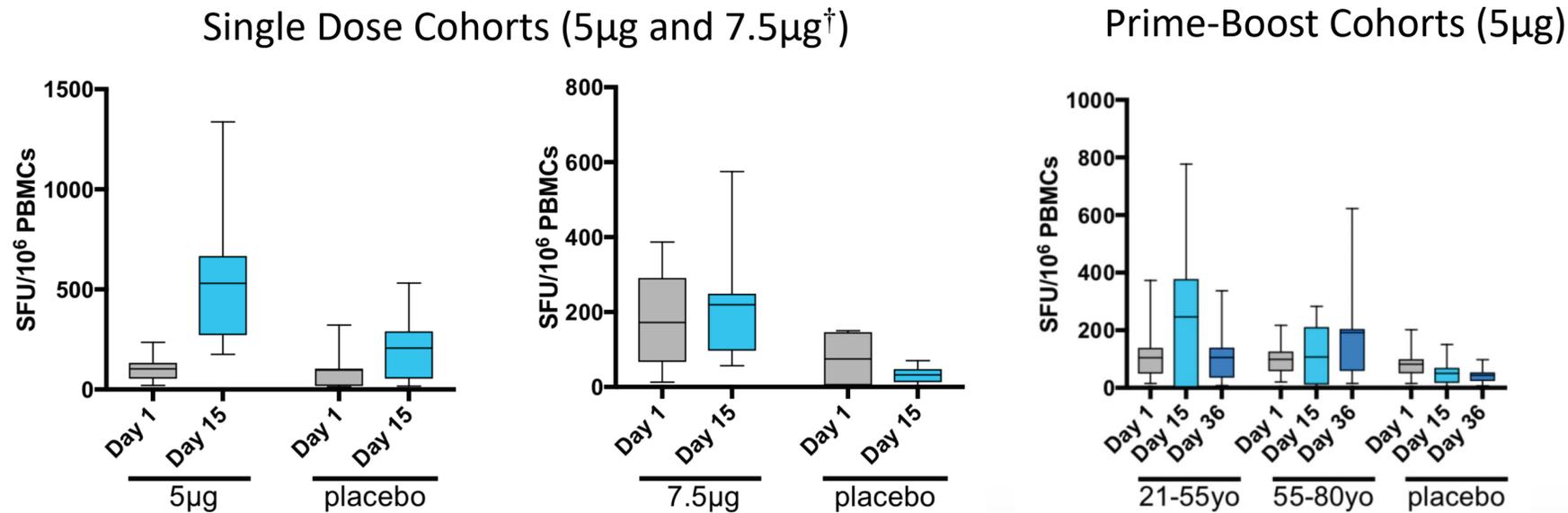


Younger Adult 5 μ g Prime-Boost Cohort Older Adult 5 μ g Prime-Boost Cohort



T-cell Responses Detectable by Day 15

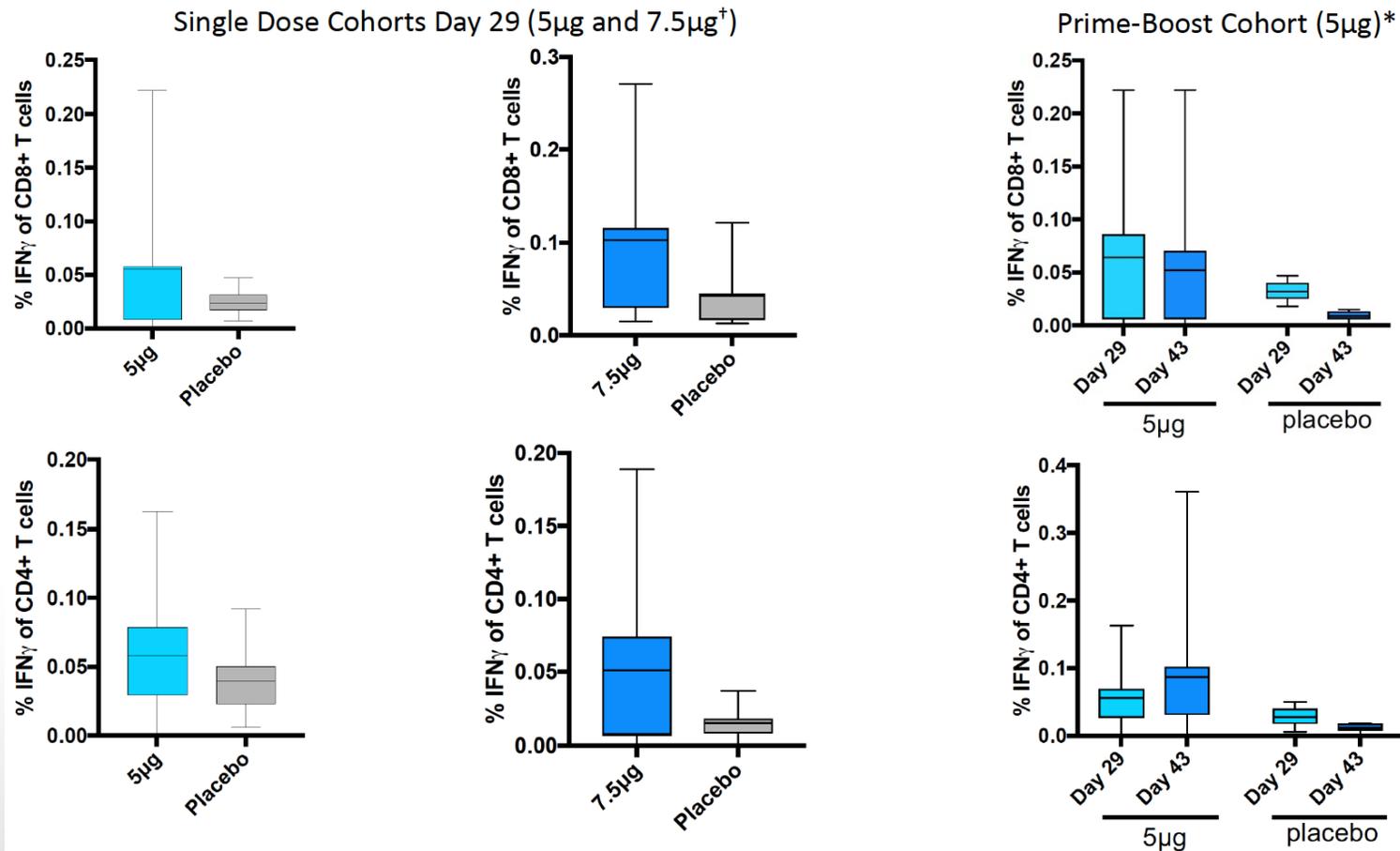
ELISpot (mean and range)



[†]Older and younger adults pooled

CD8+ and CD4+ Responses Detected

Cytokine staining (mean and range)

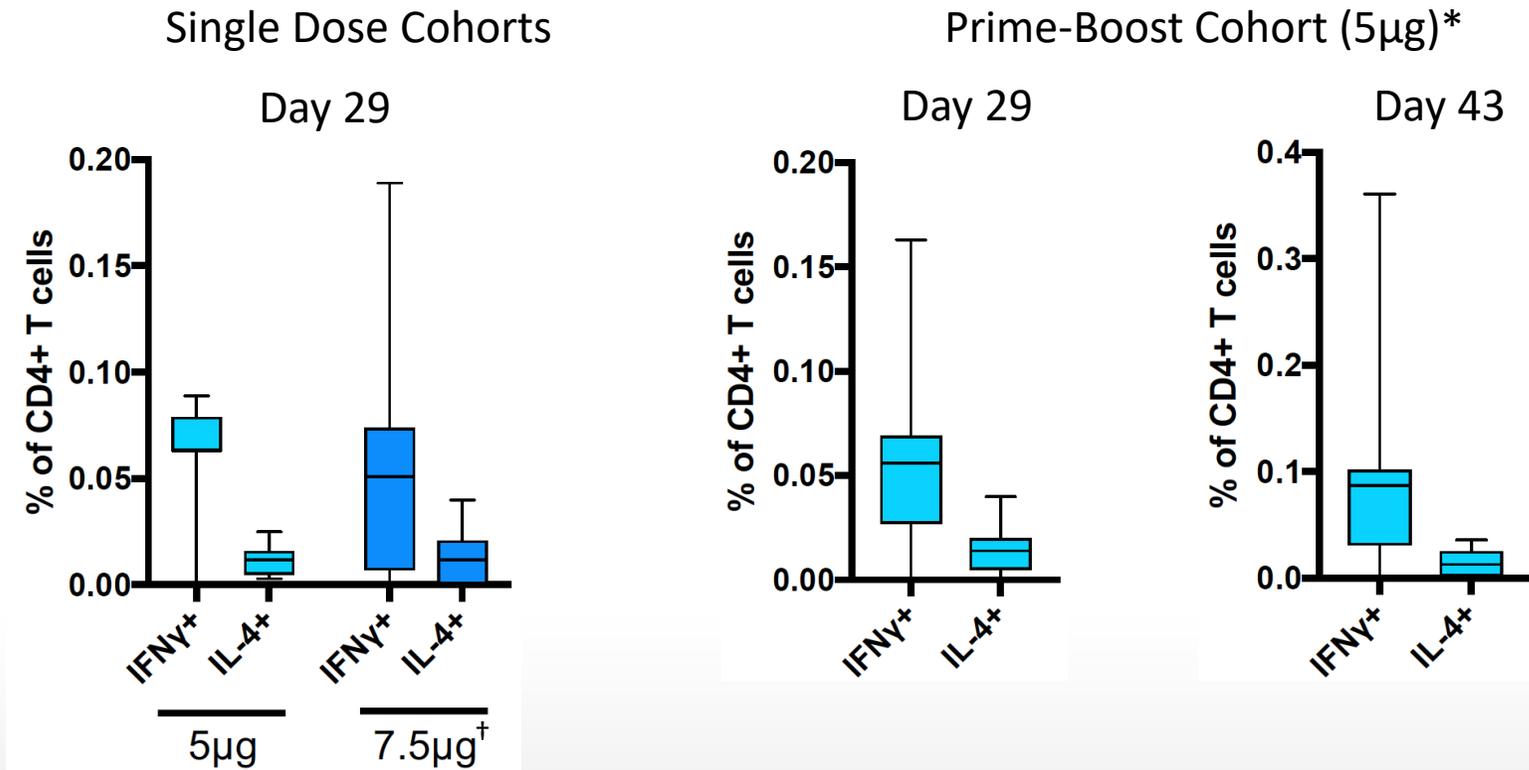


*Older adult prime-boost data not yet available

†Older and younger adults pooled

Th1 Dominant CD4+ Response

Cytokine staining (mean and range)



*Older adult prime-boost data not yet available

†Older and younger adults pooled

Next Clinical Trials

Continued Late-Stage Clinical Development

- Phase 2 Study in Singapore and USA
 - Approved in Singapore; IND pending
 - 600 healthy participants - younger and older:
 - 50% \leq 55 years, 50% $>$ 55 years, $>$ 25% \geq 65 years
 - Will test 7.5 μ g single dose; 7.5 μ g two doses; and 5 μ g two doses vs placebo
 - Objective to select dose and schedule for Phase 3
 - Interim analyses at Day 28 and Day 56 to enable Phase 3 start
- Phase 3 Study to be conducted globally
 - Targeting Q2 2021 start
 - \geq 15,000 participants (younger, older and risk groups represented)
 - Targeting interim analysis for EUA/Conditional Approval applications H2 2021



Partner in Academic Medicine



LUNAR-CoV19: Integrating the clinical and preclinical data

Eng Eong Ooi, BMBS PhD FRCPATH

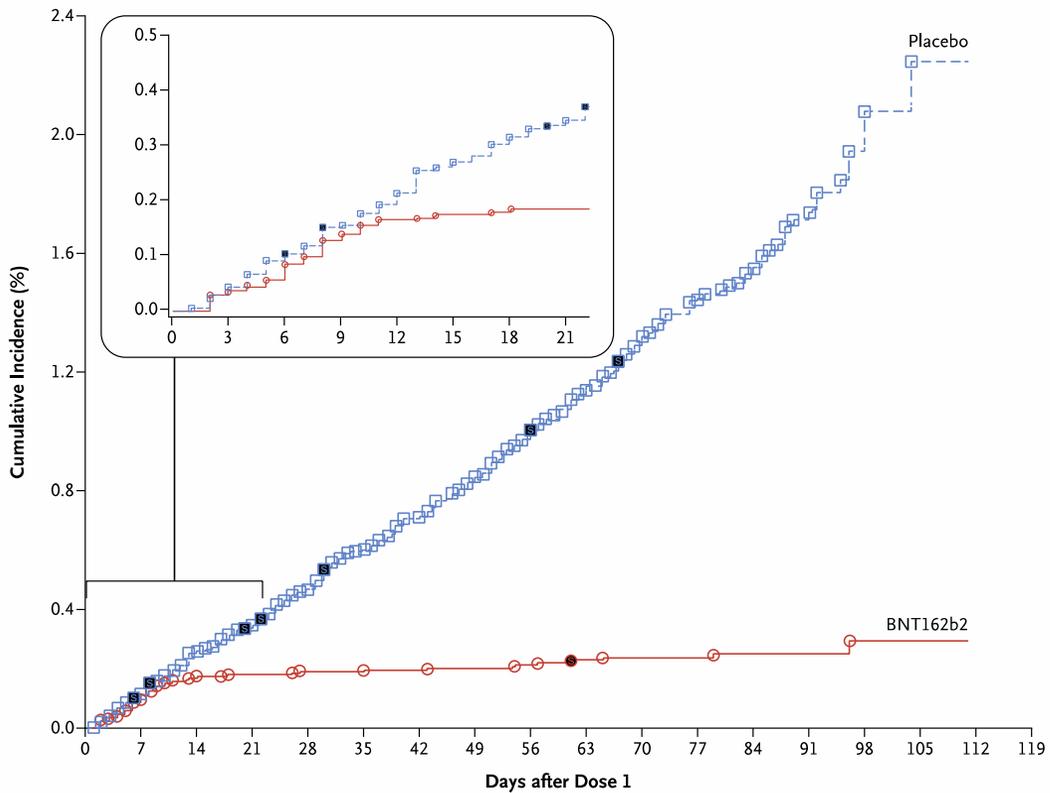
Professor

Program in Emerging Infectious Diseases

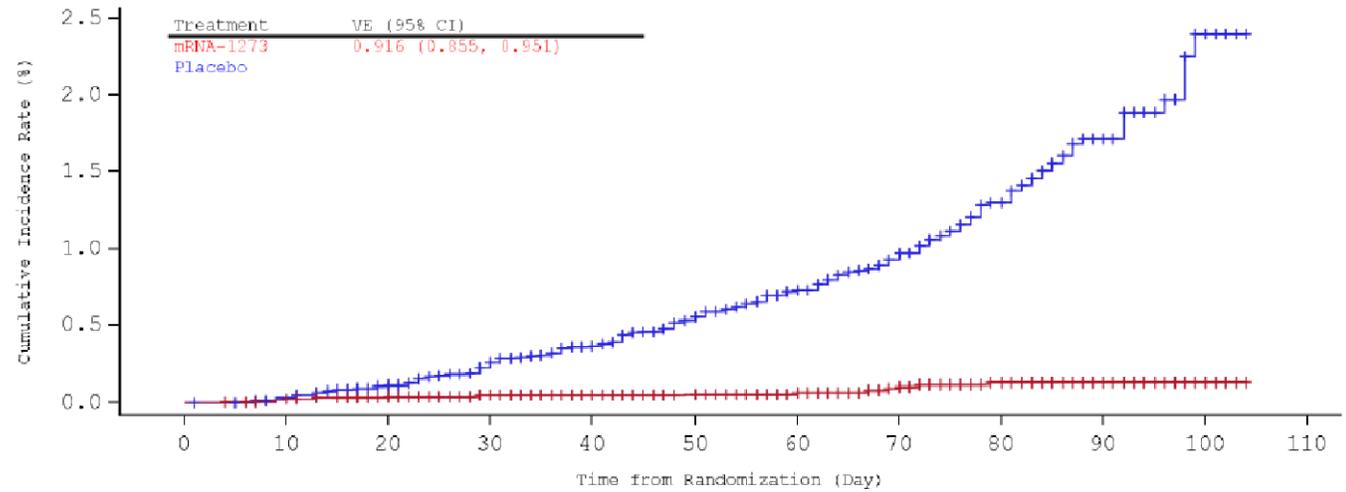
Duke-NUS Medical School

BNT162bc and mRNA1273 show efficacy ~2 weeks after 1st dose

Pfizer/BNT

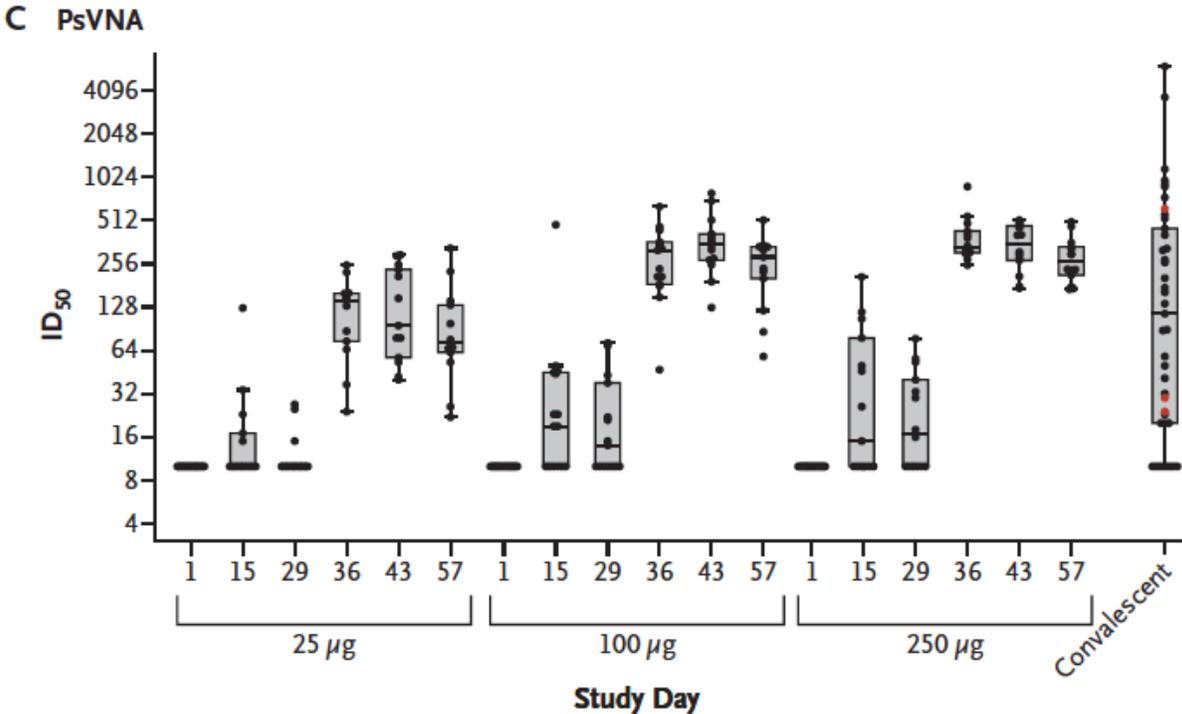
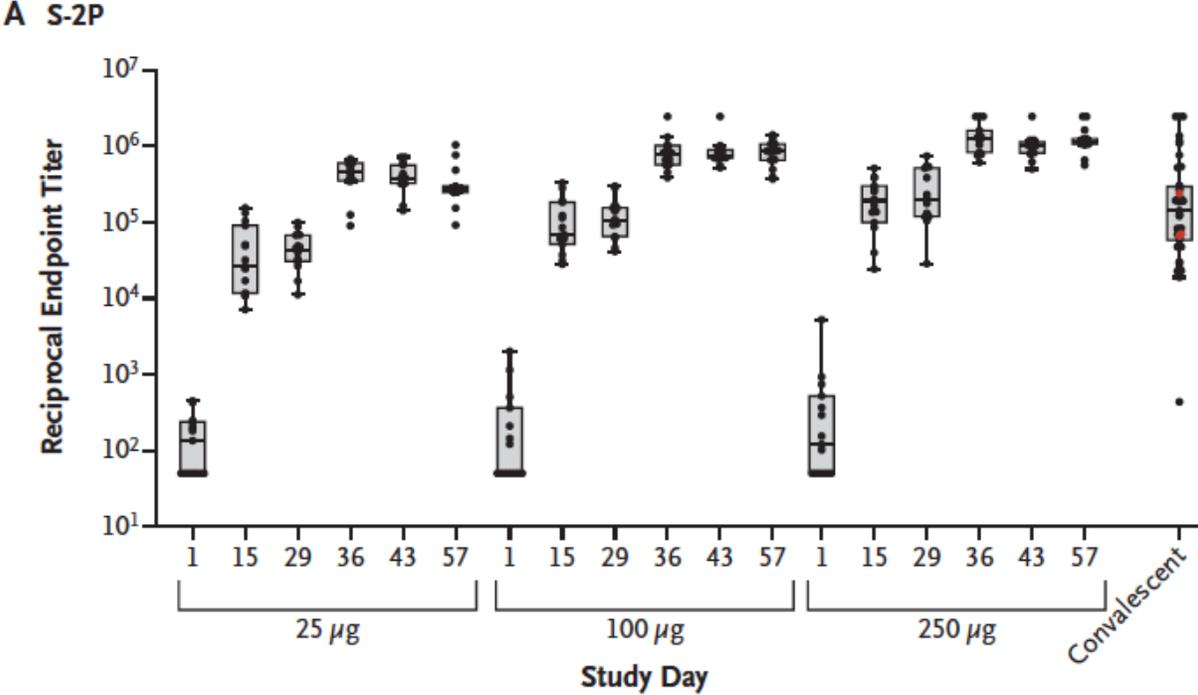


Moderna



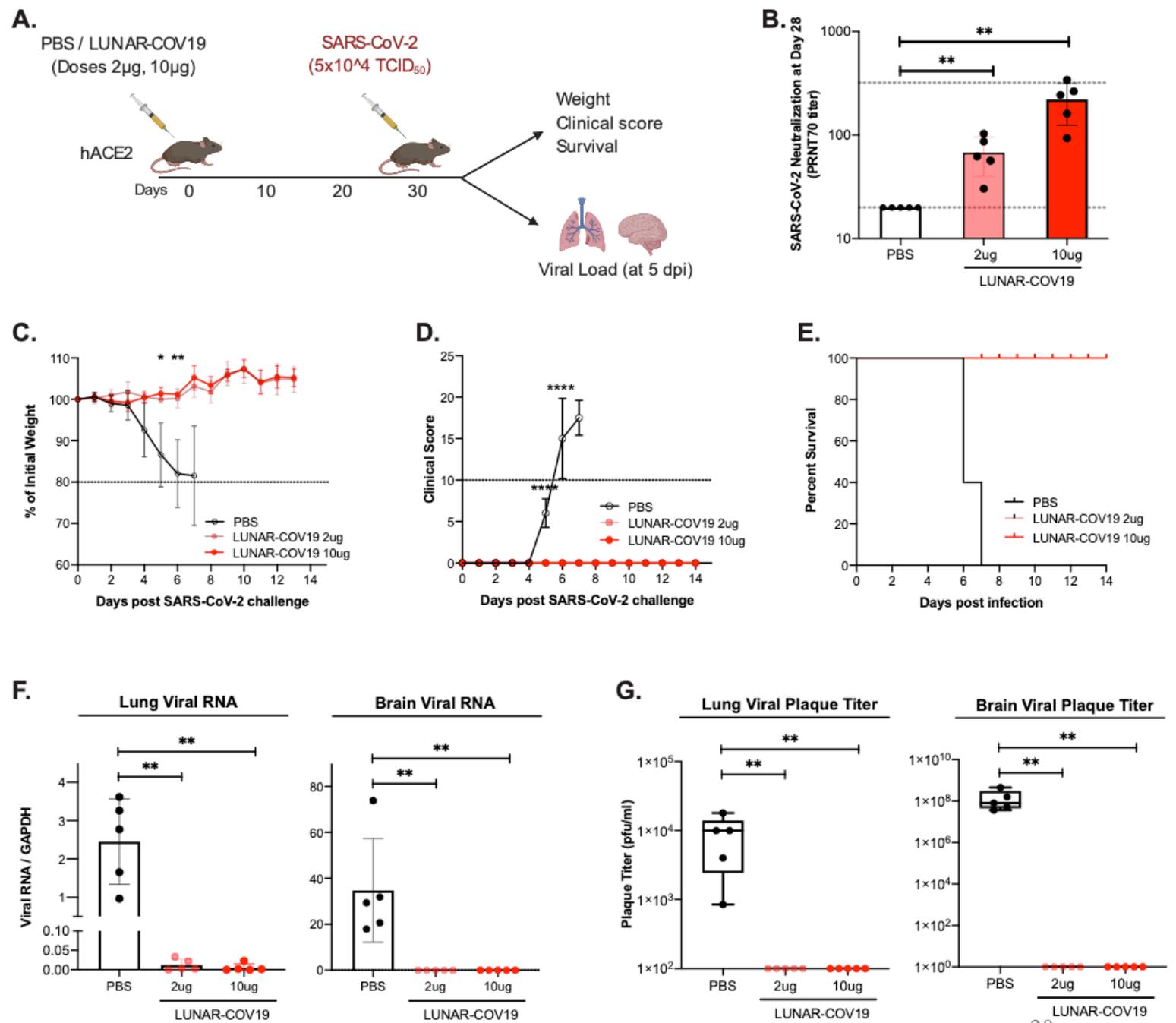
ModernaTX FDA Briefing Document

Immunogenicity of mRNA1273 vaccination



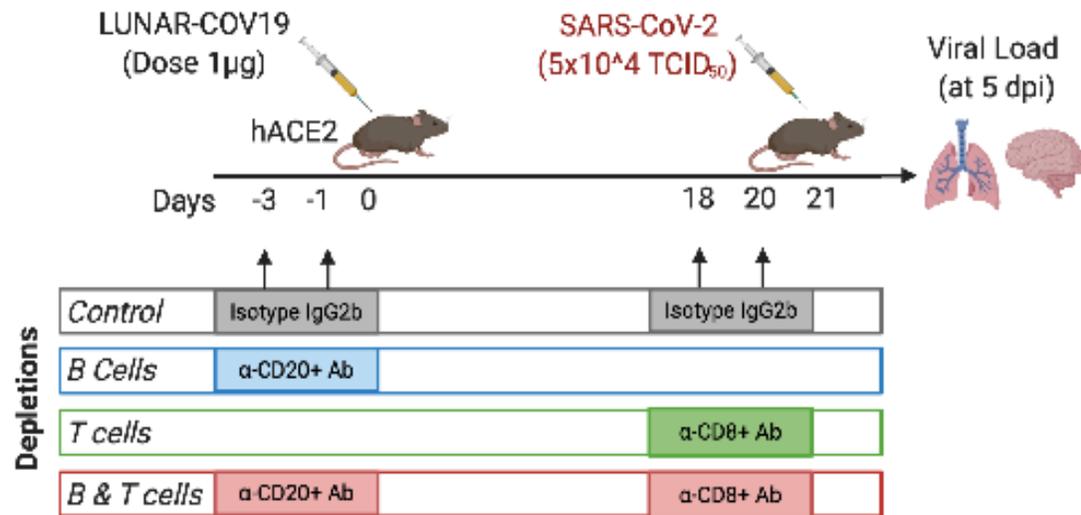
Jackson et al, NEJM 2020

A single LUNAR-CoV19 vaccination protects hACE2 transgenic mice from lethal SARS-CoV-2 infection

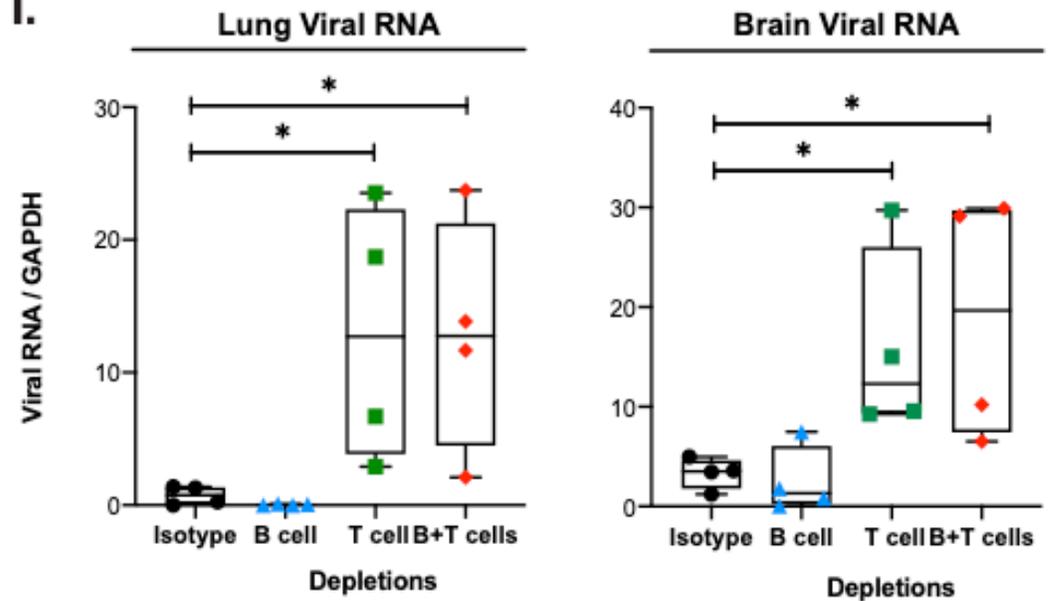


CD8+ T cells play a critical role in preventing SARS-CoV-2 infection

H.



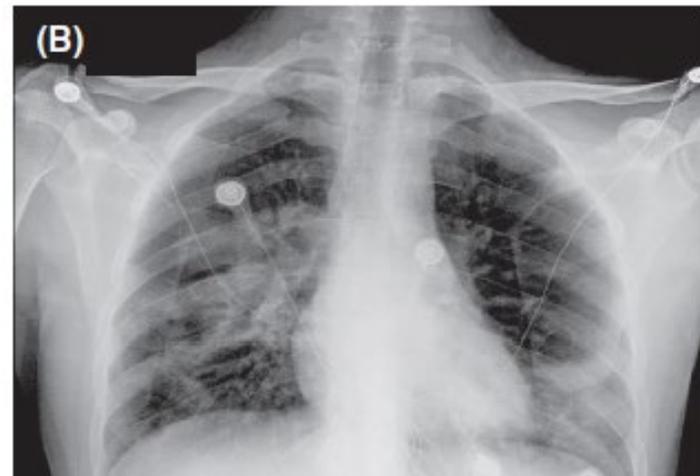
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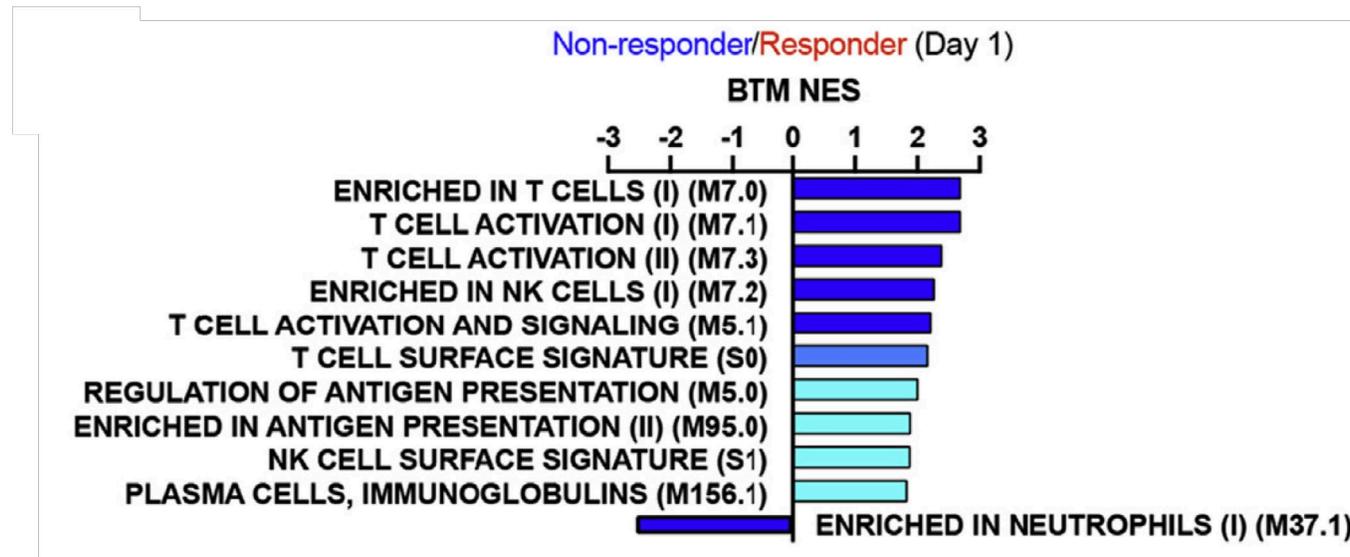
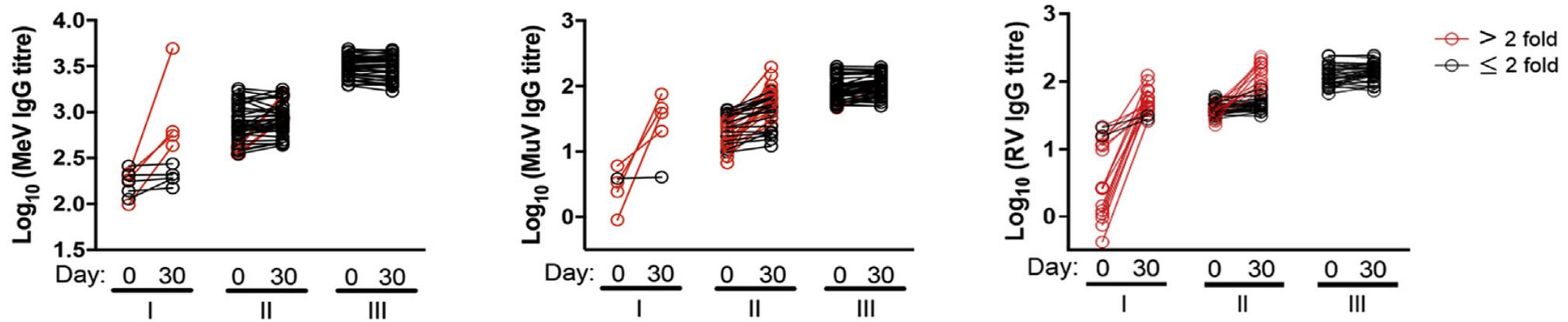
COVID-19 patients recover without antibodies

TABLE 2 Lymphocyte subsets of XLA patients

	Patient 1	Patient 2	Normal values
CD3 ⁺ T lymphocytes (%)	88.4	94.7	(57.1-87.6)
CD3 ⁺ (cells/ μ L)	1040	1791	(721-2562)
CD4 ⁺ T cells (%)	42.1	44.9	(28.5-65.6)
CD4 ⁺ (cells/ μ L)	495	849	(273-1882)
CD8 ⁺ T cells (%)	43.3	30.6	(10.5-37.7)
CD8 ⁺ (cells/ μ L)	509	578	(177-783)
$\gamma\delta$ ⁺ T cells (%)	3.8	32.4	(0.9-11.2)
B cells CD19 ⁺ (%)	-	-	(5.8-22.1)
CD19 ⁺ (cells/ μ L)	-	-	(86-684)
NK cells (CD3 ⁻ CD56 ⁺ , CD3 ⁻ CD16 ⁺ , %)	11.6	5.3	(3.4-28.4)



Early T cells protect against MMR re-infection

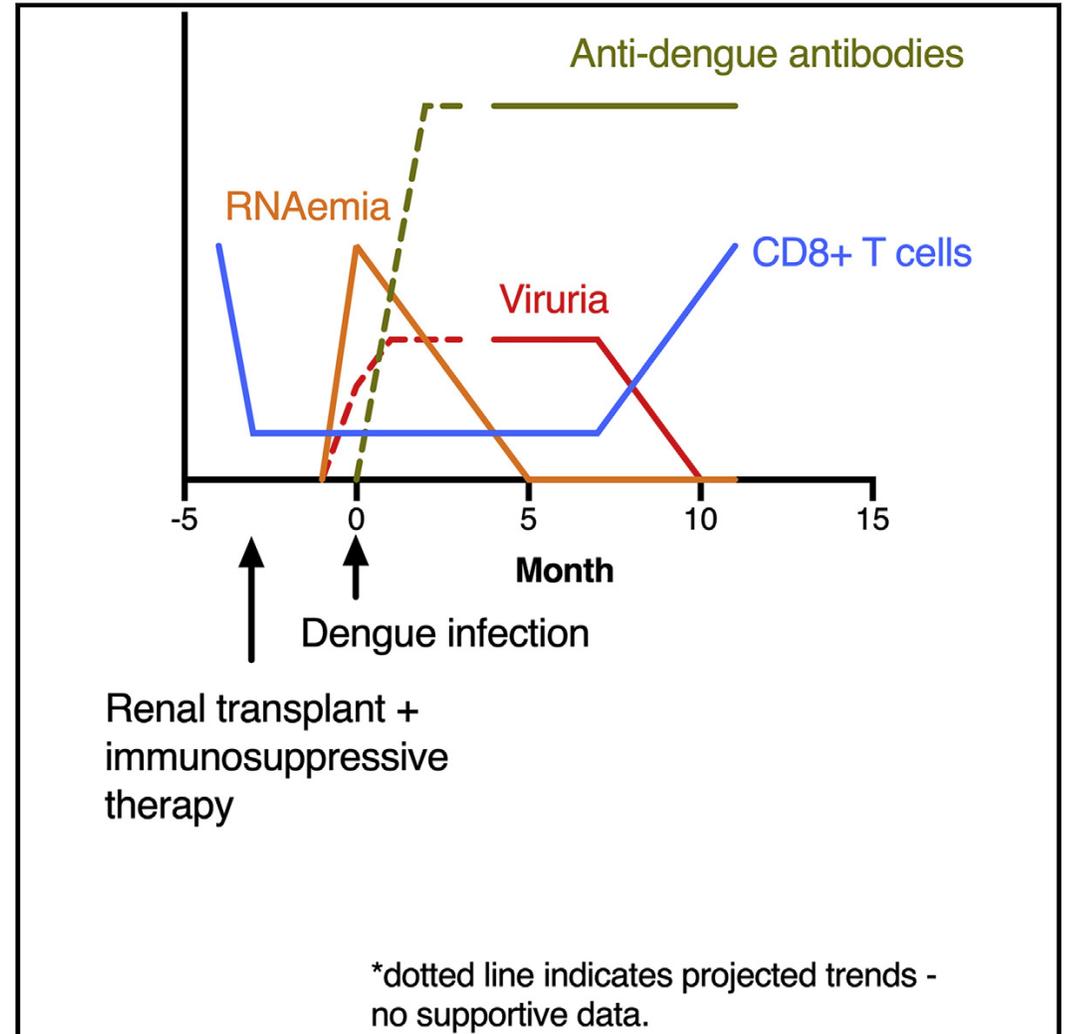


Ong et al, Antiviral Res 2019

Persistent Dengue Infection in an Immunosuppressed Patient Reveals the Roles of Humoral and Cellular Immune Responses in Virus Clearance

Kar-Hui Ng,^{1,2,9,*} Summer Lixin Zhang,³ Hwee Cheng Tan,³ Swee Sen Kwek,³ October Michael Sessions,^{3,4} Chang-Yien Chan,¹ Isaac Desheng Liu,² Chun Kiat Lee,⁵ Paul Ananth Tambyah,⁶ Eng Eong Ooi,^{3,4,7,8} and Hui-Kim Yap^{1,2,8}

Graphical Abstract



Summary

- Early protection (~12 days) after the 1st dose in both Pfizer/BioNTech's and Moderna's Covid vaccines provide a window into the correlates of protection
- A single dose LUNAR-CoV19 fully protected hACE2 mice from lethal SARS-CoV-2 challenge
- Depletion of CD8+ T cells but not B cells led to breakthrough SARS-CoV-2 infection
- Virus specific T cells is likely an important mediator of protection against Covid-19

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