Clinical development of AdCLD-CoV19, a replication-deficient adenovirus vectored vaccine

Chang-Yuil Kang, Ph.D.

Cellid Co., Ltd.

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Major Characteristics and Preclinical Studies of Cellid COVID-19 Vaccine

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■ Introduction of AdCLD-CoV19

- AdCLD-CoV19 uses a replication-defective adenovirus 5 (Ad5) vector in which the original Ad5 fiber knob is replaced by the Ad35 counterpart.
- A chimeric Ad5/35 adenoviral vector exhibits high transduction efficiency due to its capacity of CD46-mediated binding to human antigen-presenting cells.
- AdCLD-CoV19 harbors a modified form of antigen sequences based on linker technology for fusion protein construction, which expedites stable expression of S protein in transduced cells and enhance S-protein-specific immune responses.

■ The result of pre-clinical studies

- A single dose of AdCLD-CoV19 generates high titers of anti-S-protein neutralizing antibodies in mice and non-human primates.
- A single dose of AdCLD-CoV19 provides protection against live virus challenge in non-human primates and human ACE2 transgenic mice.
- AdCLD-CoV19-induced T cell immunity is skewed towards T_h1-biased immune responses, mitigating the risk of vaccine-associated enhanced respiratory disease (VAERD)

AdCLD-CoV19-001 Phase I/IIa Clinical Trial

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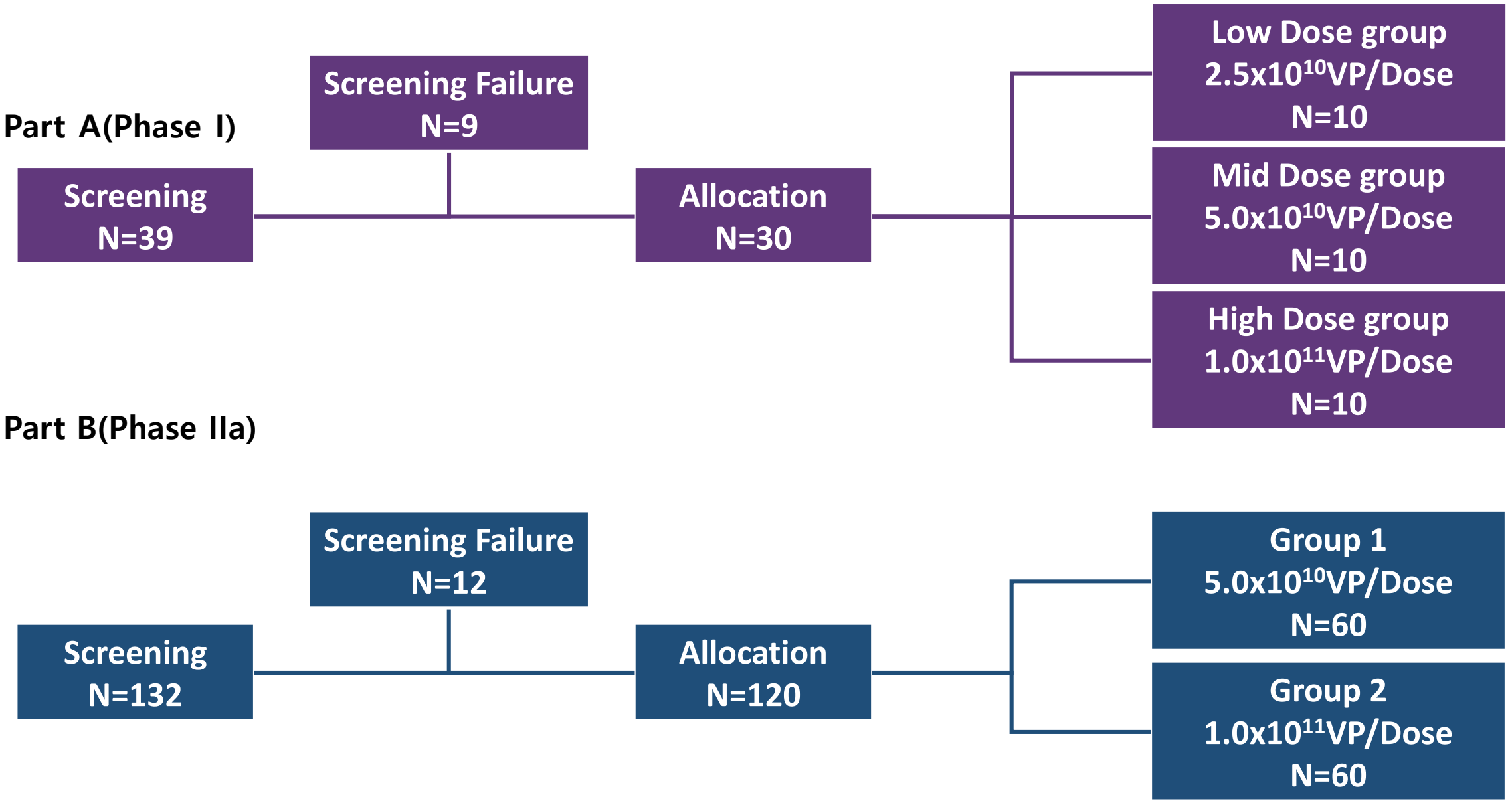
Result



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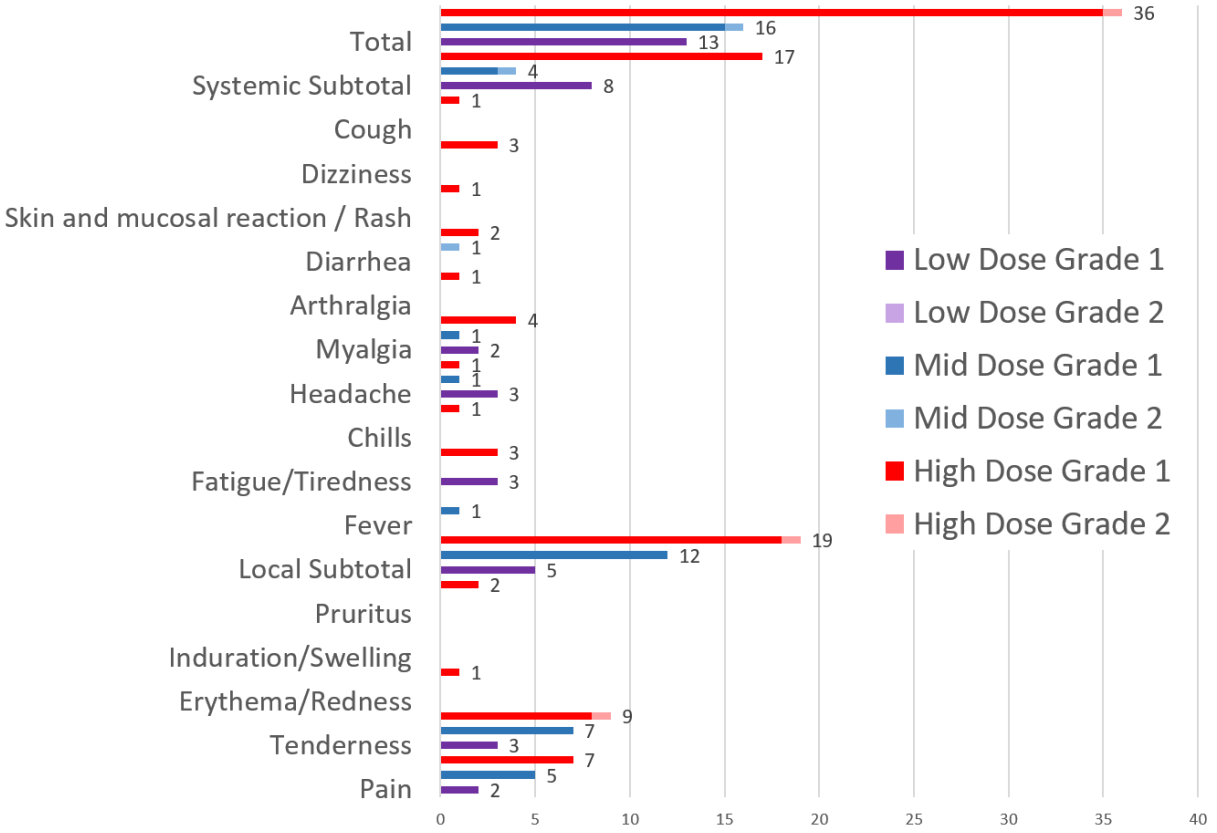
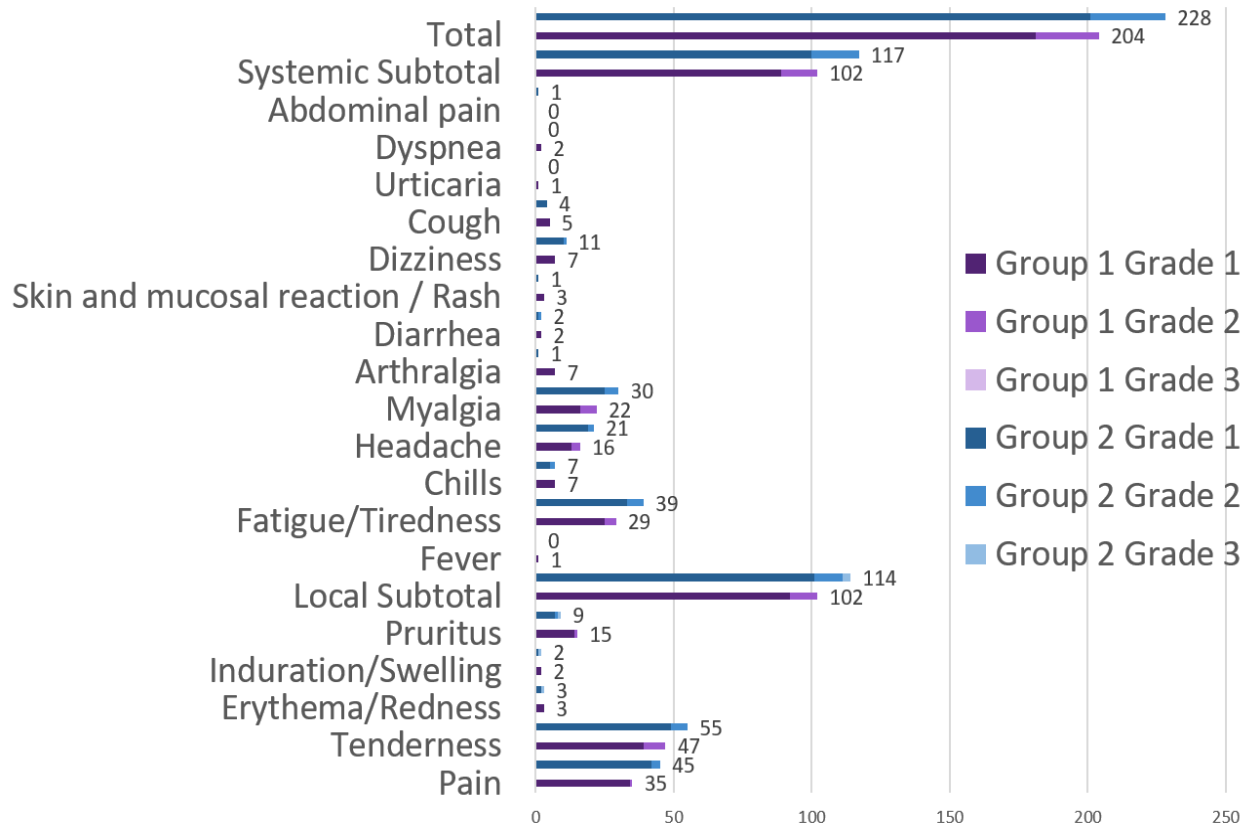
Result (Safety)

- Solicited AEs(during 7 days after the vaccine administration)

- Part A



- Part B



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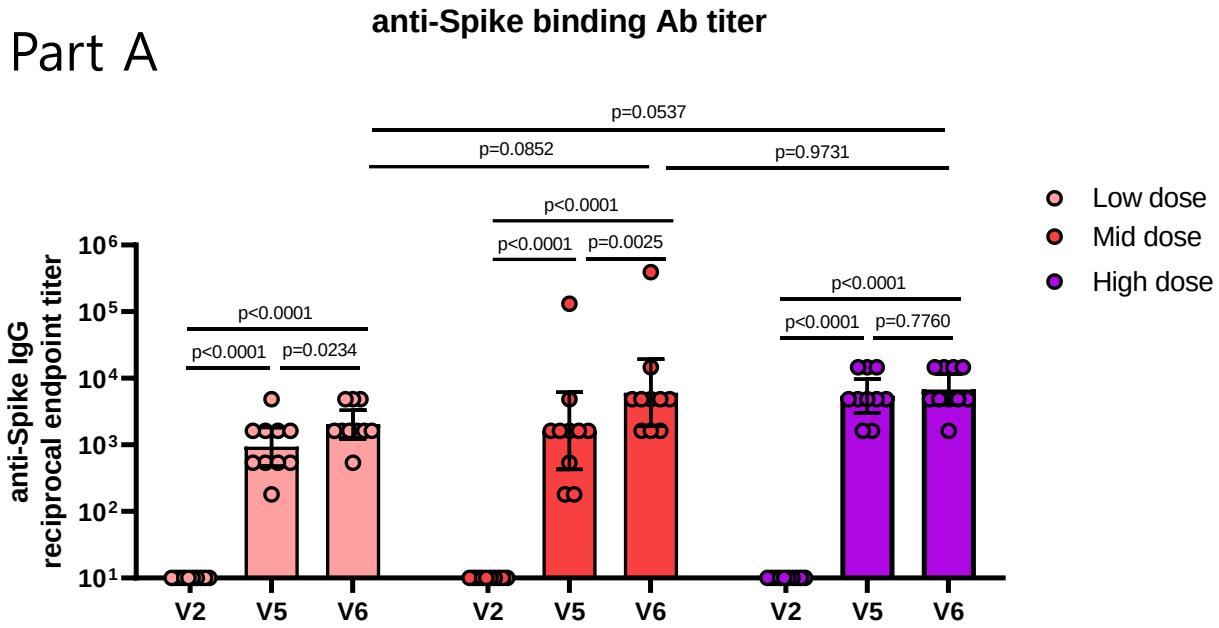
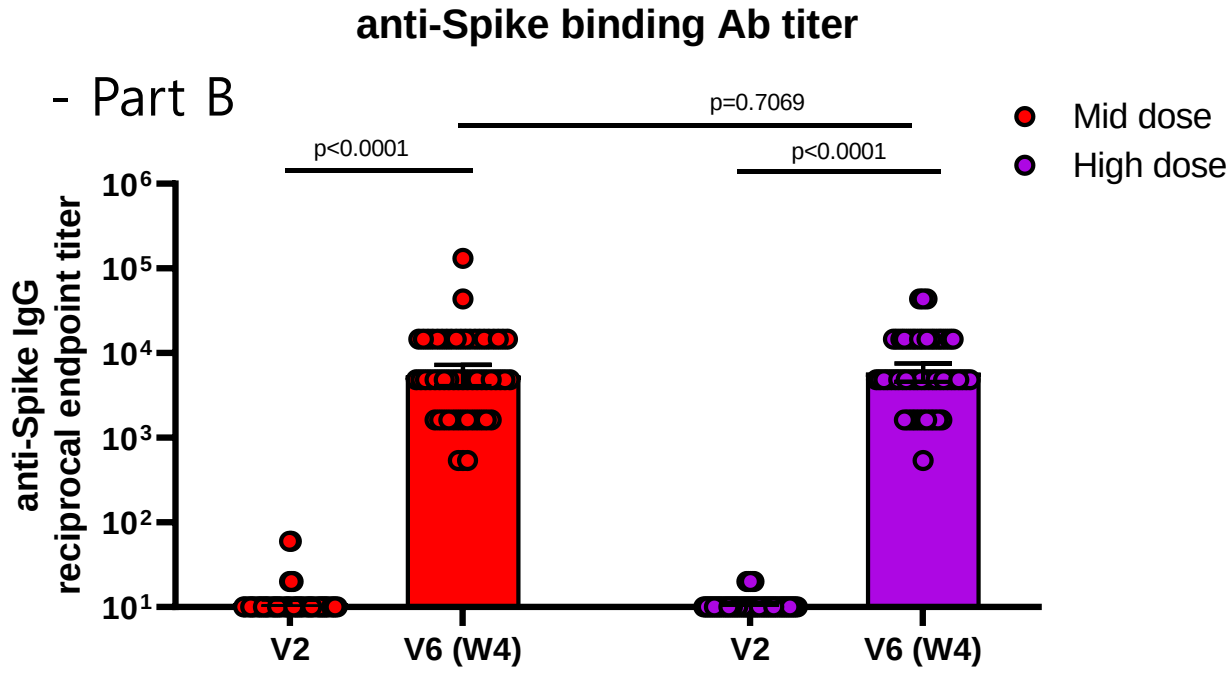
Result (Immunogenicity)

1. anti-Spike IgG endpoint titer

- Part A



- Part B



Spike IgG Endpoint titer	Low dose		Mid dose		High dose	
	GMT (95% CI)	SCR	GMT (95% CI)	SCR	GMT (95% CI)	SCR
V2(Week 0)	10.0 (10.0, 10.0)		10.0 (10.0, 10.0)		10.0 (10.0, 10.0)	
V5(Week 2)	935.3 (479.6, 1824)	100%	1620 (426.0, 6160)	100%	5424 (3037, 9687)	100%
V6(Week 4)	2018 (1228, 3317)	100%	6054 (1899, 19307)	100%	6757 (3976, 11485)	100%

Spike IgG Endpoint titer	Mid dose	High dose
	GMT (95% CI)	GMT (95% CI)
V2(Week 0)	11.14 (10.13, 12.24)	10.62 (10.08, 11.18)
V6(Week 4)	5434 (4088, 7225)	5874 (4580, 7533)
GMFR	487.79	553.11

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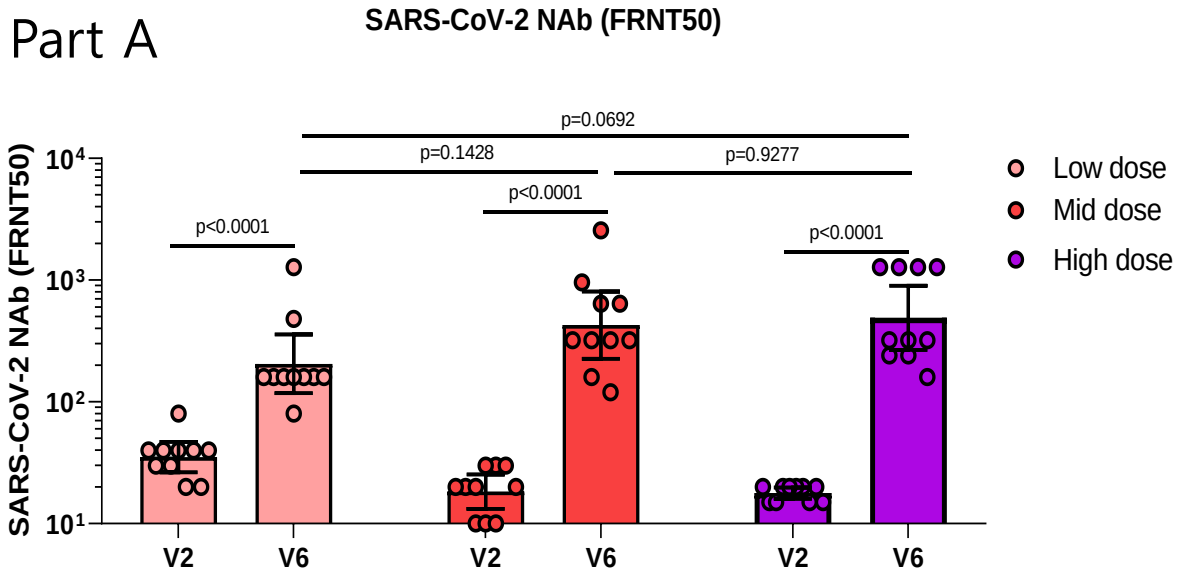
Result (Immunogenicity)

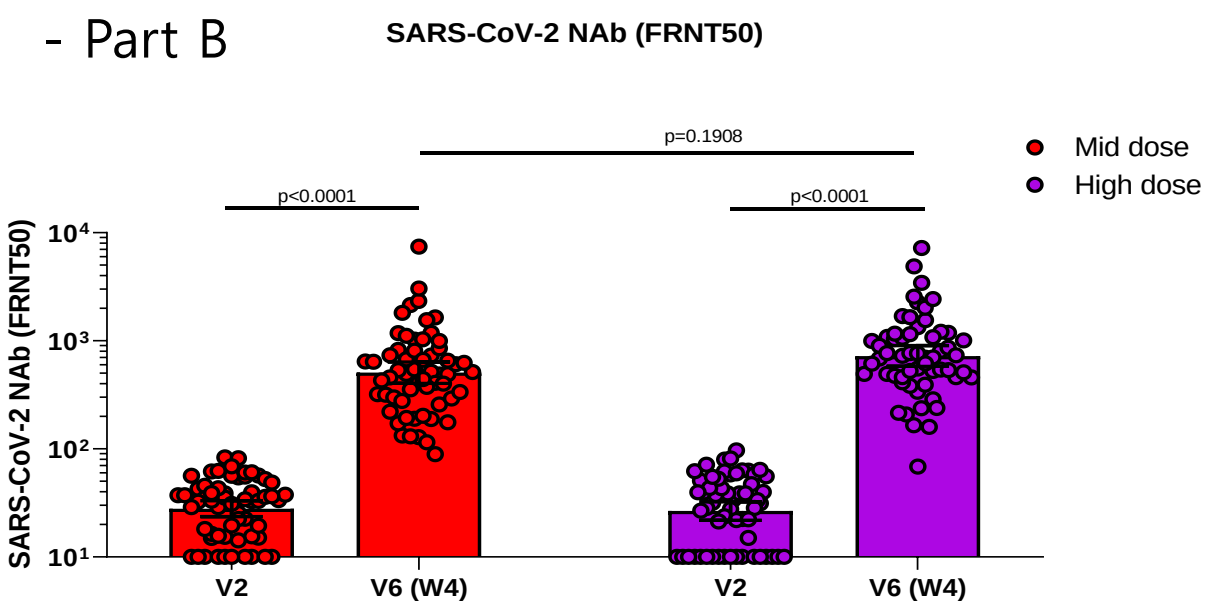
2. Neutralization Ab titer

- Part A



FRNT50	Low dose	Mid dose	High dose
	GMT (95% CI)	GMT (95% CI)	GMT (95% CI)
V2(Week 0)	35.23 (28.2, 42.2)	18.35 (13.8, 24.3)	17.83 (16.03, 19.82)
V6(Week 4)	**205.1 (55.1, 355.0)**	**427.25 (246.4, 740.9)**	**490.8 (267.2, 901.6)**
GMFR	5.82	23.29	27.53

- Part B



FRNT50	Mid dose	High dose
	GMT (95% CI)	GMT (95% CI)
V2(Week 0)	28.02 (23.69, 33.14)	26.67 (21.88, 32.52)
V6(Week 4)	**507.2 (404.4, 636.2)**	**723.6 (579.3, 903.7)**
GMFR	18.1	27.13

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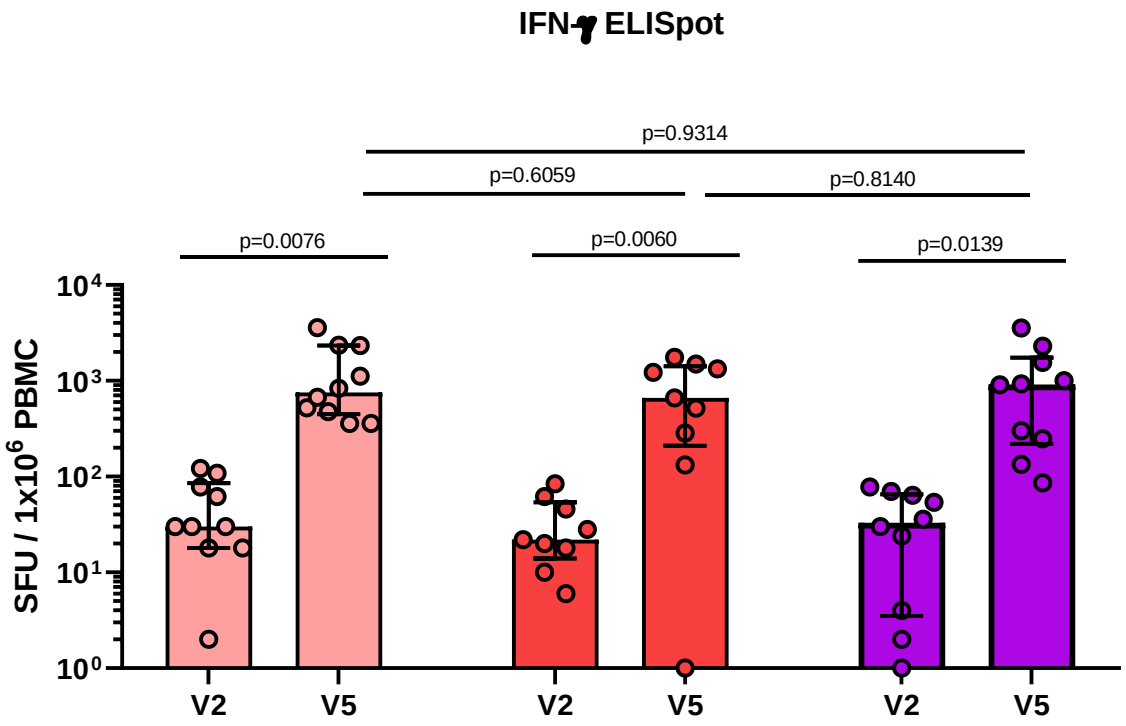
Result (Immunogenicity)

3. T cell ELISpot(Part A only)



SFU/1X10^6 PBMC	Low dose (N=10)	Mid dose (N=9)	High dose (N=10)
	Median (IQR)	Median (IQR)	Median (IQR)
V2(Week 0)	30.00 (18.00, 85.50)	22.00 (14.00, 54.00)	33.00 (3.500, 65.50)
V5(Week 2)	755.0 (447.0, 2340)	662.0 (209.0, 1416)	919.0 (219.5, 1740)

paired t test (per visit analysis)

Ordinary one-way ANOVA with Tukey's host hoc (per group analysis)

Cellid candidate vaccine targeting δ & δ+ variants

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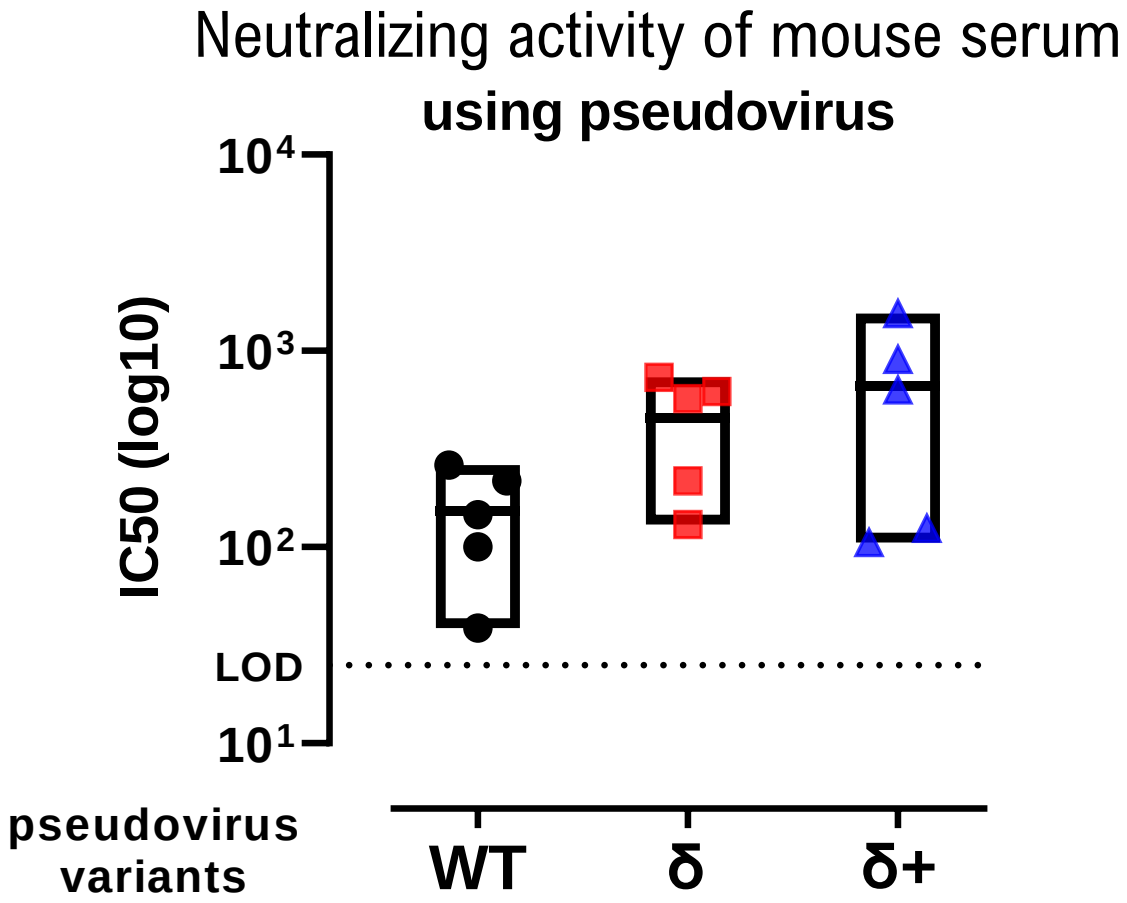

Mice were immunized with a vaccine targeting δ and δ+ variants. Two weeks after vaccination, sera were obtained and tested for the neutralizing activities using pseudoviruses.

Plan for the clinical development of COVID-19 vaccine (Domestic & global)

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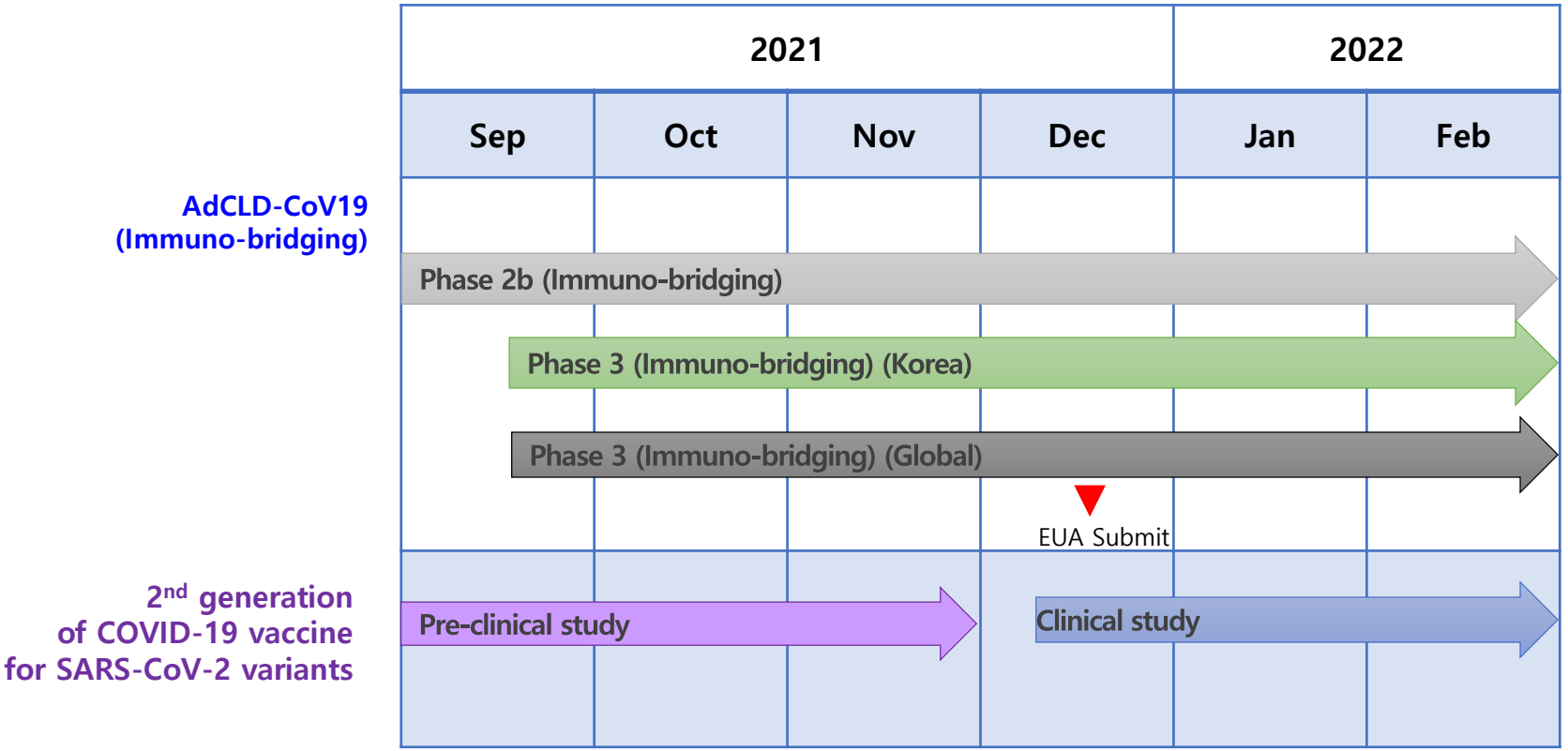

2nd generation COVID-19 vaccine

- Next version of Cellid's COVID-19 vaccine against SARS-CoV-2 variants (specifically, delta variant) has been developed
- Animal study of vaccine for variants is currently ongoing
- Clinical studies will be initiated at the end of this year.