nykode therapeutics

Initial Results from the Phase 1/2 Trial of the T Cell SARS-CoV-2 Vaccine Candidate VB10.2210

September 27, 2022

Forward-looking statement

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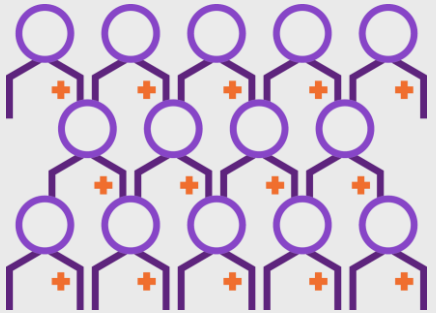
A number of material factors could cause actual results and developments to differ materially from those expressed or implied by these forward-looking statements.

Nykode and Adaptive's technologies provides a potential synergistic collaboration

Proven technology to optimize T cell responses to antigens included in the APC targeted vaccine



Rapidly identify broadly immunogenic T cell epitopes through TCR sequencing from clinical samples

Synergistic collaboration

- accelerating drug development
- increasing likelihood of broad T cell responses
- PoC in COVID-19, may warrant future collaboration in oncology, infectious diseases and/or autoimmune disorders

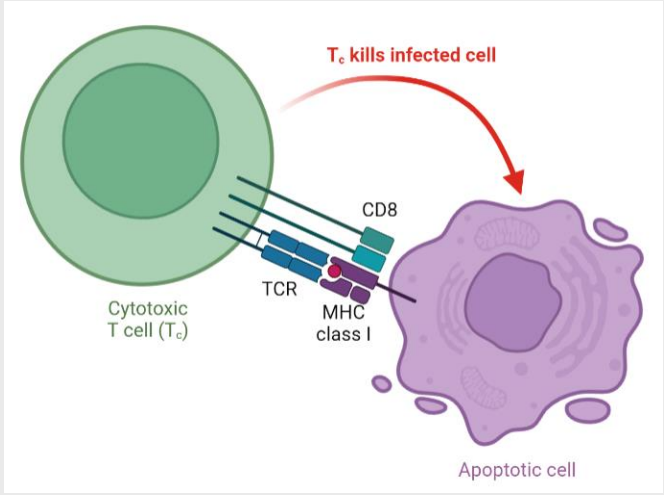
Executive Summary

- VB10.2210 is a novel SARS-CoV-2 vaccine candidate designed to induce T cell responses against validated epitopes in Spike and seven additional viral proteins conserved across variants of concern
- The safety and ability of VB10.2210 to induce T cell responses up until day 35 were evaluated in a First-in-human trial in previously vaccinated individuals
- VB10.2210 was well tolerated with a favorable safety profile
- VB10.2210 induced broad T cell responses with the strongest and broadest responses at the highest dose level
- The results successfully demonstrate proof of concept that the combination of the Vaccibody™ vaccine technology with T cell epitopes selected by Adaptive Biotechnologies generates broad T cell responses post-vaccination

Rationale for a T cell-based vaccine

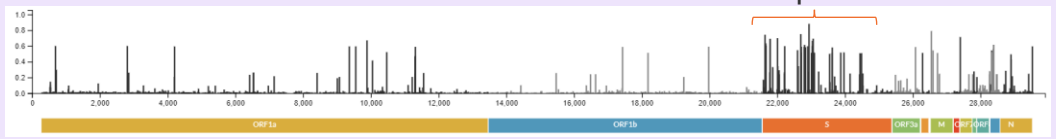
- Increasing evidence of the importance of broad T cell responses against COVID-19:
  - Pre-existing T cell responses associated with protection against disease in previously seronegative individuals
  - Non-delayed CD8+ response is associated with mild disease
  - T cell responses in Spike-vaccinated human subjects coincide with early protection
  - Vaccine induced protection against severe disease and death is maintained when new COVID variants evade antibodies
  - “T cell only vaccines” protective in challenge studies
- Approved vaccines are based on Spike variants, a protein subject to high immune selection pressure and mutation frequency

MECHANISM OF ACTION



- CD8+ T cells recognize viral peptides on the cell surface and eliminate infected cells
- CD4+ T cells supports CD8+ responses

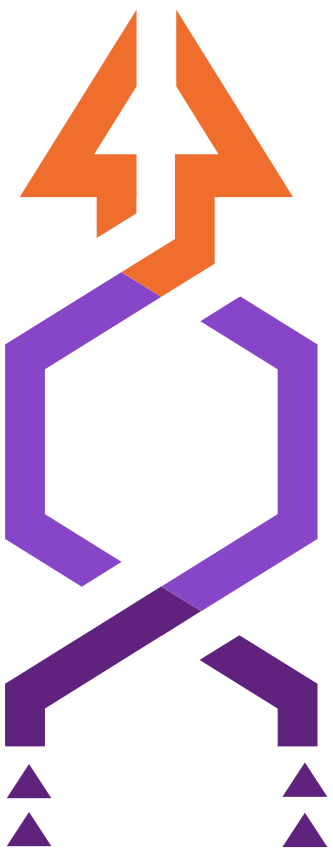
SARS-COV-2: PANGENOMIC DIVERSITY



Design: Efficacy across populations and future variants of concerns would require a vaccine with a large set of validated T cell epitopes across multiple antigens with broad HLA* coverage and a platform able to induce strong T cell responses, including CD8 T cell responses

* HLA: Humal Leukocyte Antigen. Cell surface molecule presenting T cell epitopes for stimulation and recognition by T cells
Kent et al. Nature Rev Immunol. 2022;22:387–397, Swadling et al Nature 2022;7891:110-117; nextstrain.org; Biorender.

VB10.2210 includes a large set of 96 validated and conserved viral T cell epitopes

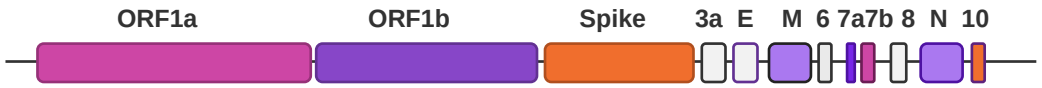


Targeting unit: CCL3L1

Dimerization unit

Antigenic unit: contains epitopes against majority (colored) of SARS-CoV-2 antigens

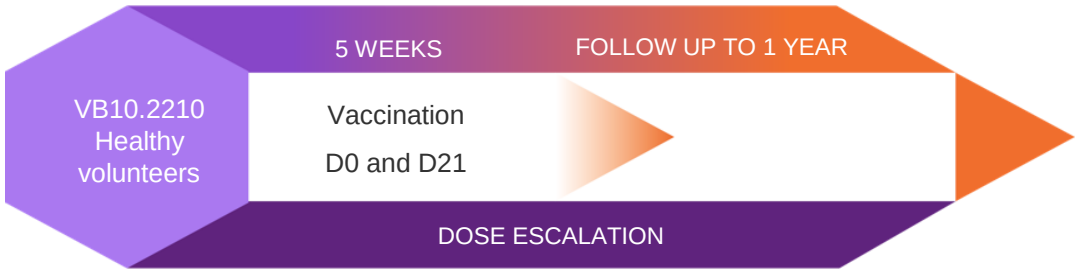
- High mutational drift in Spike are likely to affect both Spike-specific antibody and T cell responses
- VB10.2210 is designed to induce T cell responses against Spike and seven additional antigens less affected by mutational drift
- VB10.2210 epitopes from non-Spike antigens and are thus highly conserved across previous and existing SARS-CoV-2 variants, including Omicron



First-in-human trial investigating VB10.2210 as booster in previously vaccinated subjects

A Phase 1/2, open label, dose escalation trial to determine safety and of the T-cell candidate (VB10.2210) (NCT05069623)

- Booster in COVID-19 naïve healthy adults (18-60y)
- Vaccinated with at least 2 doses mRNA vaccine >8 weeks since last dose
- 2 sites in Norway (Oslo University Hospital Ullevål, and Haukeland University Hospital, Bergen)
- Primary objective: Safety and reactogenicity
- Secondary objective: Cellular immunogenicity
- 34 subjects enrolled to 3 dose levels

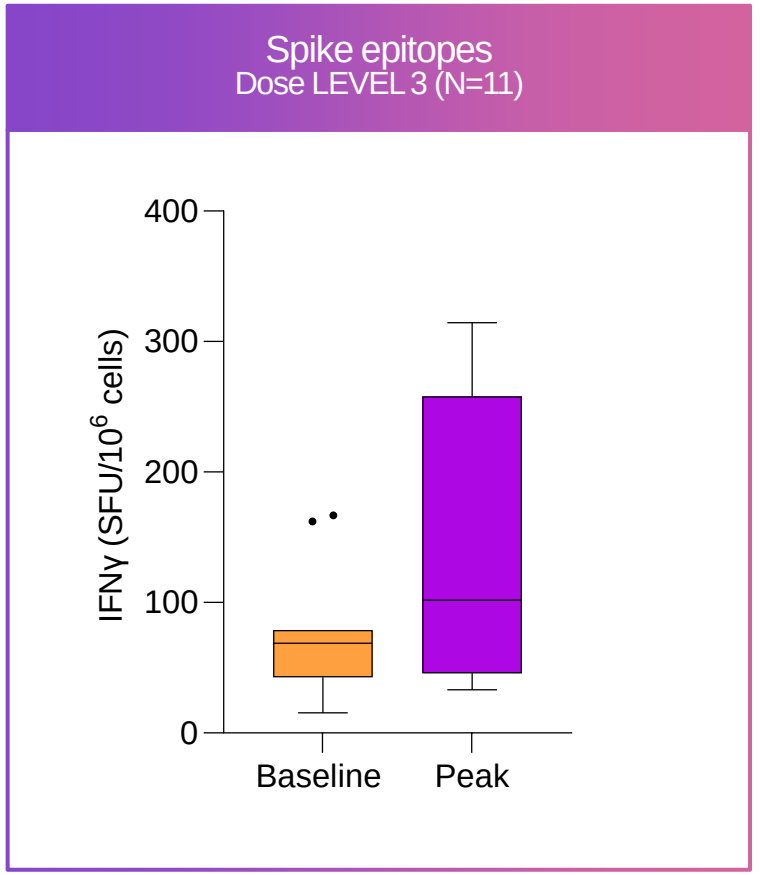


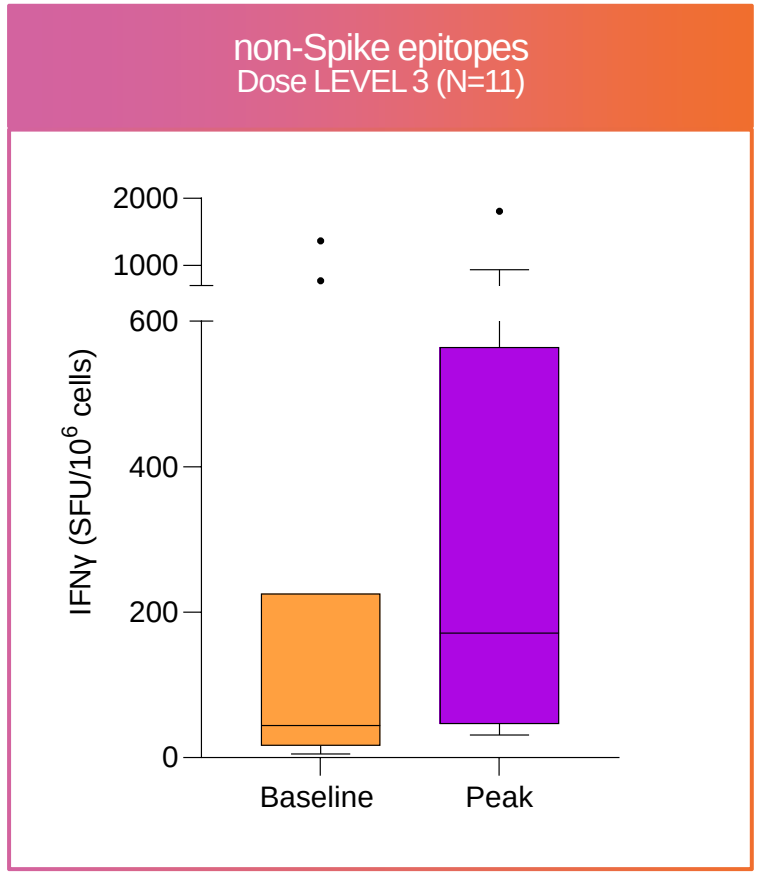
VB10.2210 was safe and well tolerated

- VB10.2210 was safe and well tolerated up to the highest dose of 3 mg with no dose limiting adverse events
- No fatal adverse events, no serious adverse events, or no adverse events of special interest were reported
- Local reactions were mainly mild injection site reactions (pain, tenderness and bruises)
- Systemic reactions were mainly mild or moderate and of short duration
- There were no signs of increase in adverse events or reactogenicity after the second dose

VB10.2210 novel T cell vaccine induces T cell responses against conserved epitopes in Spike and non-Spike of SARS-CoV-2

- T cell responses were analyzed by ex vivo ELISpot up until day 35
- VB10.2210 amplified responses to Spike and induced novel T cell responses towards epitopes in non-Spike Antigens
- Responses were dose-dependent with the highest response observed in Dose Level 3

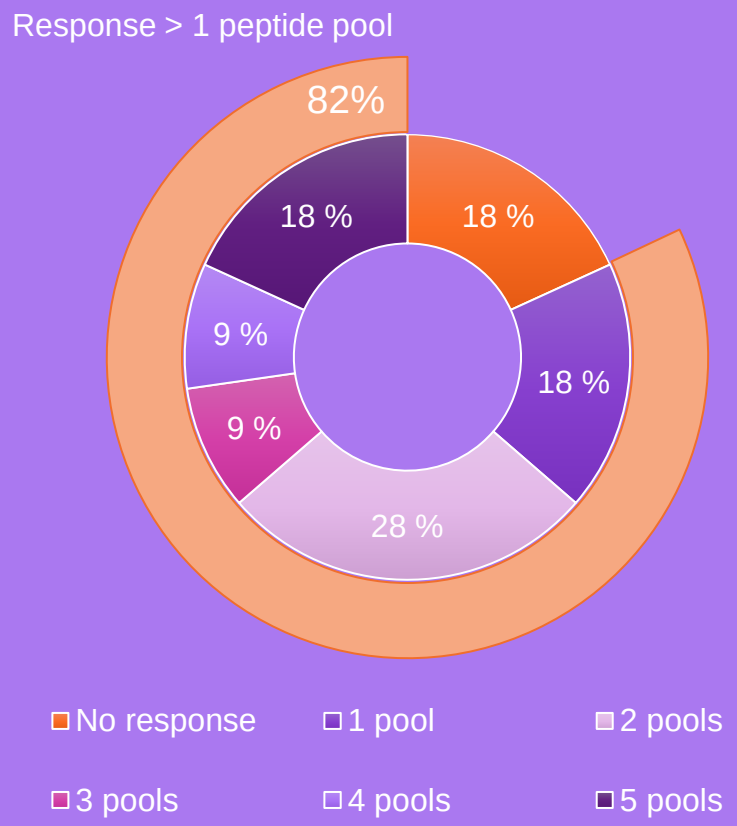


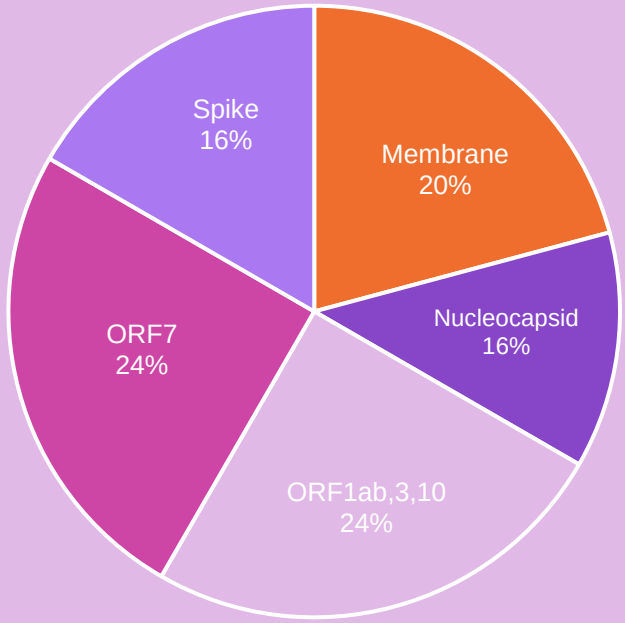


Graph depicts sum of responses to N, M, ORF1, 3, 10, 7 epitopes

Box plots depict median. Whisker depict down to 25th percentile (- 1.5 IQR) and up to the 75th percentile (+ 1.5IQR).

VB10.2210 induces response to all 5 peptide pools from Spike and non-Spike





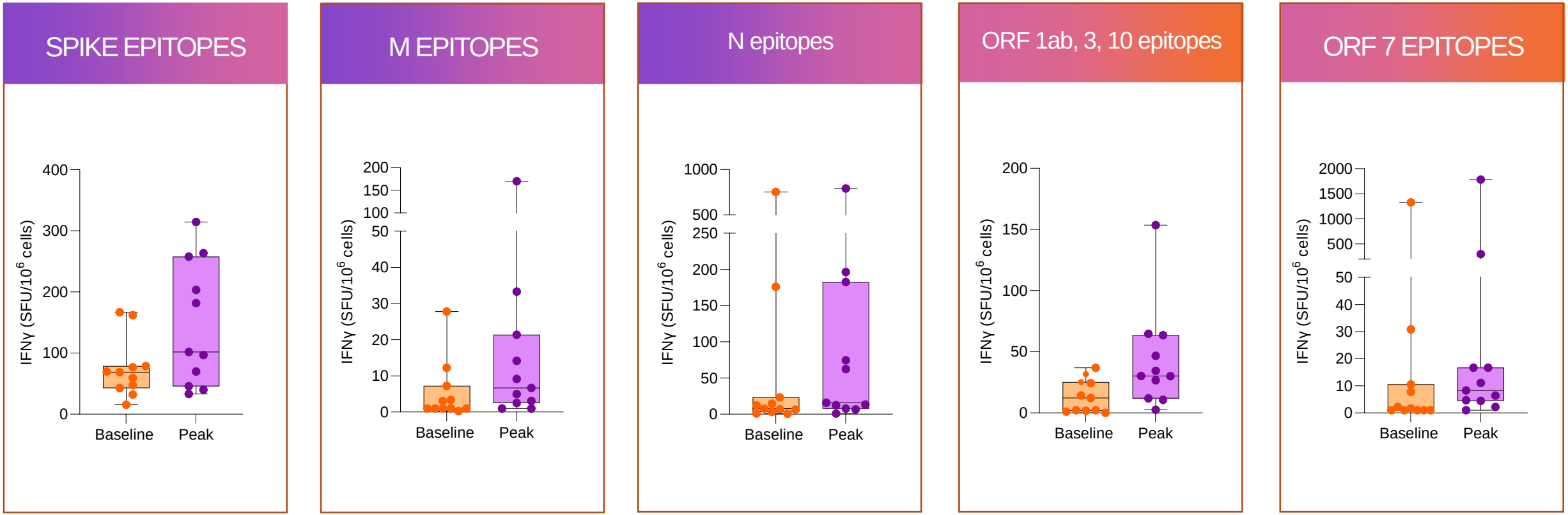
Number of responders to each peptide pool

- 82 % (9/11) of the subjects vaccinated with VB10.2210 responded to at least 1 peptide pool
- All peptide pools in VB10.2210 vaccine induced a response
- 2 subjects responded to all 5 peptide pools

Confirming induction of a broad response to the selected vaccine epitopes

> 2-fold increase from baseline was defined as response

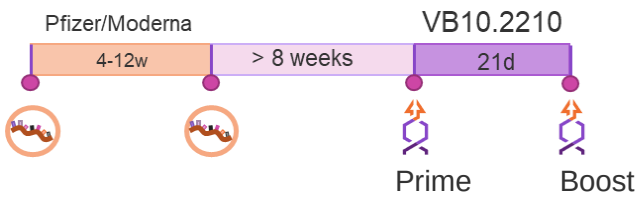
VB10.2210 induced de novo T cell responses to all four non-Spike antigens conserved across SARS-CoV-2 variants

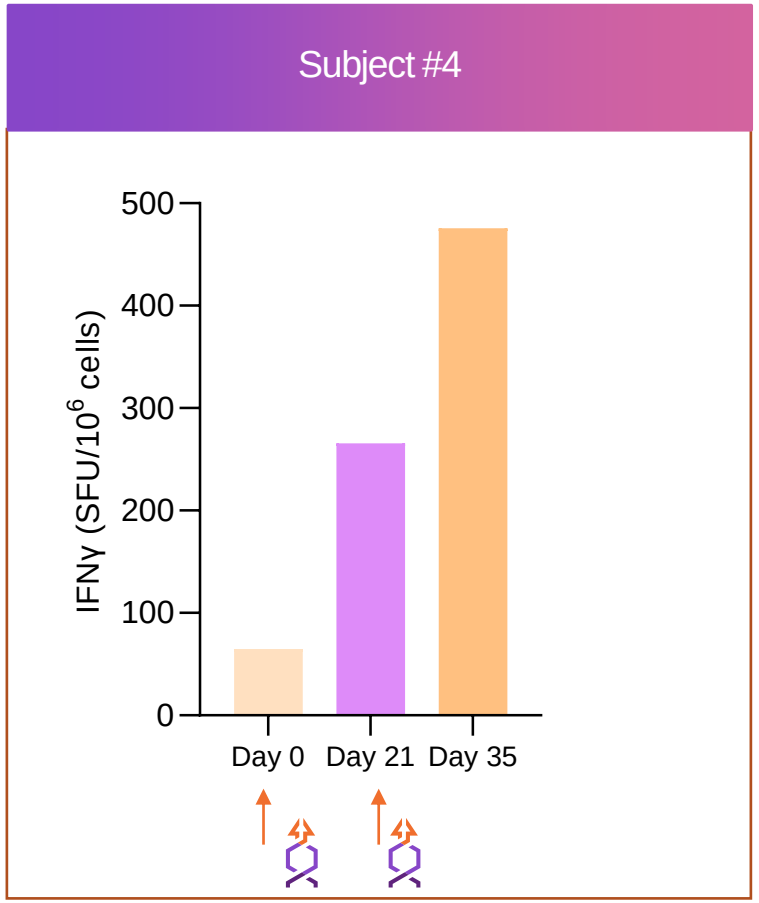


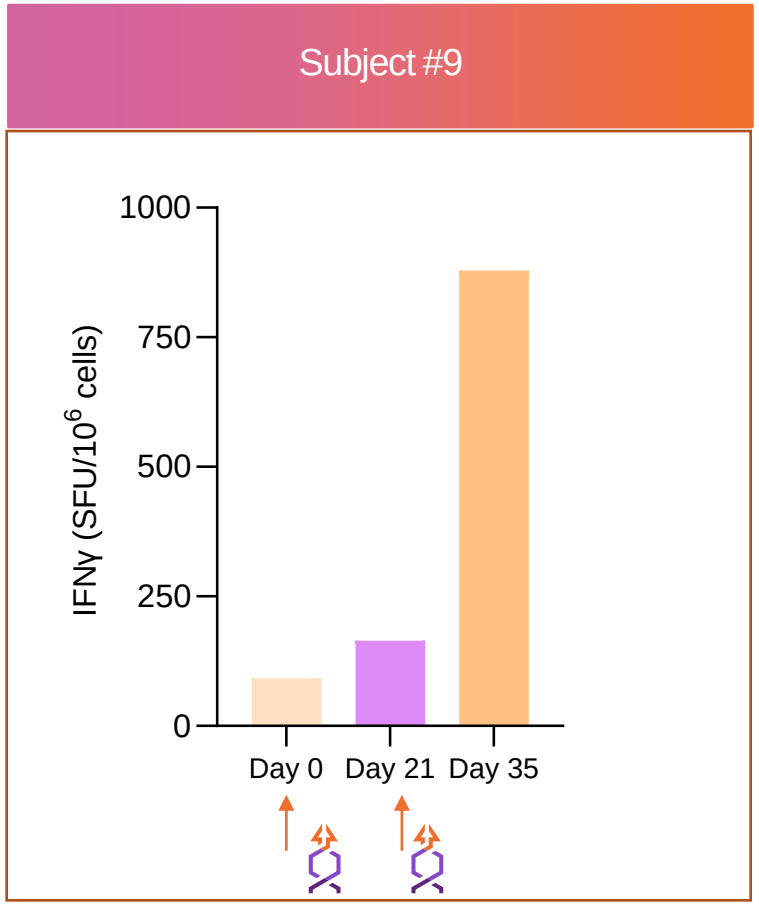
Box plots show median; whiskers show min and max values

VB10.2210 induces T cell responses by a single DNA vaccination further boosted by a second vaccination

- **A single injection of VB10.2210 vaccine in pre-vaccinated subjects induced a strong T cell response**
- **T cell responses were further boosted following a second injection**



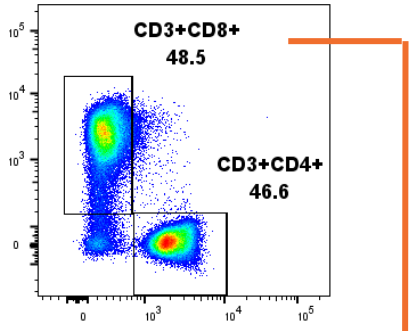




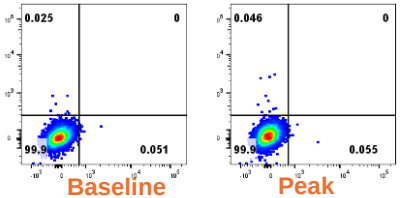
Preliminary data indicates that the T cell responses are dominated by polyfunctional CD8+ T cells

- CD4/CD8 distribution determined in 5 patients.
- A dominant CD8 response observed in all 5 patients

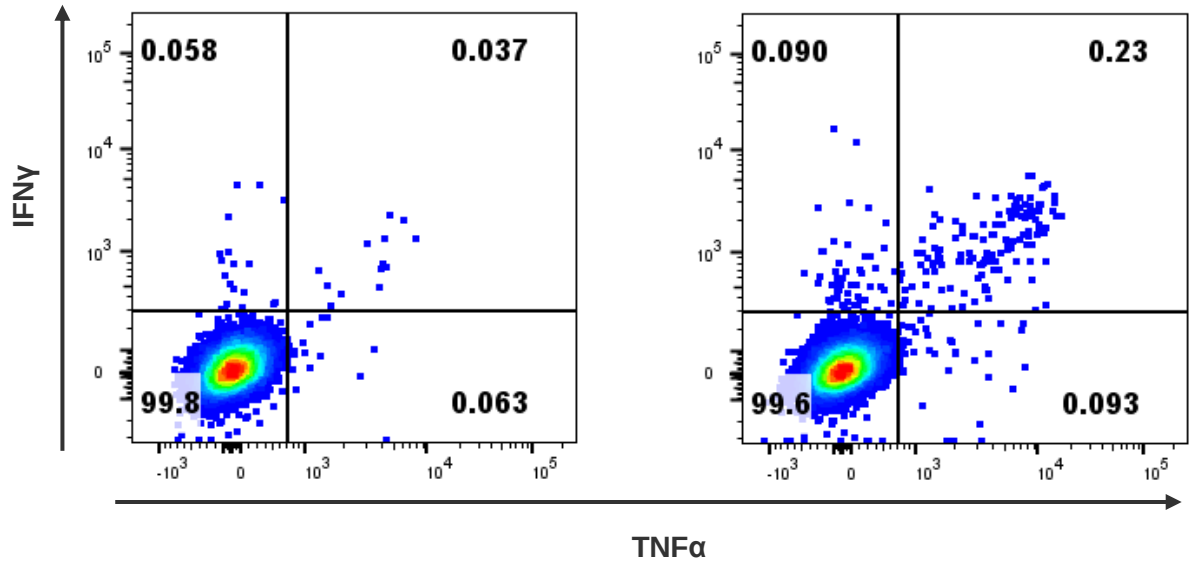
Responses to VB10.2210 were dominated by CD8+ T cells expressing IFNγ and TNFα



Negative control



Non-Spike epitopes in N, M, ORFs

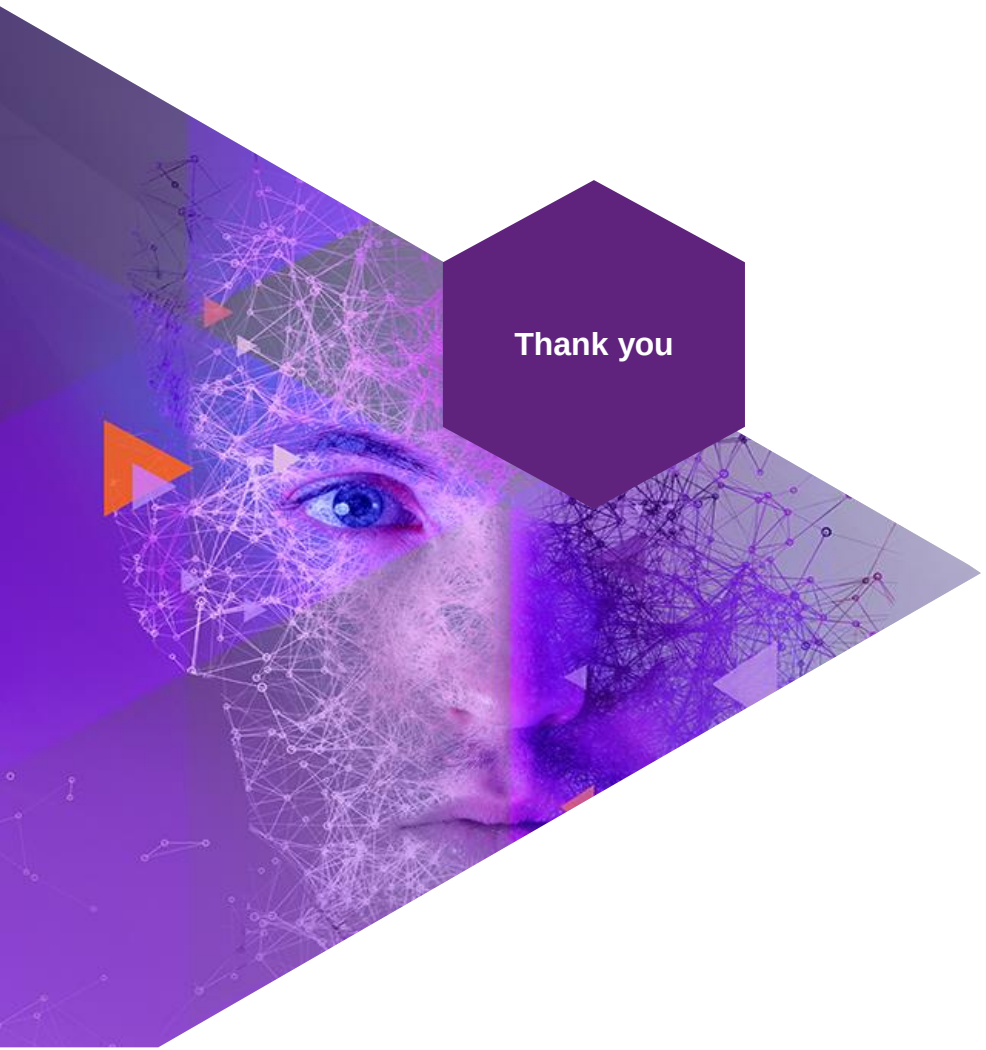


Ex vivo stimulated PBMC in ICS flow

Conclusions and next steps

- Successful proof of concept for the combination of Nykode's APC-targeted Vaccibody technology with T cell epitopes from SARS-CoV-2 selected by Adaptive Biotechnologies
- Confirms the ability of Nykode's platform to generate broad T cell responses dominated by CD8 T cells, which recognize viral peptides on the cell surface and has the potential to eliminate infected cells
- Substantiates the favorable safety profile of our Vaccibody platform
- Nykode will further assess the evolution of the COVID-19 pandemic and the overall regulatory environment in order to determine next steps for VB10.2210
- Based on this successful proof of concept, we are exploring additional opportunities to encode Adaptive discovered T-cell epitopes with the potential to treat other diseases with high clinical unmet need

Acknowledgements



We would like to thank the participants as well as investigators for their participation in the trial

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