

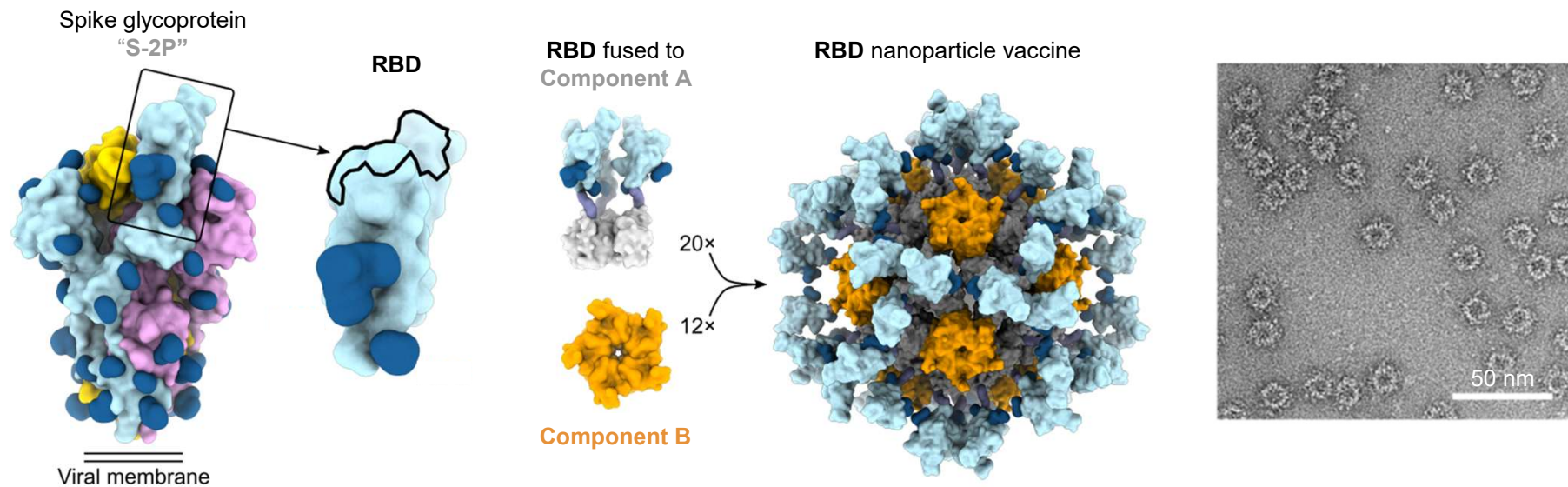


# Pan-sarbecovirus vaccine development (GBP511)

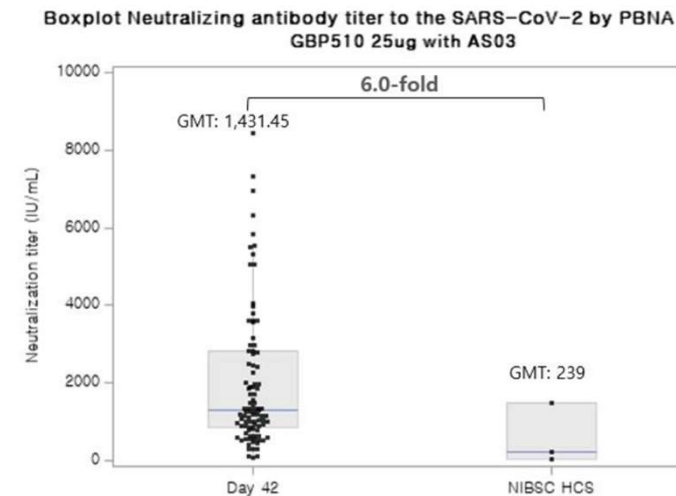
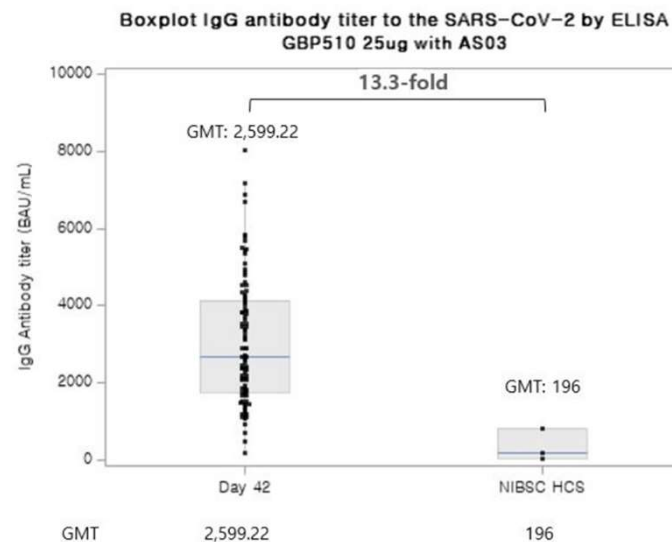
28 Jan 2022



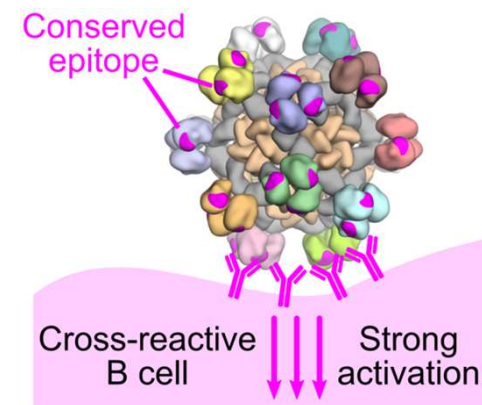
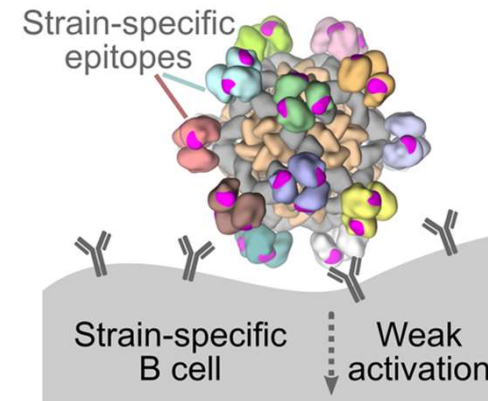
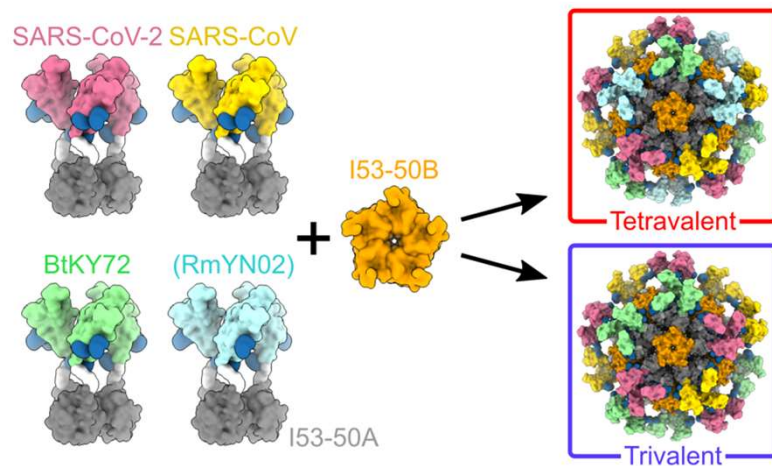
# Two-component nanoparticles displaying the SARS-CoV-2 S RBD induce potent neutralizing antibody responses



# Two-component nanoparticles displaying the SARS-CoV-2 S RBD induce potent neutralizing antibody responses

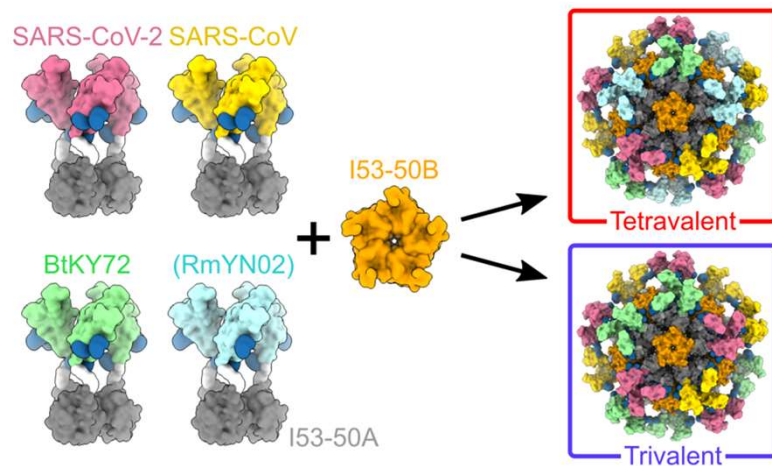


# Mosaic nanoparticle immunogens as a potential route to broadly protective vaccines

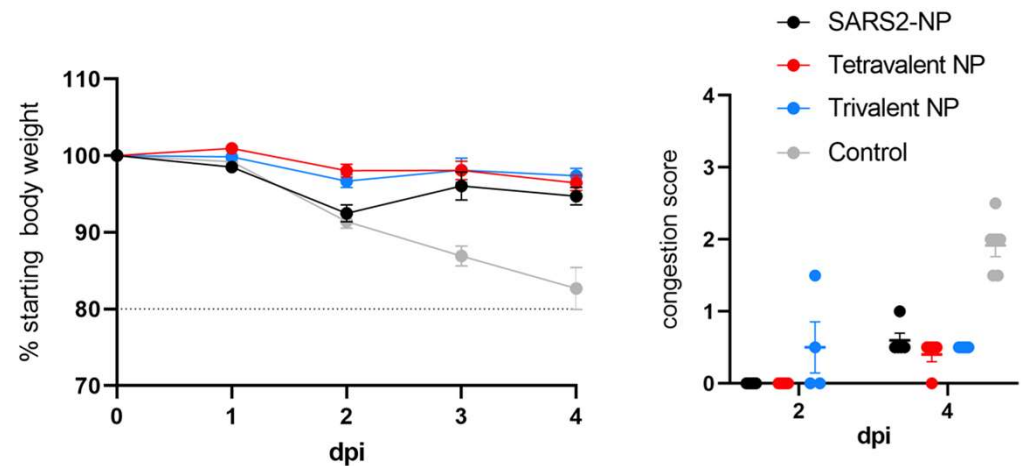


With Baric lab, University of North Carolina

# A pan-sarbecovirus vaccine candidate protects against stringent heterologous challenge



Protection from SHC014





# COVID-19 vaccine development utilizing nanoparticle technology (GBP510)



## Key Product Profile

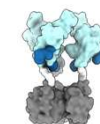
Type / Adjuvant	Nanoparticle SARS-CoV-2 RBD Vaccine w/ AS03
Indication	Active immunization to prevent COVID-19 disease caused by SARS-CoV-2 in adults and elderly
Antigen	Nanoparticle containing 25 µg of RBD
Container	5mL borosilicate Glass vial, USP Type I
Presentation	10-dose vial (5mL vial filled with 3.1mL of antigen and 3mL vial filled with 3.1mL of adjuvant, mixed before injection at field)
Storage	2 – 8 °C (35.6 – 46.4 °F)

## Current Stage of GBP510

- SK bioscience's RBD-based nanoparticle vaccine (GBP510) is under phase III study and its safety and immunogenicity were confirmed in phase I/II study.
- Manufacturing processes have been established and scaled up successfully for the commercial production with appropriate quality control.
- Target approval time: 2Q 2022

## Diagram of Nanoparticle

### Intermediates

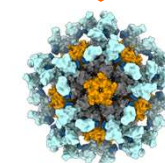


Displays genetically fused RBD subunit



Assists formation of nanoparticle

**self-assembly**



Nanoparticle Antigen

**Nanoparticle DS  
w/60 copies of RBD**

### Drug Product



GBP510  
Antigen



AS03  
Adjuvant

**2 Vial Finished Product (Bed-side mix)**

## Pan-Sarbecovirus Vaccine development (GBP511)



- SK bioscience will develop Pan-sarbecovirus vaccine in collaboration with UW and UNC **through the prior intensive knowledge and manufacturing experiences from GBP510.**
- This project aims to develop a sarbecovirus vaccine which provides a broad protection against known and unknown sarbecoviruses based on the two-component nanoparticle antigen platform (granted from CEPI).

### Key Milestones

- ✓ Lead immunogen/adjuvant candidate selection: Q3 2023
- ✓ FIH clinical trial initiation in Q4 2023

Category	Activities	Responsibility	2022				2023				2024				2025	
			Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2
Preclinical development	Candidate design / Preliminary Process and analytical Development	King(UW)														
	Optimize and characterization studies	King(UW)														
	Development of Animal Models	Baric (UNC)														
	Challenge studies/Passive transfer	Baric (UNC)														
	Immunogenicity studies (ELISA, Pseudo)	Veesler(UW)														
Process development & Clinical preparation	RCB/ Process / Analytical Method Development	SK														
	MCB/WCB Production and Characterization	SK														
	Nonclinical Safety Studies	SK														
	Lab scale lot, Engineering Run & GMP production	SK														
	Preparation for IND dossier	SK														
Clinical development	IND submission / approval	SK														
	First-in-human clinical trial (POC)	SK														

at risk

Lead candidate / Adjuvant Downselection

**End of Document**