

Progress on the booster study of inactivated COVID-19 vaccine

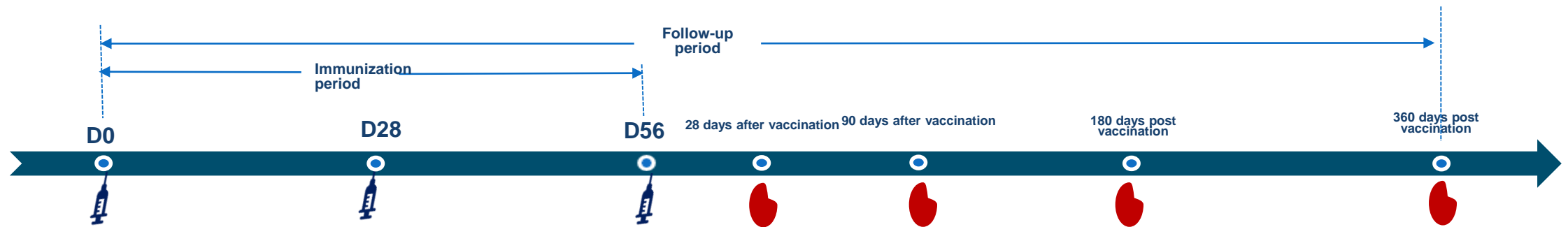
China National Biotech Group
Beijing Institute of Biological Products

25-October-2021

Phase I/II Clinical Study Protocol



Phase I/II: To evaluate vaccine safety in different populations, different doses, and different immunization schedules, and to explore immunogenicity

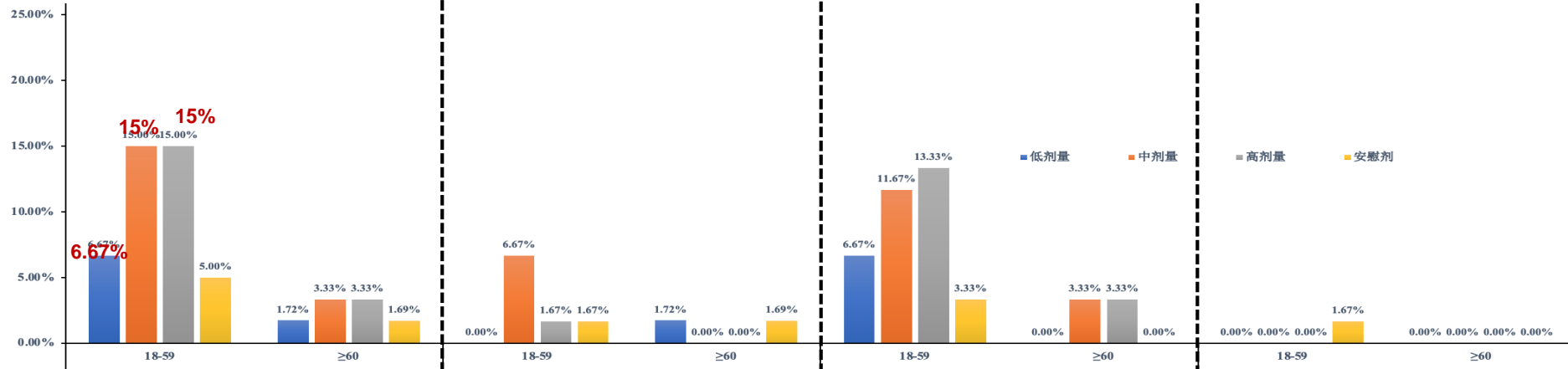


- Total subjects: 480 subjects in PhI; 1648 subjects in PhII
- Immunization schedule: 0, 28, 56 days
- Age group: 3-5 years old, 6-12 years old, 13-17 years old, 18-56 years old, 60 years old
- Immunogenicity: Neutralizing antibodies 28 days after full course vaccination
- Safety: regular phone calls, follow-up visits, safety observations
- Immune persistence: 90, 180 and 360 days after full course vaccination

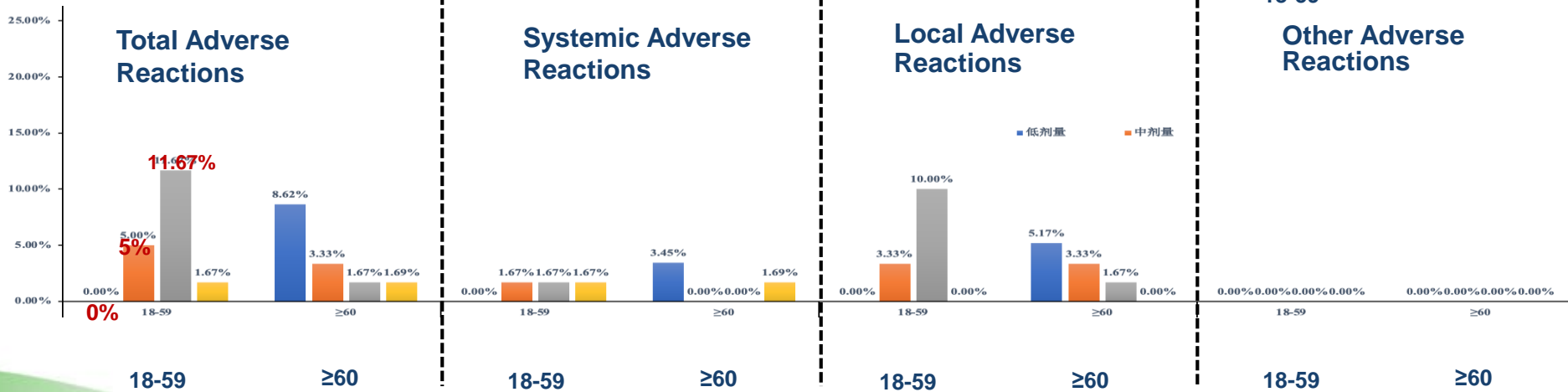
Clinical Study: Safety Results

Comparison of safety between 2 doses and 3 doses

2nd dose



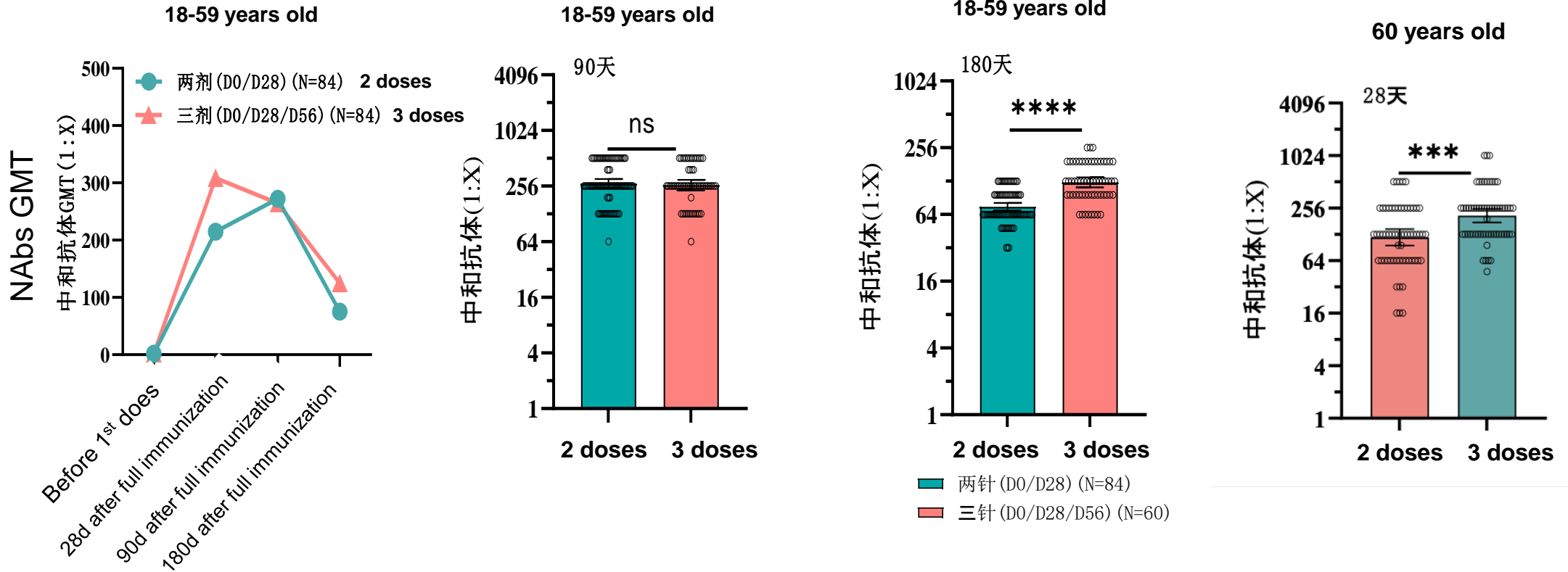
3rd dose



- The incidence of adverse reactions after the third dose (0%, 5%) was lower than that of the second dose (6.67%, 15%) in the low and middle dose groups.
- There was no difference in the incidence of adverse reactions after the third dose (11.67%) and the second dose (15%) in the high-dose group.

Clinical Study: Immunogenicity and Immune Persistence

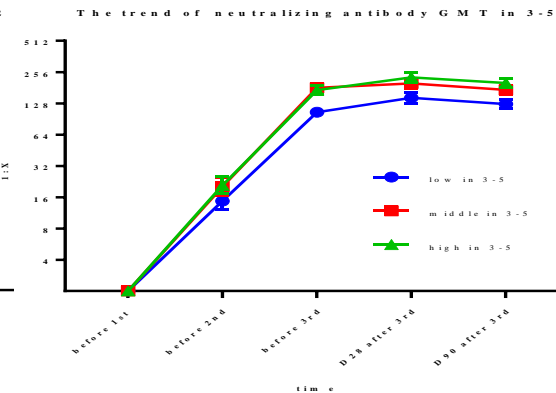
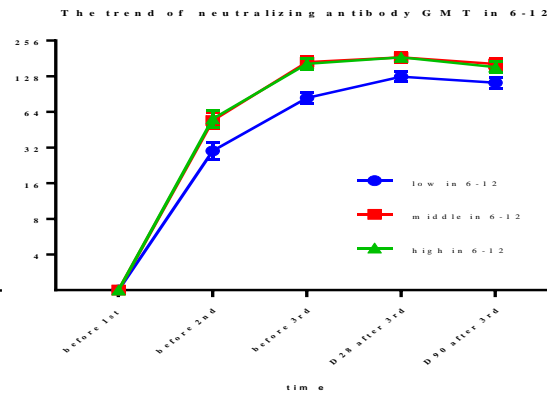
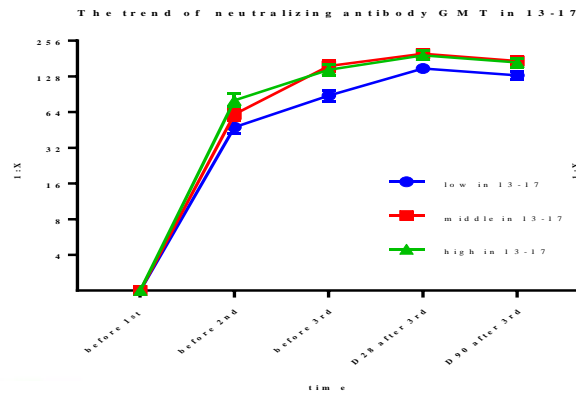
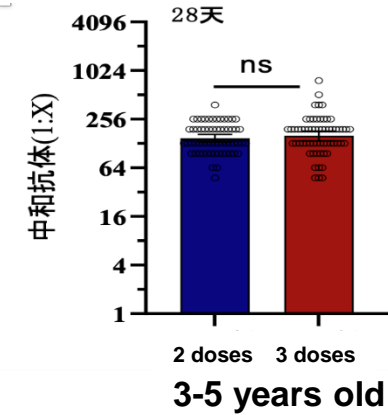
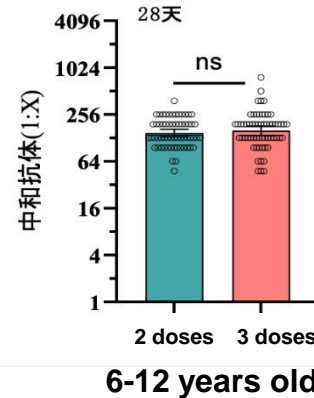
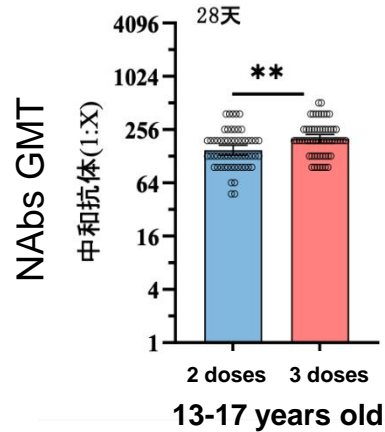
Comparison of neutralizing antibodies between 2 and 3 doses in the age groups of 18-59 and 60 years



- 90 days after the full course of immunization, there was no difference in the level of neutralizing antibodies between 2 doses and 3 doses.
- 90 days after the full immunization, the antibody level did not decrease significantly, and 180 days after the immunization, there was a decline trend;
- **The level of neutralizing antibodies after 3 doses of vaccination is superior than that of 2 doses.**

Clinical Study: comparison of immunogenicity in younger age groups

Comparison of neutralizing antibodies between 2 and 3 doses in the 3-17-year-old age group



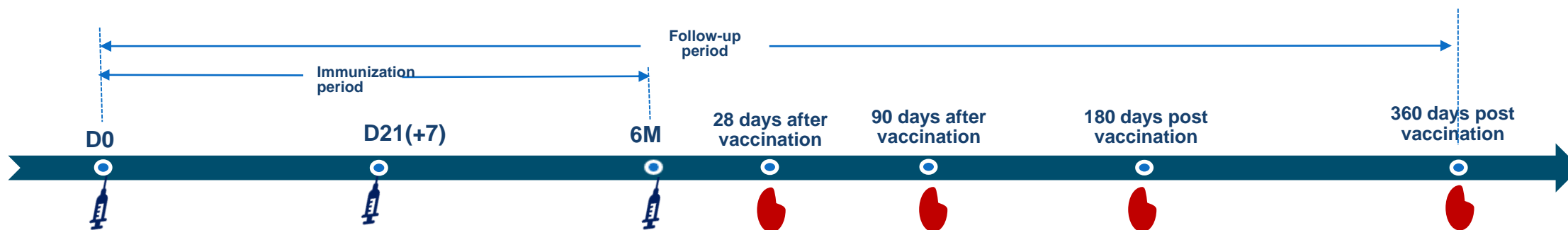
- In the 13-17-year-old group, the neutralizing antibody level after 3 doses was significantly higher than that of 2 doses, and the antibody level increases with the increase of doses;
- The antibody GMT at 90 days after the full immunization was slightly lower than that at 28 days, but it still maintained a high level

Phase III clinical study: booster immunization

➤ Booster vaccination:

- Maintain the original protocol, BIBP group, WIBP group and placebo group were vaccinated with booster vaccines according to the original grouping

➤ The 3rd dose was administered 6 months after the 2nd dose, and 9,000 people were vaccinated

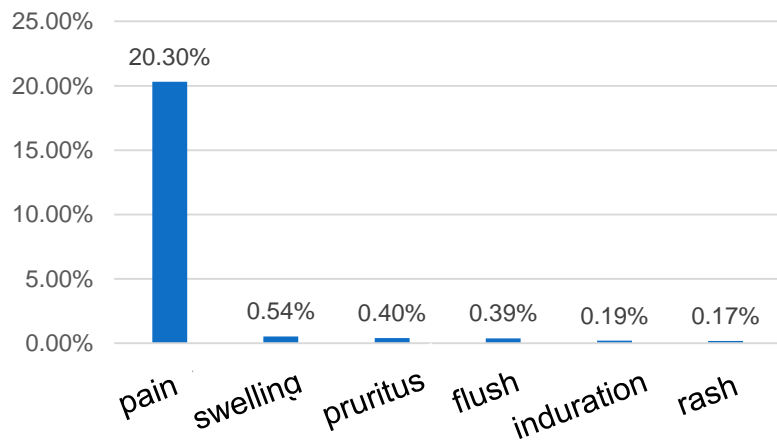


- Immunization schedule: 0, 21(+7) days, 6M
- Age group: ≥ 18 years

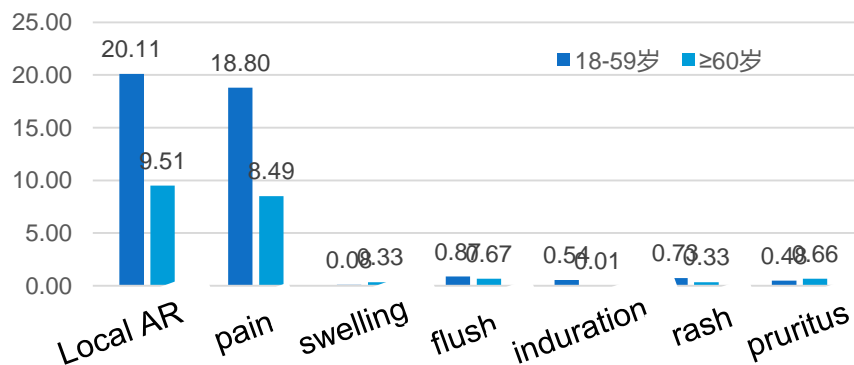
Good safety after booster immunization



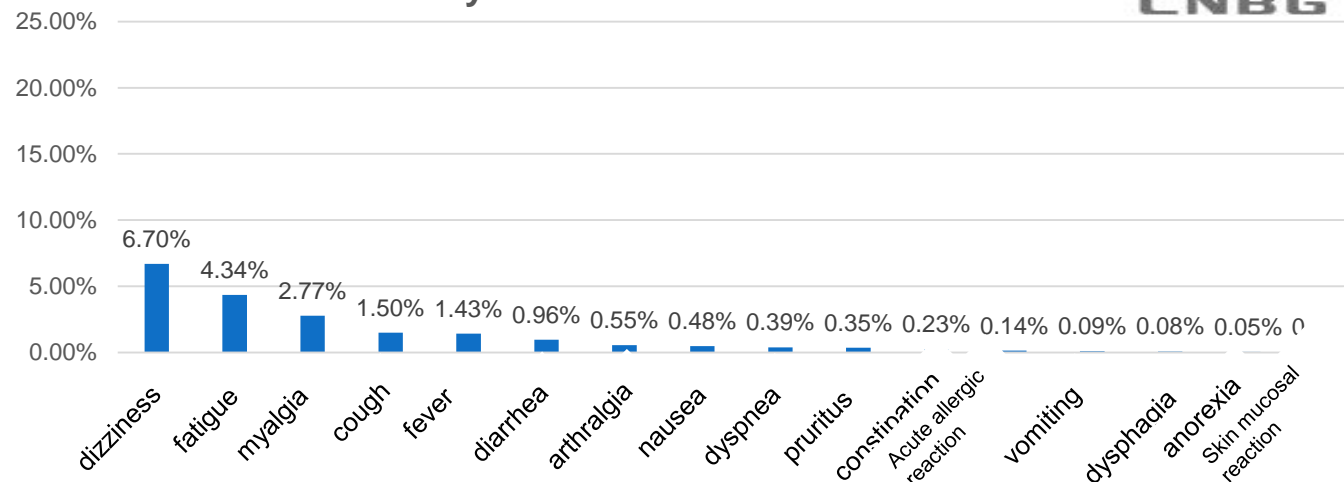
Local Reaction after 3 Doses



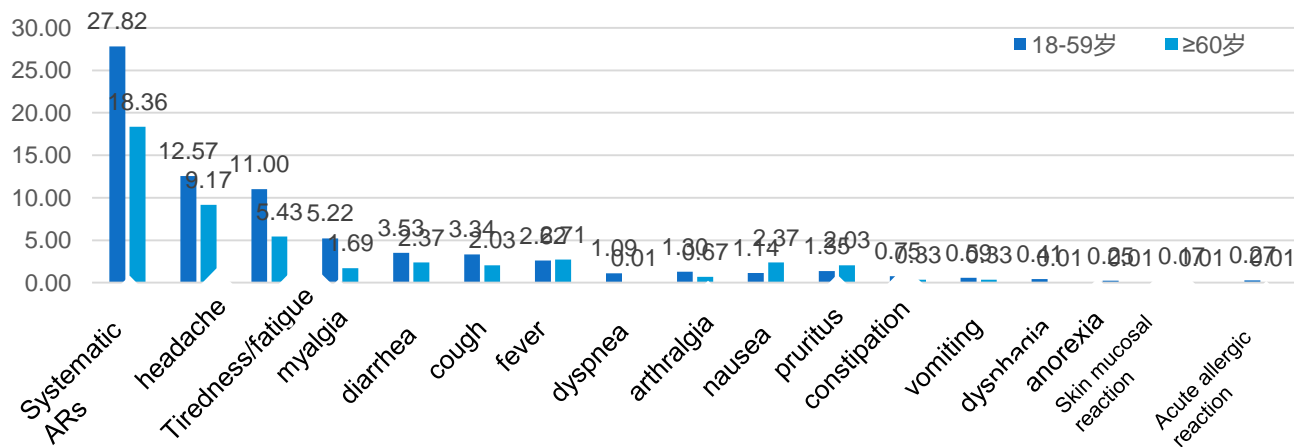
Local Reaction After 2 Doses



Systematic Reaction after 3 Doses



Systematic Reaction After 2 Doses



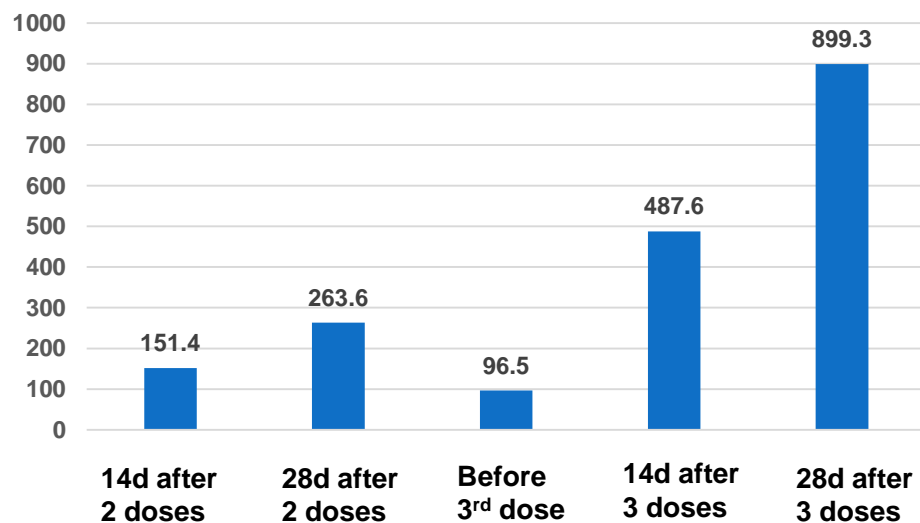
- Local adverse reactions after 3rd dose were mainly pain, with an incidence of 21%; Not significantly different from the first two doses (19%)
- Systemic adverse reactions after 3rd dose were mainly headache, fatigue and muscle pain, which were lower than the incidence of corresponding symptoms after the first two doses.

Changes over time in antibody level after booster immunization

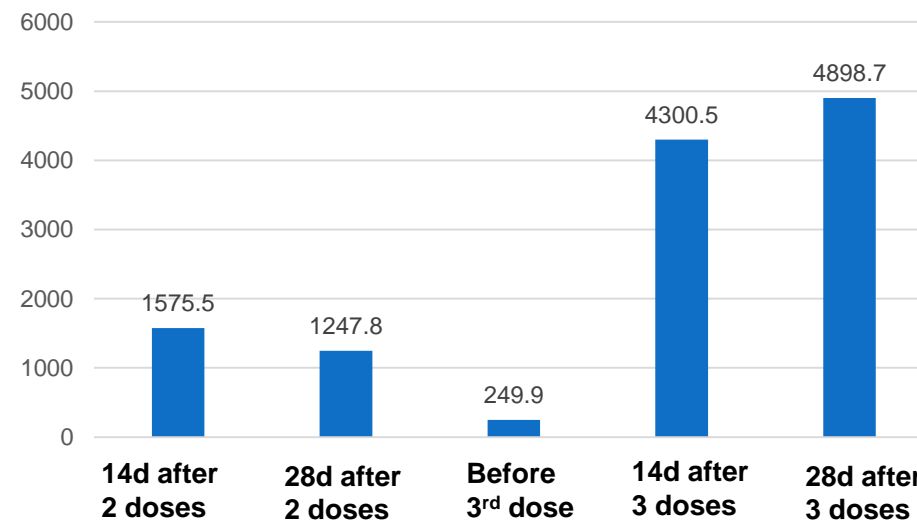


Comparison of neutralizing antibody titers against different strains between 2 and 3 doses

NAb GMTs over time after 3 doses



Binding Ab GMTs over time after 3 doses

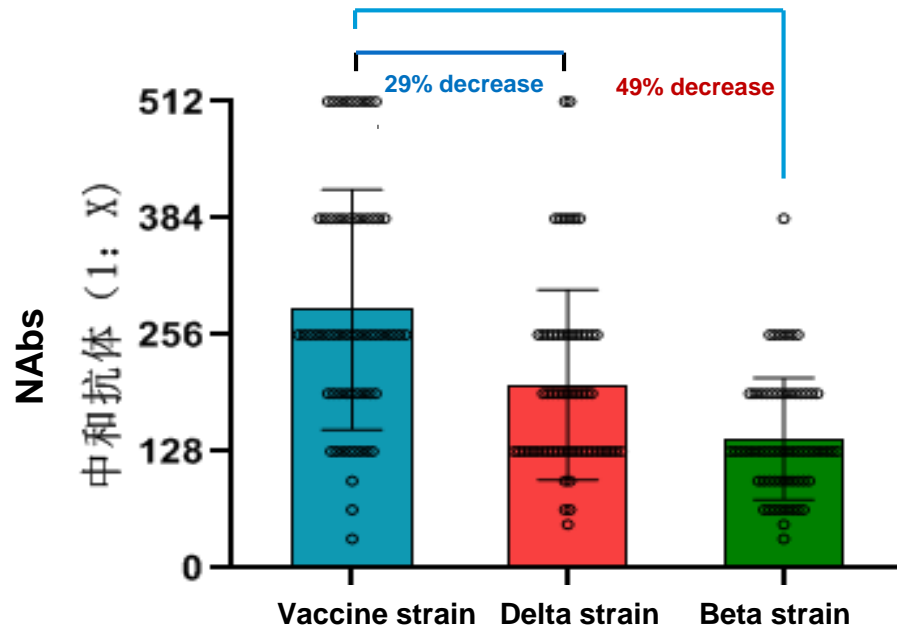


- 6M after 2 doses, 14 days after 1 dose of booster immunization, neutralizing antibodies increased rapidly, 10 fold antibody increase 28 days after booster immunization
- **Seroconversion rate was 100%**

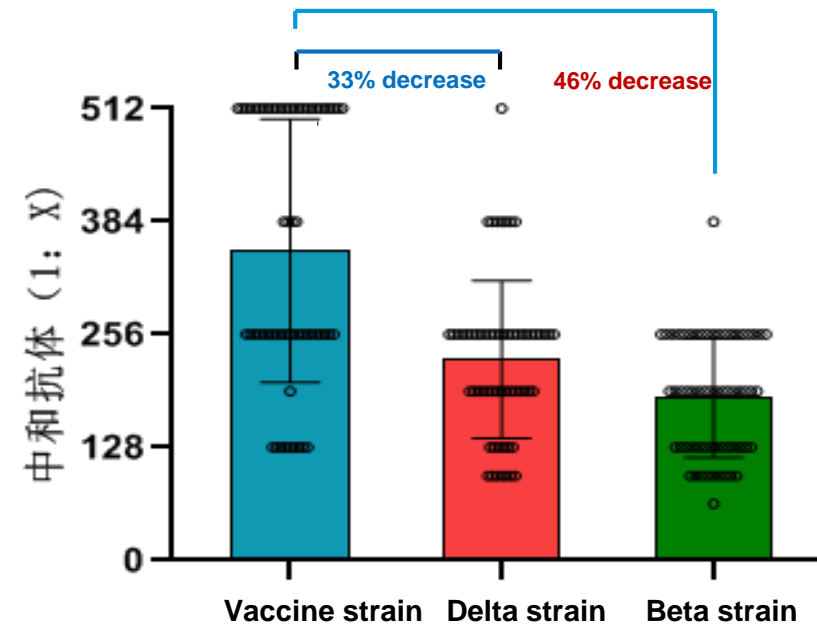
Cross-neutralization against different variants

Comparison of neutralizing antibody titers against different variants between 2 and 3 doses

Neutralizing antibody titers 28 days after 2nd dose in middle dose group in Phase II



Neutralizing antibody titer 28 days after 3rd dose in middle dose group in Phase II



- Both 2 doses and 3 doses can produce cross-protection effects against Beta strain and Delta strain;
- In comparison with the neutralizing antibody titer against the Vaccine strain, there is relatively small decrease in the antibody titer against Delta strain, and the magnitude of decrease against Delta strain was less than that of Beta strain, but still, it showed a protective effect.

Thank you!