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Poliomyelitis Vaccine (Inactivated),Sabin Strain

Clinical Development

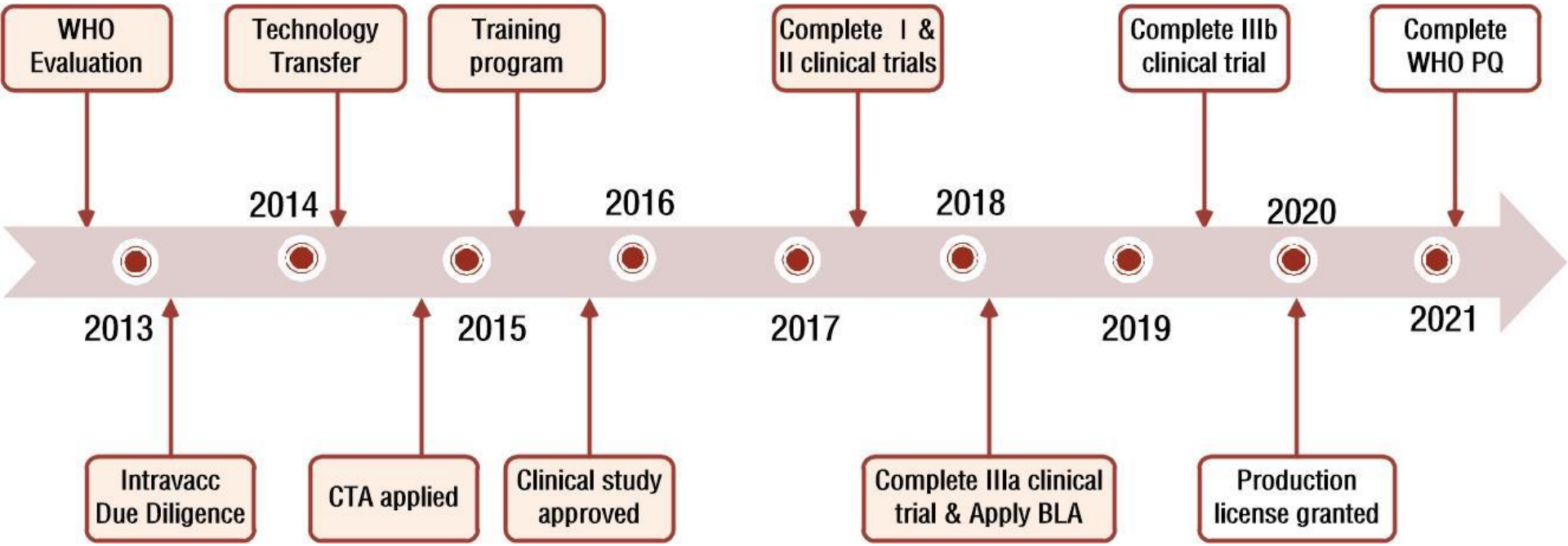
31 Oct. 2018

Contents

1 Quality Target Product Profile

Product attribute	Target
Strain used	Sabin polio virus type I/II/III
Product type	Inactivated Vaccine
Mode of administration	Intramuscular injection
Dosage form	Liquid in vial, single/multiple dosage
Preservative	Preservative free （single dose）
Shelf life	36 months at 2-8^{o}C
VVM	≥7 days
Adjuvant	$Al(OH)_3$ for multiple dosage
Immunogenicity	Immunogenicity is non-inferior to IPV/sIPV
Safety	Safety is non-inferior to IPV/sIPV
Host Cell Protein	≤100ng/dose
Host Cell DNA	≤50pg/dose
BSA	≤50ng/dose

2 Sinovac sIPV Project Overview



CTA：Clinical Trail Application
BLA：Biologics License Application

3 Clinical Trials Design

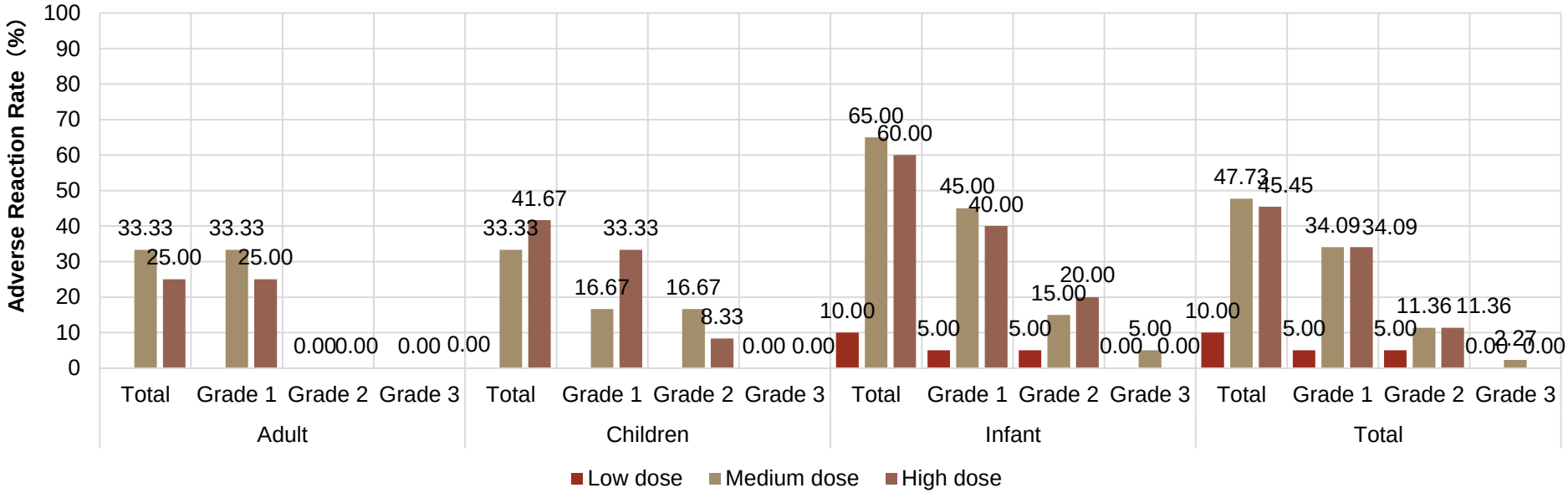
	Phase I-II	Phase IIIa	Phase IIIb
Dosage target DU/dose	Open (phase I); Blinded (phase II) Randomization and Reference 7.5-22.5-22.5 15-45-45 22-67-67	Blinded Randomization Reference 15-45-45	Blinded Randomization Reference 15-45-45
Reference DU/dose	Kunming sIPV (30-32-45 at phase II) Pasteur IPV (40-8-32 at phase II) against Sabin strain	Pasteur IPV (40-8-32) against Sabin strain	
Objective	Safety & Immunogenicity	Non- inferiority (seroconversion rate)	Lot consistency Non- inferiority
Endpoint	Seroconversion rate GMTs	Seroconversion rate GMTs	Seroconversion rate GMTs
Vaccination schedule	2, 3, 4m	2, 3, 4, 18m	2, 3, 4m
No. of subject	108 (phase I); 600 (phase II)	1200	900
Period	2016.10-2017.6	2017.8-2018.1	2019.5

3-1 Clinical Trial Phase I

Safety

Age group	Immunization schedule	Low dose	Target dose	High dose	In total
		No. of subjects			
Adult	1 dose	-	12	12	24
Children	1 dose	-	12	12	24
Infant (2 months old)	3 doses	20	20	20	60
Safety Result					

Total Adverse Reaction



- There is not any serious adverse reaction.
- Adverse reactions were mainly of grade 1 and 2, with a low incidence of grade 3.

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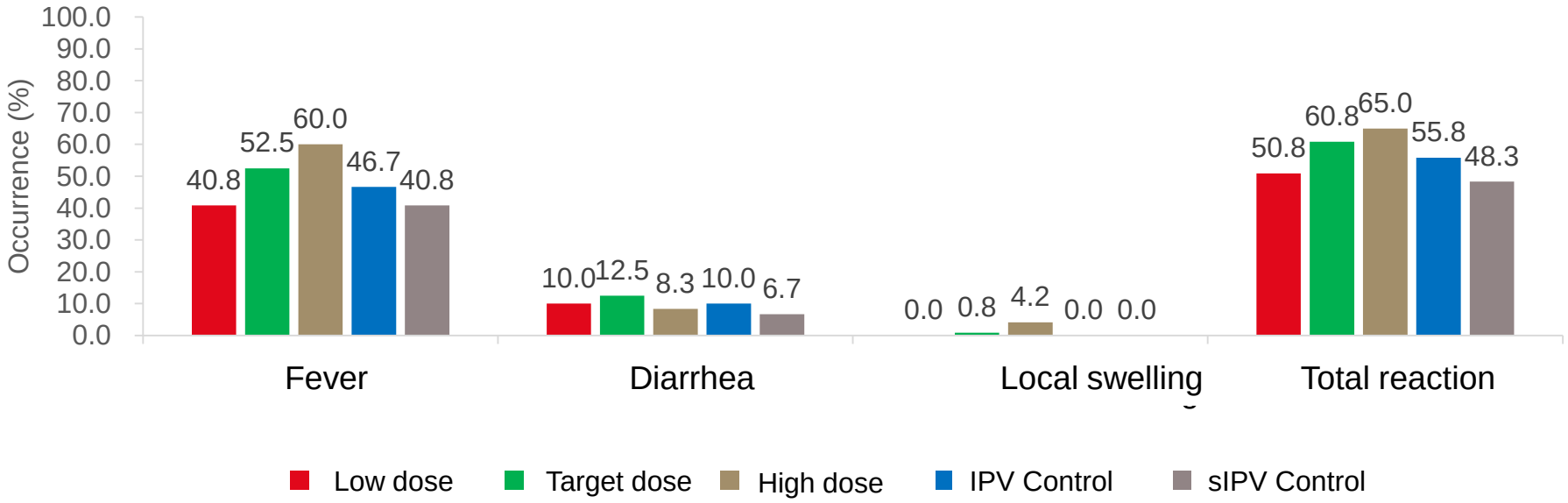
3-2 Clinical Trial Phase II

Safety

Age group	Immunization schedule	Low dose	medium dose	High dose	Control (wIPV)	Control (sIPV)	In total
Infant Group (2 months old)	m	No. of subjects					
	2/3/4	120	120	120	120	120	600
	Safety Result						



➢Target & high dose groups have higher reaction rate (non-significant), major reaction is fever. Comparable results in low dose and control groups.

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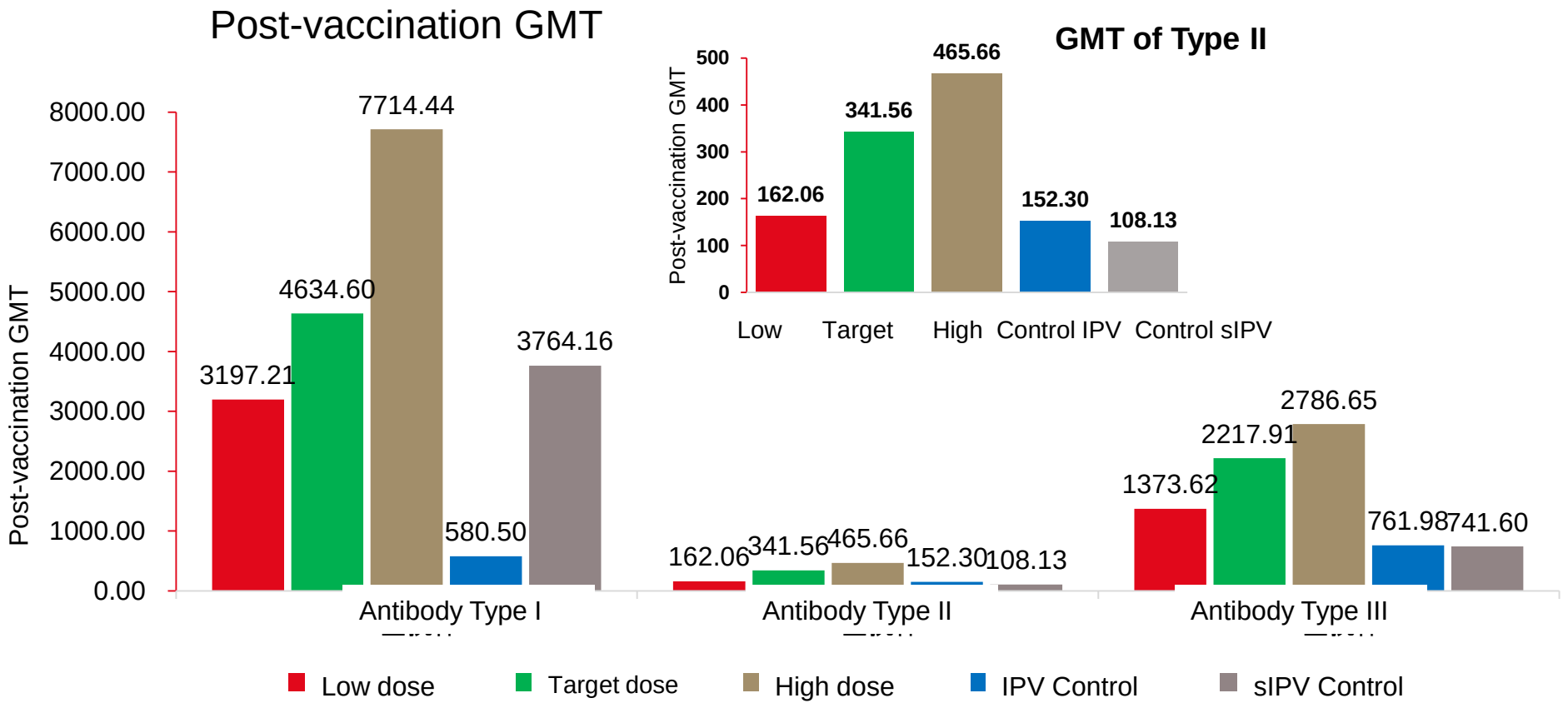
3-2 Clinical Trial Phase II

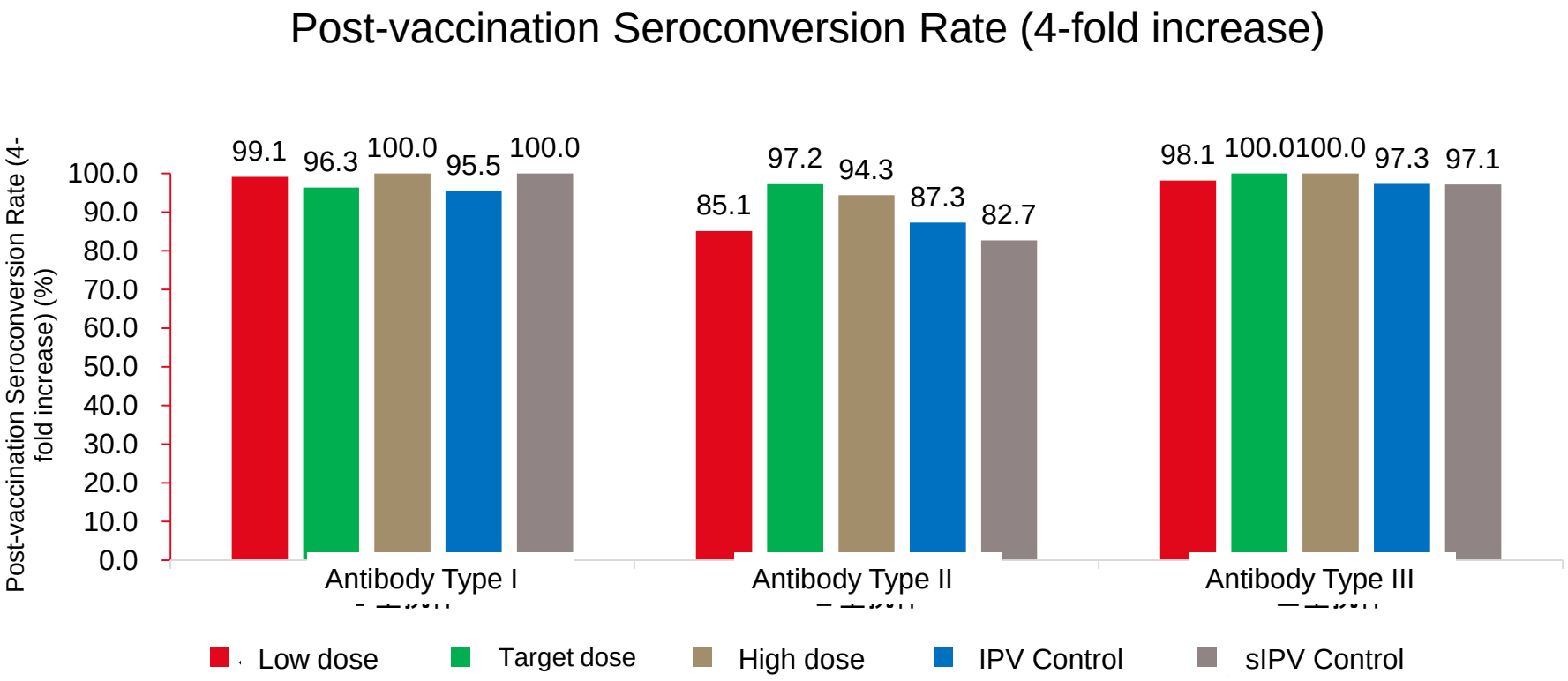
Immunogenicity



- Clear dose-effect relation on sIPV, GMT value is proportional to antigen dosage.
- All trial groups have higher GMT values than the two control groups.

3-2 Clinical Trial Phase II

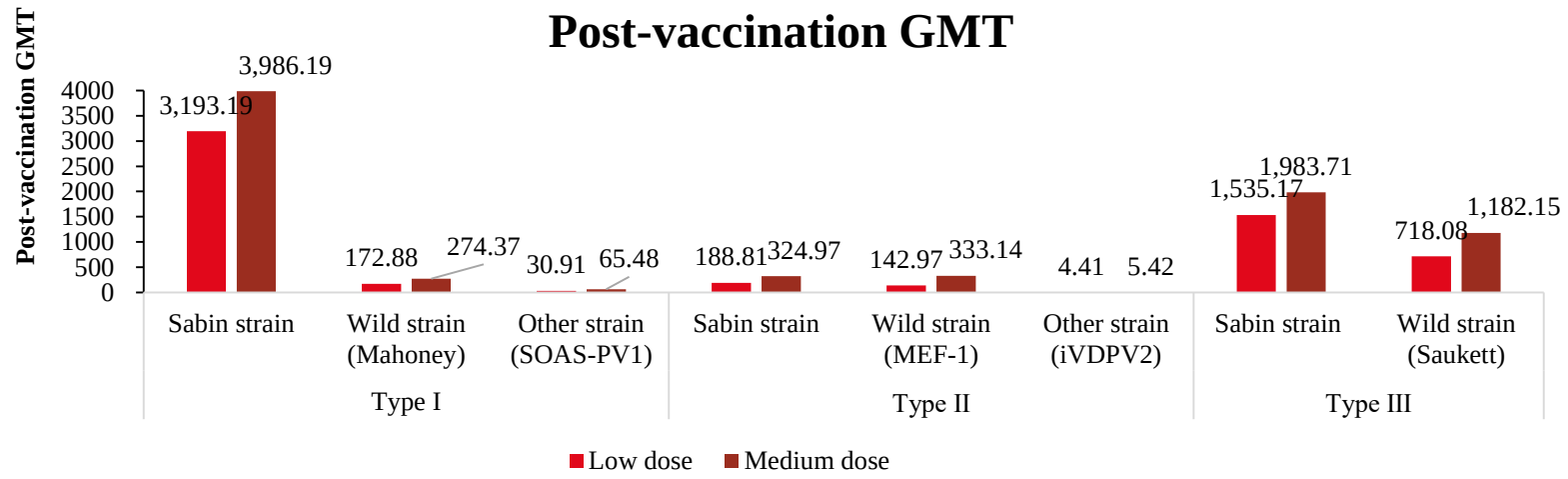
Immunogenicity

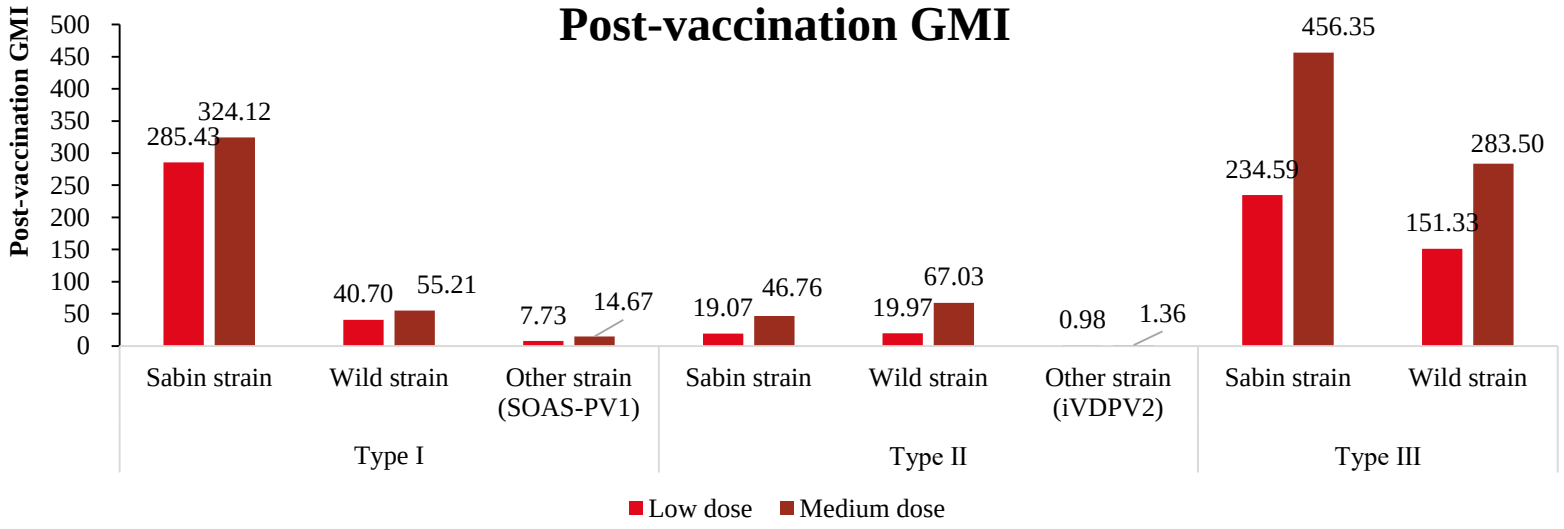


- All groups of type I & III are immunogenic, seroconverstion rate＞95%.
- Seroconversion rates of target & high dose groups are higher than controls.

3-2 Clinical Trial Phase II

Cross-neutralization
For different types





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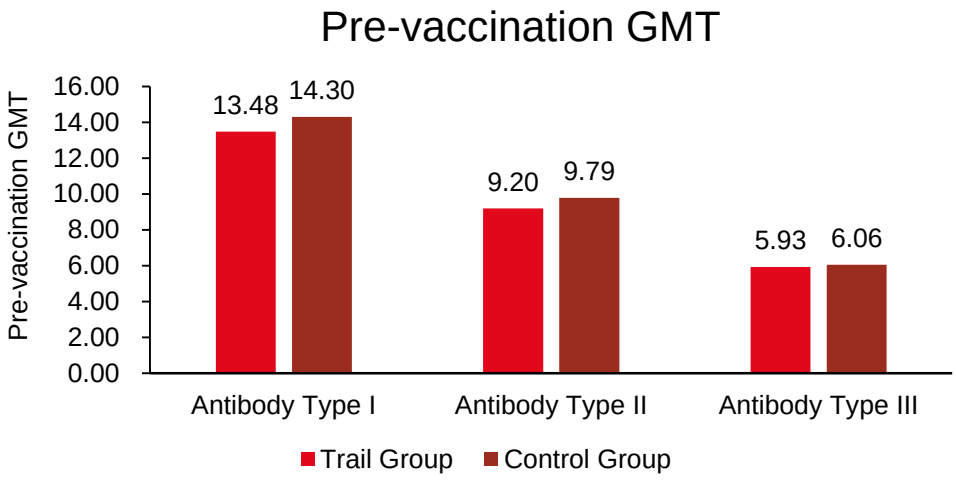
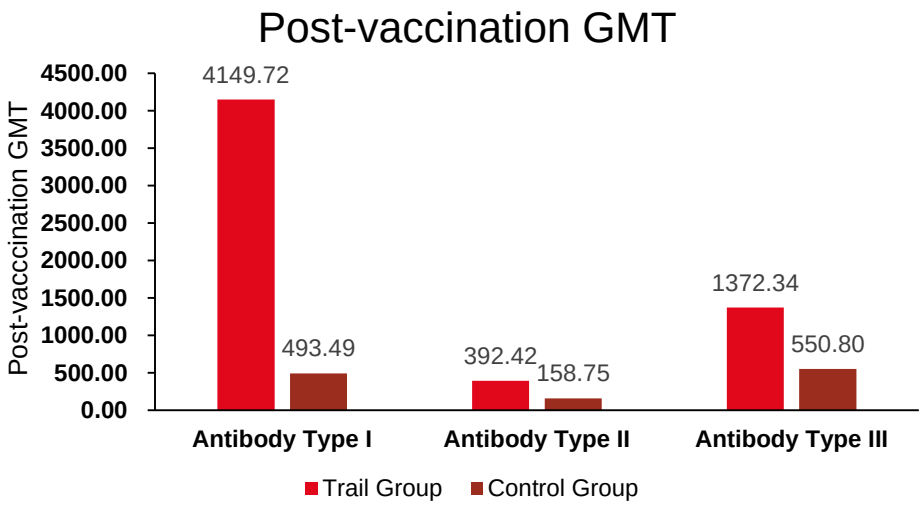
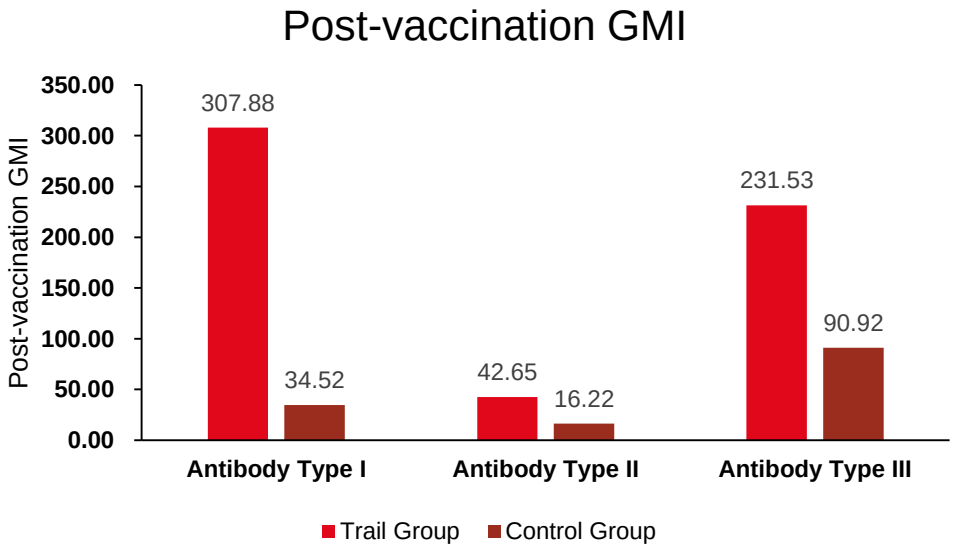
3-3 Clinical Trial Phase III

Immunogenicity



- Before vaccination, GMT of each trail group is very low;
- After vaccination, GMT and GMI of each trail group are both higher than the control group.





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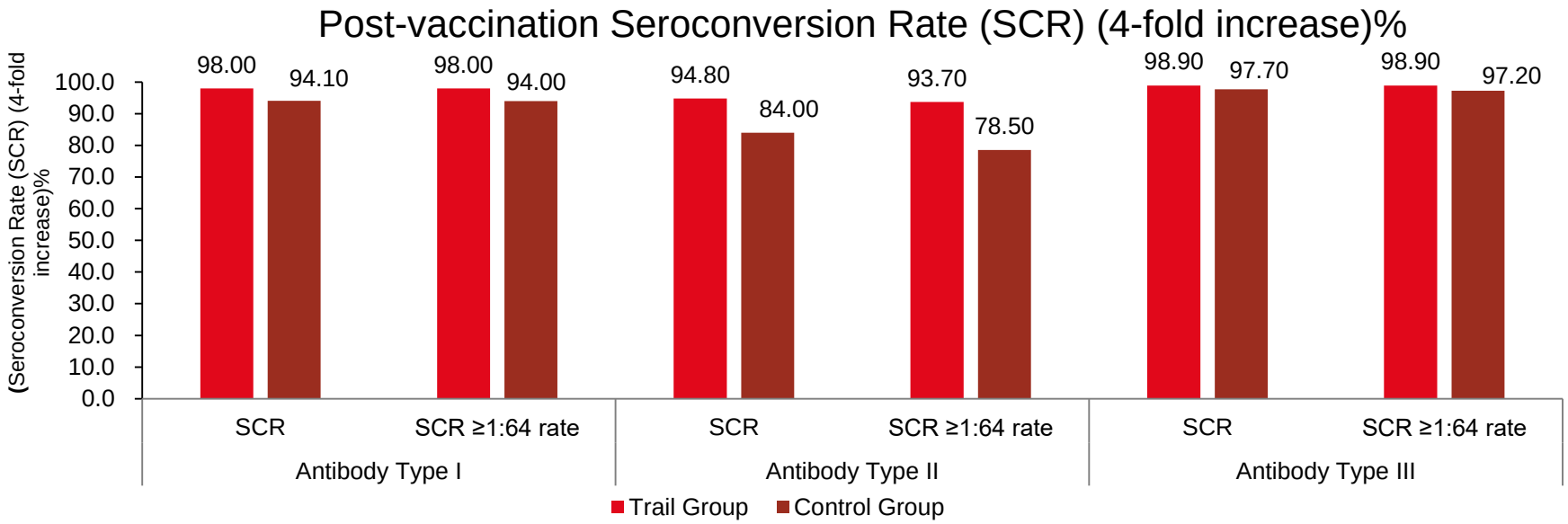
3-3Clinical Trial Phase III

Immunogenicity



- Regarding all types, the seroconversion rates after vaccination from trail group are at least non-inferior comparing with control group.
- The seroconversion of type II from trail group is even superior comparing with control group.

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Thank you!