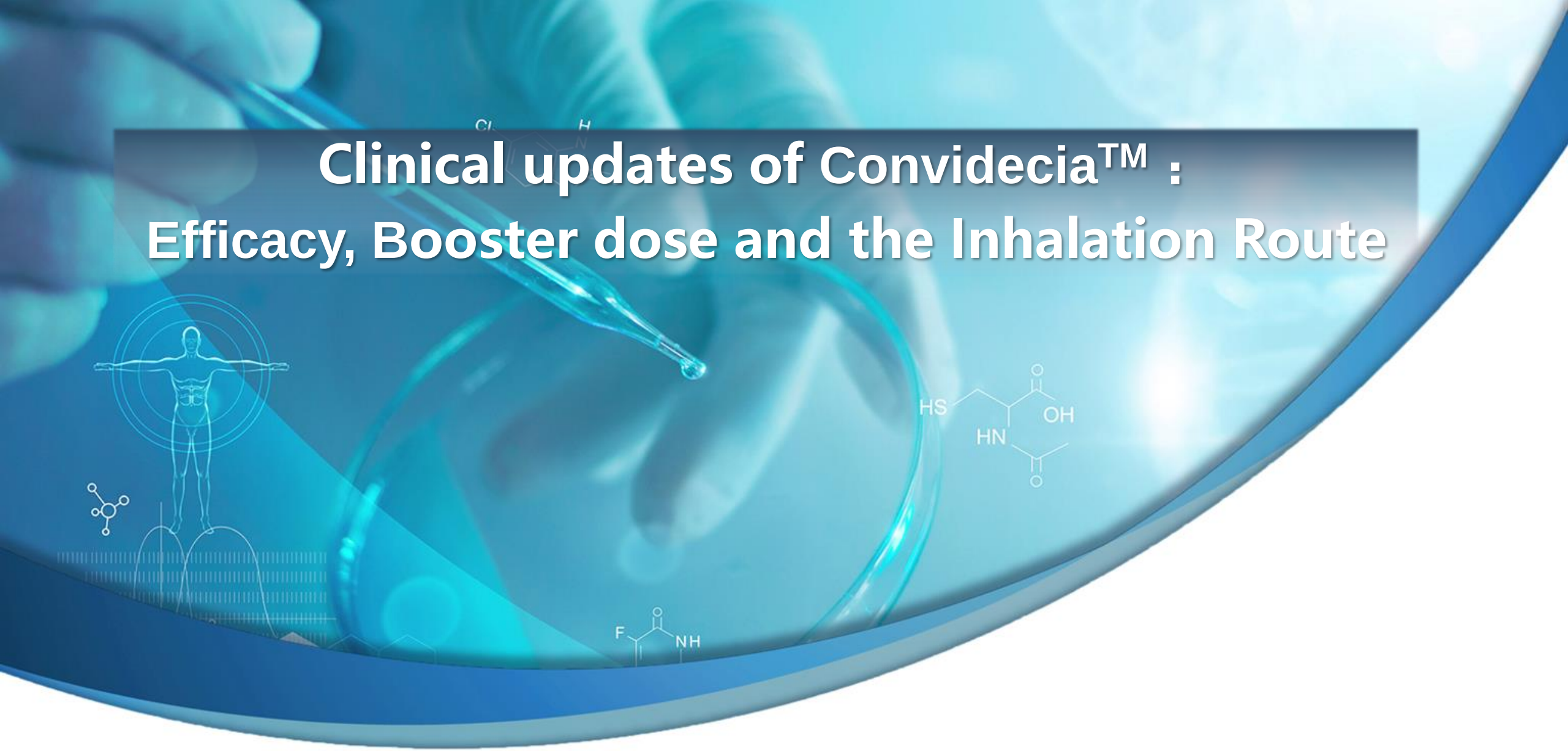
Clinical updates of Convidecia™ : Efficacy, Booster dose and the Inhalation Route



康希诺生物
CanSinoBIO

October. 25, 2021

Agenda

康希诺生物股份公司
CanSino Biologics Inc.

1. Phase III efficacy trial
2. Clinical trials and results of Homologous booster dose
3. Clinical trials and results of Heterologus booster dose

1. **Phase III efficacy trial**

Phase III Efficacy results

康希诺生物股份公司 CanSino Biologics Inc.

Efficacy of 14 days post single-dose

Analysis	group	N	Confirmed cases	Severe cases	Efficacy% (95%CI)	Efficacy against severe disease % (95%CI)
Interim analysis	Ad5-nCoV	13077	49	1	68.8 (57.0，77.4)	95.5 (66.4，99.4)
	placebo	13050	156	22		
Final analysis	Ad5-nCoV	14591	77	1	63.7 (52.9，72.1)	96.0 (70.5，99.5)
	placebo	14586	211	25		

Efficacy of 28 days post single-dose

Analysis	Group	N	Confirmed Cases	Severe cases	Efficacy% (95%CI)	Efficacy against severe disease % (95%CI)
Interim analysis	Ad5-nCoV	8816	26	1	65.3 (45.7，77.8)	90.1 (22.4，98.7)
	Placebo	8791	74	10		
Final analysis	Ad5-nCoV	10660	45	1	57.5 (39.7，70.0)	91.7 (36.1，98.9)
	Placebo	10590	105	12		

Phase III Version 2.0

康希诺生物股份公司
CanSino Biologics Inc.

➢ **Efficacy Objective**

The efficacy of Ad5-nCoV in preventing virologically confirmed COVID-19 disease occurring 28 days after first dose vaccination and before the second dose vaccination, regardless of severity.

and the relative efficacy of Ad5-nCoV(2 dose vs. 1 dose) in preventing virologically confirmed (PCR positive) COVID-19 disease occurring from 14 and 28 days to 24 weeks after the second vaccination, regardless of severity.

➢ **Safety Objective**

To evaluate the incidence rate of SAEs and MAEs after the first dose until 24 weeks after the second dose of Ad5-nCoV vaccination in all participants.

➢ **Dosage:** 0.5 ml (5×10^{10} vp) IM Injection

Current status of the Phase III Study - second dose

Total number of subjects vaccinated	Pakistan	Mexico	Chile	Argentina	Russia
20761	6921	8870	455	1425	3090

Preparing for the first analysis

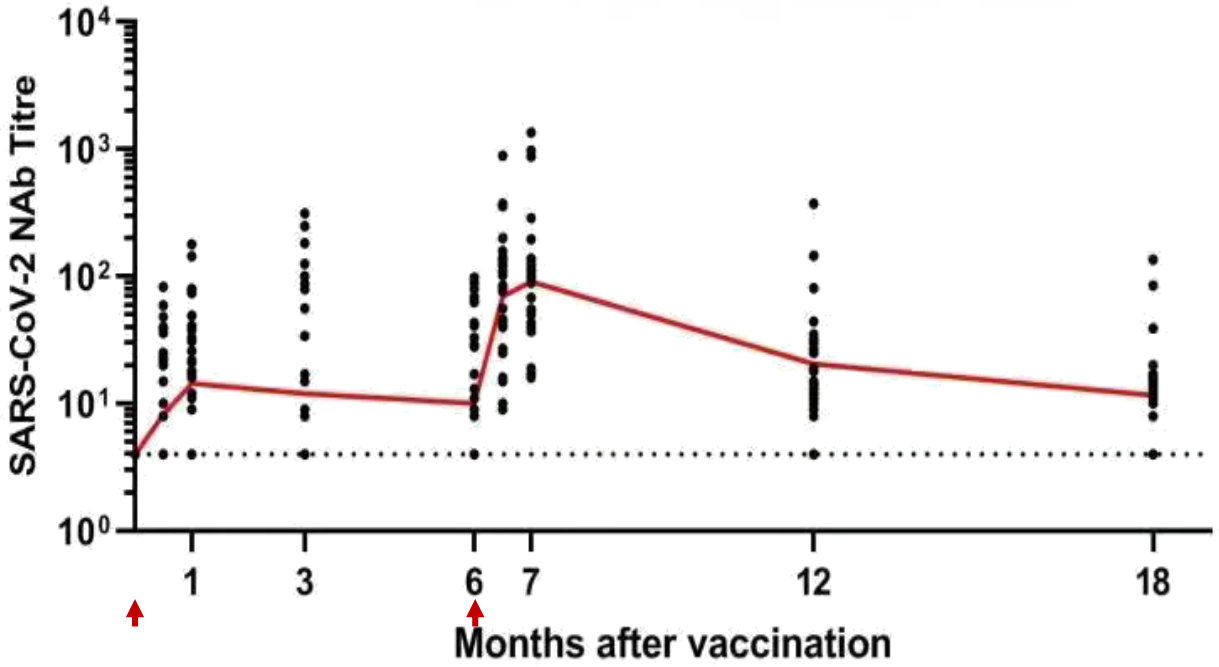
2. **Clinical Trials and Results of Homologous Booster Dose**

Results on immune persistence and booster effect

im Route

康希诺生物股份公司
CanSino Biologics Inc.

Trial JSVCT088



1. 6 months after 1st dose, neutralizing antibody maintains 70% of the peak level.
2. Boosted at month 6, the neutralizing antibody increased by about 8 times compared with the peak level of 1st dose.
3. 12 months after the booster, antibody level still maintain higher than the peak of the 1st dose.

Good immune persistence and homologous booster effect

Inhaled homologous booster study (Trial JSVCT092)

ih Route

康希诺生物股份公司 CanSino Biologics Inc.

- The interval between 2 dose is 56 days, using a randomized, double-blind, placebo-controlled design
- 5 groups in the phase I trial (0.05ml IH, 0.1ml IH, 0.2ml IH, IM+IH mix, single-dose IH), sample size 120
- 2 age group in the phase II trial, 18-59 years old and ≥60 years old, with 6 subgroups in each age group (0.05ml IH, 0.1ml IH, 0.2ml IH, IM+IH mix, single-dose IH, single-dose IM control) ,sample size 720

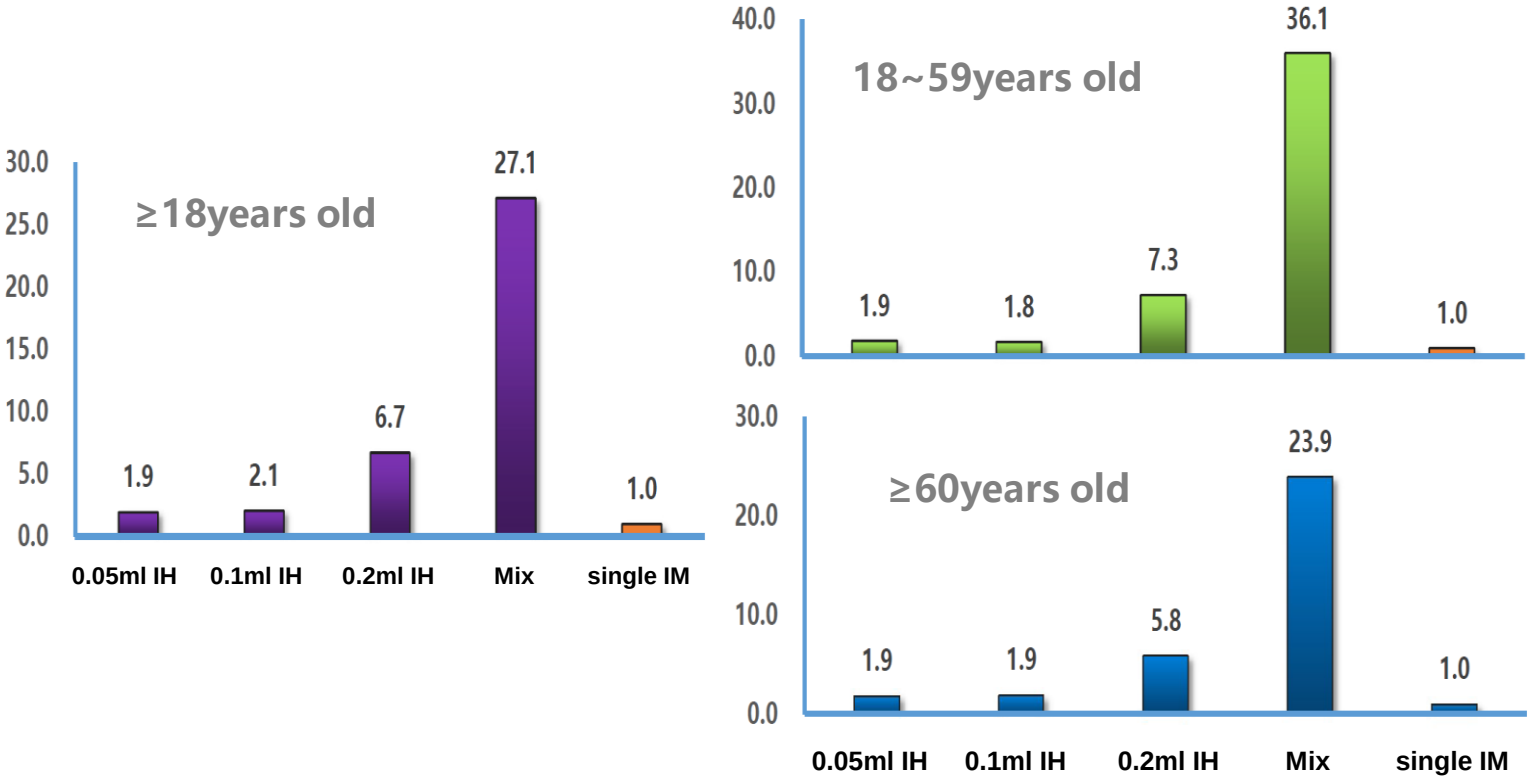
		Day0	14 Days after A1 enrollment	After 1st IDMC meeting	14 Days afterA3/A4 enrollment	Day56	After 2nd IDMC meeting	56 Days afterA3/A4 enrollment	56 Days after B3/B4/B 9/B10 enrollment
Phase Ⅰ(A)	1st dose	A1	A2、A5	A3、A4					
	2nd dose					A1	A2	A3、A4	
PhaseⅡ(B)	1st dose		B1、B5、B7、B11	B2、B6、B8、B12	B3、B4、B 9、B10				
	2nd dose						B1、B7	B2、B8	B3、B4、B 9、B10

Results on Inhaled homologous booster effect

ih Route

康希诺生物股份公司 CanSino Biologics Inc.

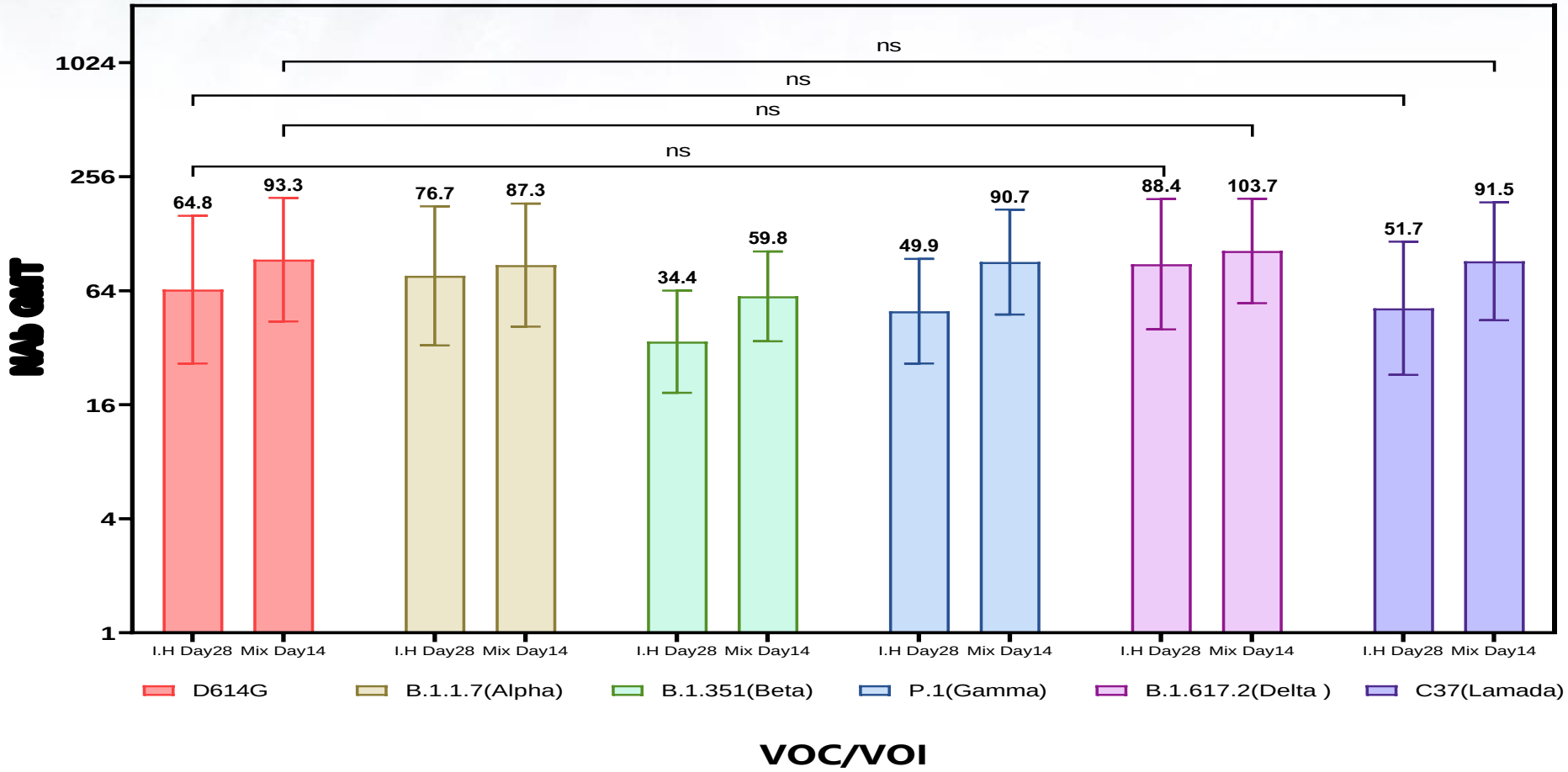
Wild Type NAb ratio compared with single IM dose (Trial JSVCT092)



1. **56 days interval** between the first IM dose and the second IH dose
2. The neutralizing antibody is about **27 times** compared with the **peak level of Single IM dose.**

IM + IH shows great advantages

VOC/VOI Cross neutralization assay (Serum from JSVCT092)



中国食品药品检定研究院
National Institutes for Food and Drug Control
国家药品监督管理局医疗器械标准管理中心
Center for Medical Device Standardization Administration NMPA
中国药品检验总所
China National Institutes for Drug Control

Compared with D614G, the NAb induced by the inhalation route against Delta and Lamada strains, which are currently widely concerned, did not show a significant decrease

3. **Clinical Trials and Results of Heterologus Booster Dose**

Trial: JSVCT116

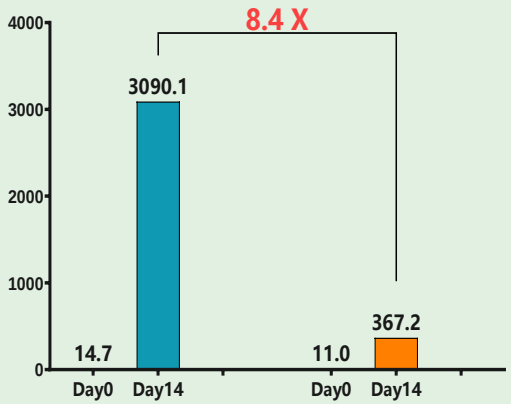
Group	N	Primary Dose	Booster Dose	Interval
A	100	2 dose CoronaVac	Convidecia (1dose)	3-6 months after the primary dose
B	100		CoronaVac (1dose)	
C	50	1 dose CoronaVac	Convidecia (1dose)	1-2 months after the primary dose
D	50		CoronaVac (1dose)	
Total	300			

Heterologus Study of Intramuscular Route

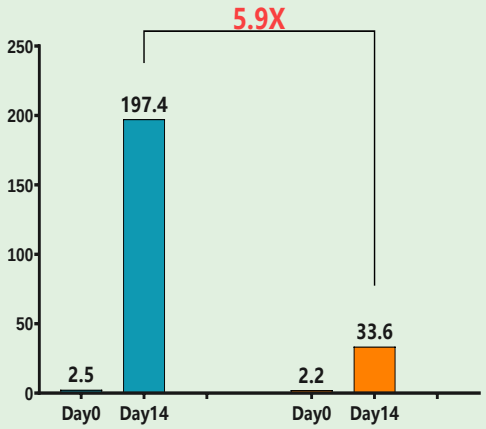
CoronaVac(Sinovac) + Convidecia™(Cansino) *im Route*

康希诺生物股份公司
CanSino Biologics Inc.

2 CoronaVac + 1Convidecia *vs.* 3 CoronaVac

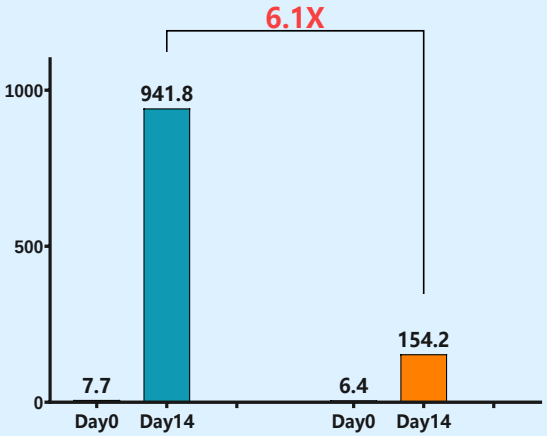


S-RBD IgG antibody

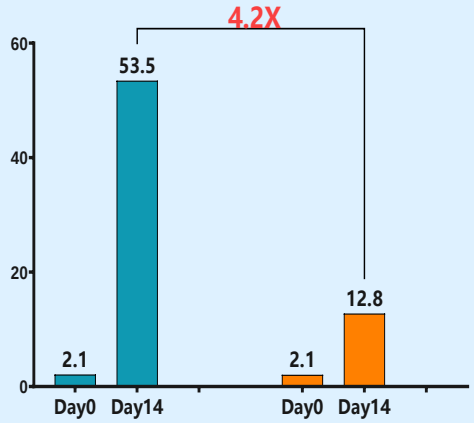


Wild type virus neutralizing antibody

1 CoronaVac + 1Convidecia *vs.* 2 CoronaVac



S-RBD IgG antibody



Wild type virus neutralizing antibody

Heterologous booster dose has significant immunity advantages

Adverse reactions within 28 days after the booster dose compared with the historical data

	This trial * (N=147)	Phase Ⅰ,Ⅱ (N=165)
Any	46 (31.29%)	126 (76.36%)
Grade 3	2 (1.36%)**	3 (1.82%)

*Combined Data of group A and C
** All are Pain at local injection site

Heterologous booster dose has significant safety advantages

CoronaVac(Sinovac) + Convidecia™(Cansino) *ih Route*

康希诺生物股份公司
CanSino Biologics Inc.

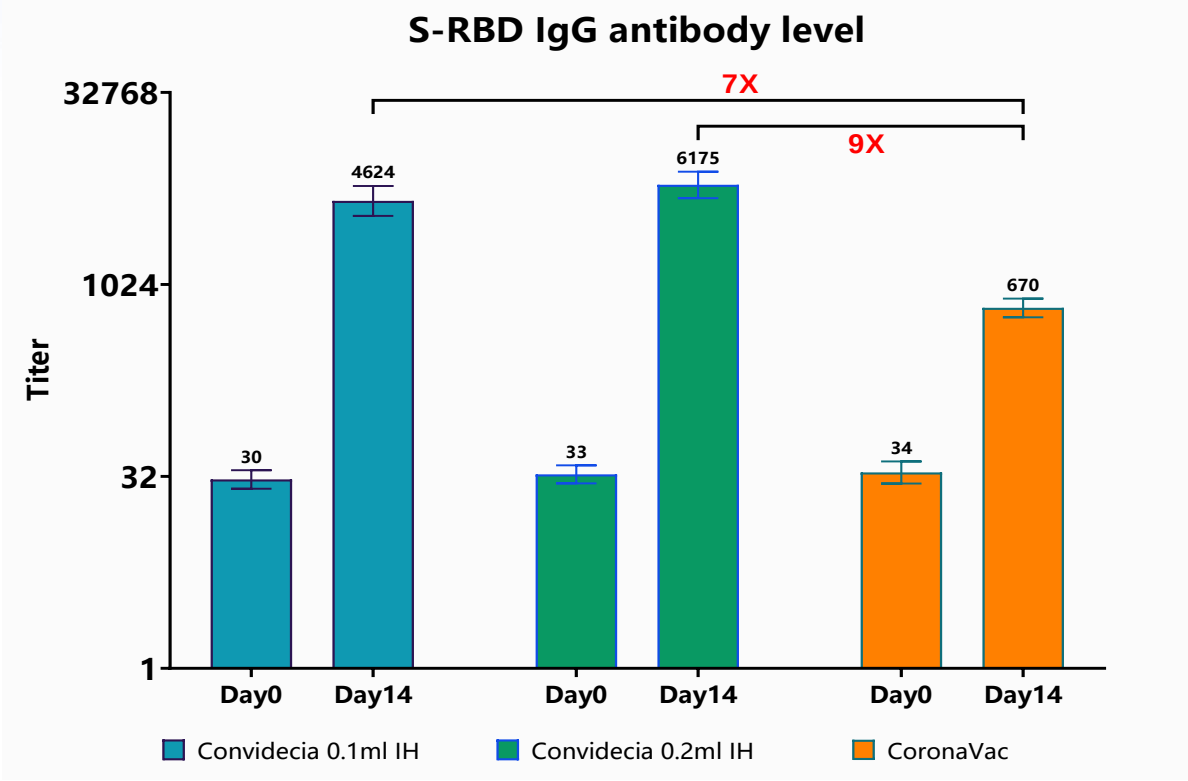
Trial:JSVCT127

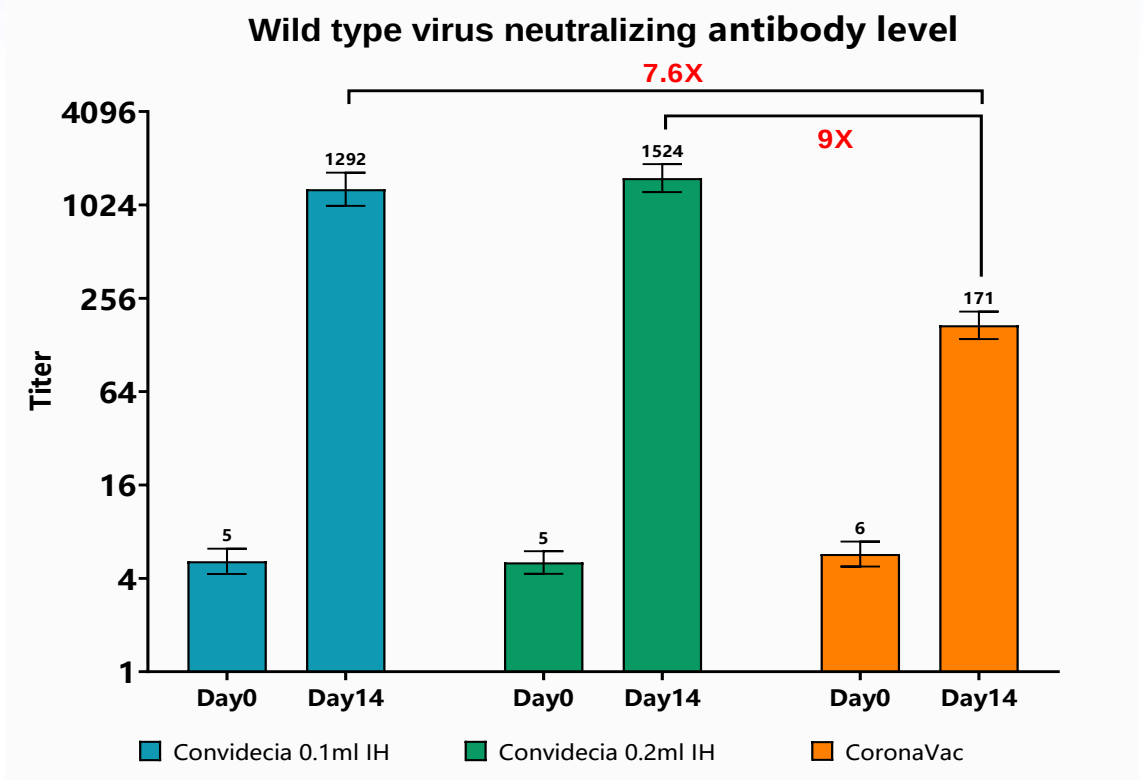
Group	Primary Dose	Booster Dose	N	Interval	Immune persistence subgroup
A	2 dose CoronaVac	Convidecia (0.1ml Inhalation)	140	3-9 months	40
B		Convidecia (0.2ml Inhalation)	140		40
C		CoronaVac	140		40
	Total (n)	420			120

Heterologus Study of Inhalation Route

CoronaVac(Sinovac) + Convidecia™(Cansino) *ih Route*

康希诺生物股份公司
CanSino Biologics Inc.



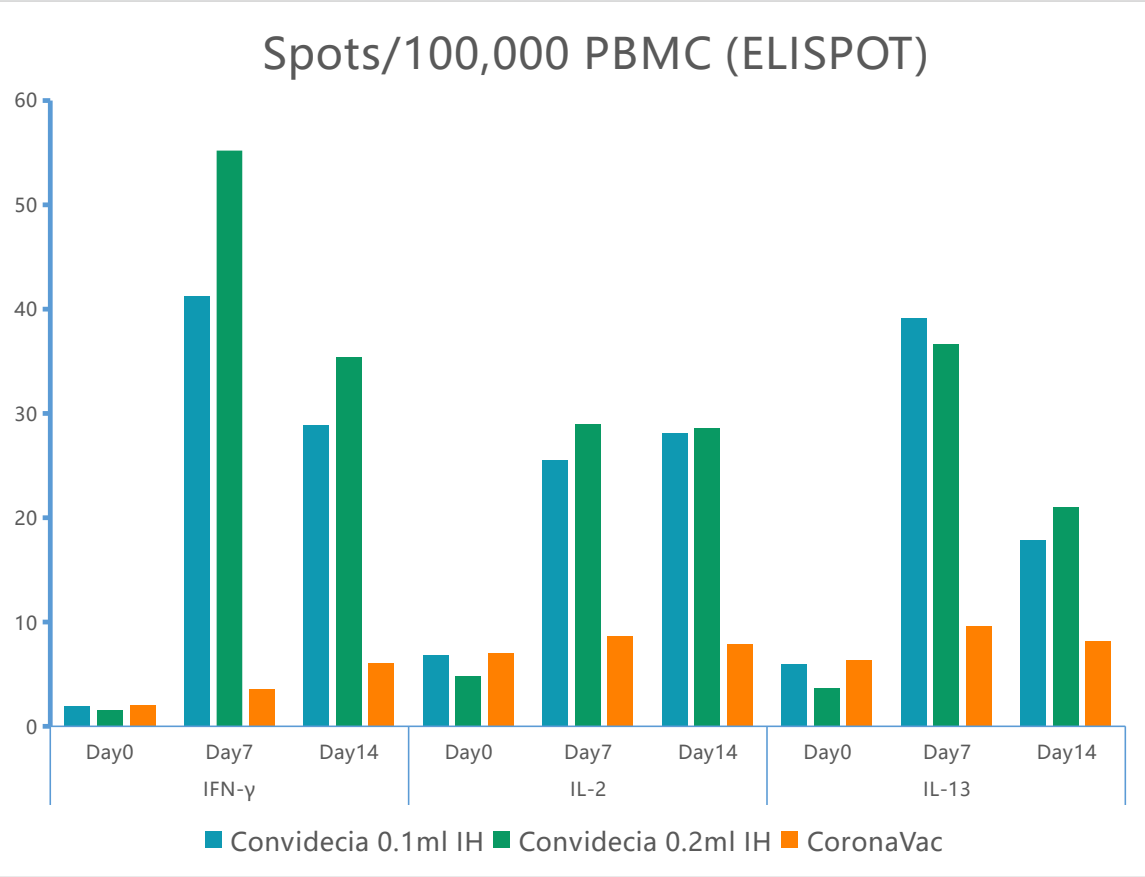


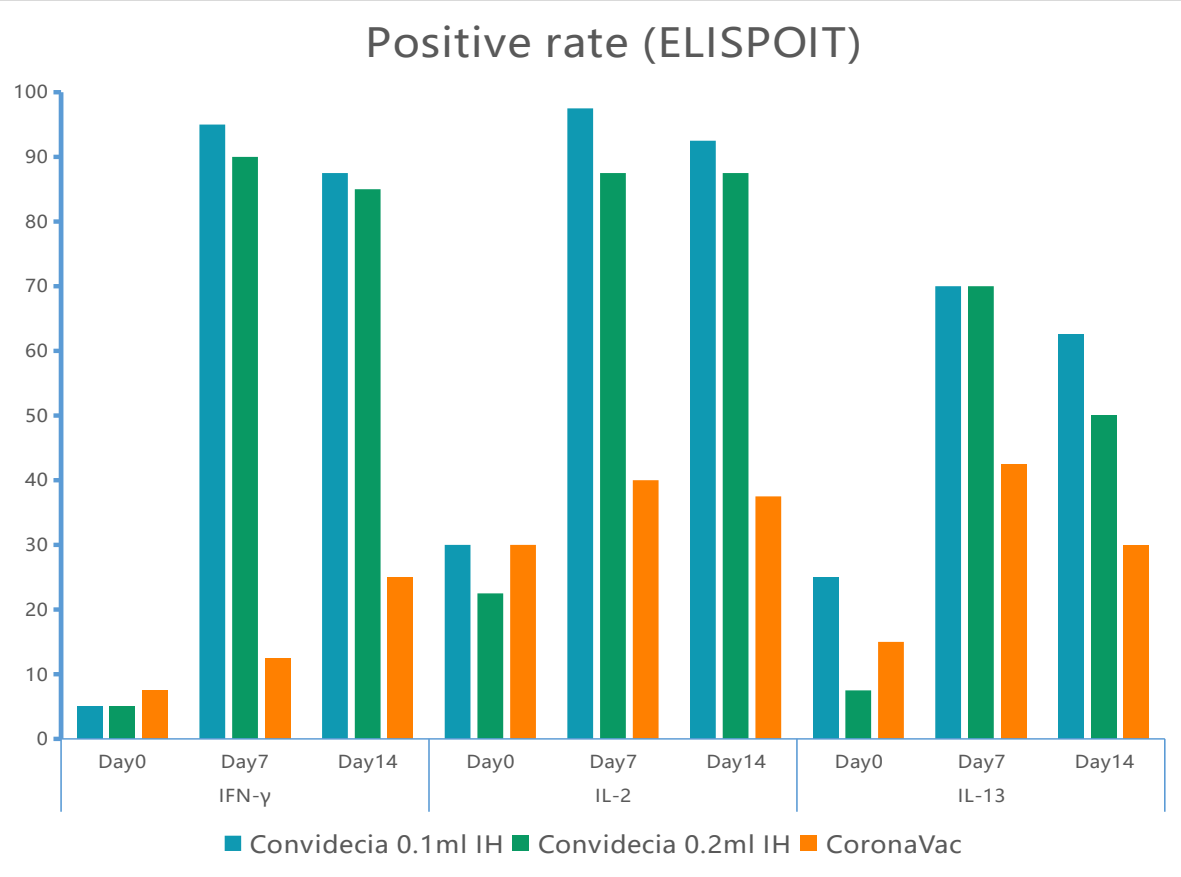
0.1 or 0.2ml IH booster dose can induce very high levels of antibody, much higher than the level of Inactivated booster.

Samples above the upper limit of dilution are calculated as 2 times of the upper limit

CoronaVac(Sinovac) + Convidecia™(Cansino) *ih Route*

康希诺生物股份公司
CanSino Biologics Inc.

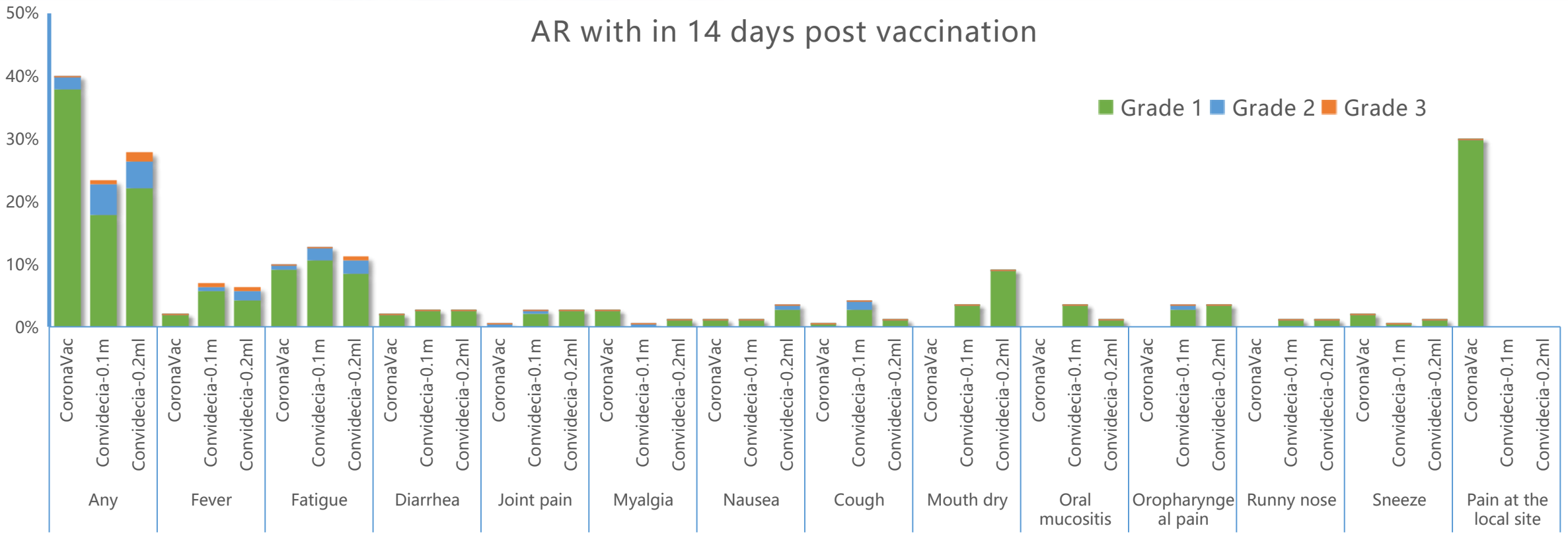




0.1 or 0.2ml IH booster dose can induce strong cellular immune response, which is much better than inactivated booster

CoronaVac(Sinovac) + Convidecia™(Cansino) *ih Route*

康希诺生物股份公司
CanSino Biologics Inc.



- **Both 0.1 and 0.2ml IH group, the overall AR is lower than the third dose of inactivated vaccine group.**
- **Grade 3 AR is fever (0.7% for the 0.1 and 0.2ml IH groups) or fatigue (0.7% for 0.2ml IH group).**

Sputnik V(Gamaleya) + Convidecia™(Cansino) *im Route*

康希诺生物股份公司
CanSino Biologics Inc.

Trial: FH 62

Group	Primary Dose	Booster Dose	Interval	Sample size
A	1st dose of Sputnik V (Ad26)	1st dose of Convidecia	≥ 21 and ≤ 90 days	450
B	2 doses of Sputnik V	-	As registered	200
Total	450			

Heterologus Study of Intramuscular Route

Ongoing in Argentina


CanSino Biotechnology
Production01
raise respect agility innovation superiorquality

Thank you!