



# SARS-CoV-2 Vaccine (Vero cell), Inactivated

科兴控股生物技术有限公司  
SINOVAC BIOTECH LTD.

# CONTENTS

About SINOVAC

SARS-COV-2 VACCINE (VERO CELL), INACTIVATED

# Our History & Products

We focus on the Research, Development, Manufacture and Commercialization of vaccines for infectious diseases with significant unmet medical need.

2001

**SINOVAC**

Sinovac Beijing  
Established

2004

**Inactivated SARS Vaccine**  
(Phase 1 Completed)

2006



流感病毒裂解疫苗

**Influenza Vaccine (Split Virion), Inactivated**

2009



甲型H1N1流感病毒裂解疫苗

**H1N1 Influenza A Vaccine (Split Virion), Inactivated**

**SINOVAC**

Sinovac LifeSciences  
Established

2012



**Mumps vaccine, Live**

2020...



新型冠状病毒灭活疫苗

**Varicella Vaccine, Live**  
**Quadrivalent Influenza Vaccine**  
**COVID-19 Vaccine**  
PPV23  
Sabin-IPV

Provide Chinese Children with Top Quality Vaccines, Provide Children around the World with Vaccines Made in China

**Hepatitis A Vaccine, Inactivated**  
(WHO PQ, 2017)



甲型肝炎灭活疫苗

2002

**Hepatitis A & Hepatitis B Combined Vaccine**



甲型乙型肝炎联合疫苗

2005

**Pandemic Influenza Vaccine, Inactivated (H5N1)**



大流行流感病毒灭活疫苗

2008

Sinovac Dalian Established

**SINOVAC**

2010

**Enterovirus Type 71 Vaccine, Inactivated**



肠道病毒71型灭活疫苗

2016

# Production Sites

Area : 22,264.21 m<sup>2</sup>  
Floorage : 14,200.38 m<sup>2</sup>

HepA

Influenza

HepA&B combo

PPV23

Haidian-Beijing (Headquarter)



Dalian-Liaoning



Area : 95,685.6m<sup>2</sup>  
Floorage : 20,000m<sup>2</sup>

Mumps

Varicella

Area : 29,021m<sup>2</sup>  
Floorage : 32,322m<sup>2</sup>

EV71

Sabin-IPV



Changping-Beijing



Daxing-Beijing

Area : 45,523 m<sup>2</sup>  
Floorage : 69,124.5 m<sup>2</sup>

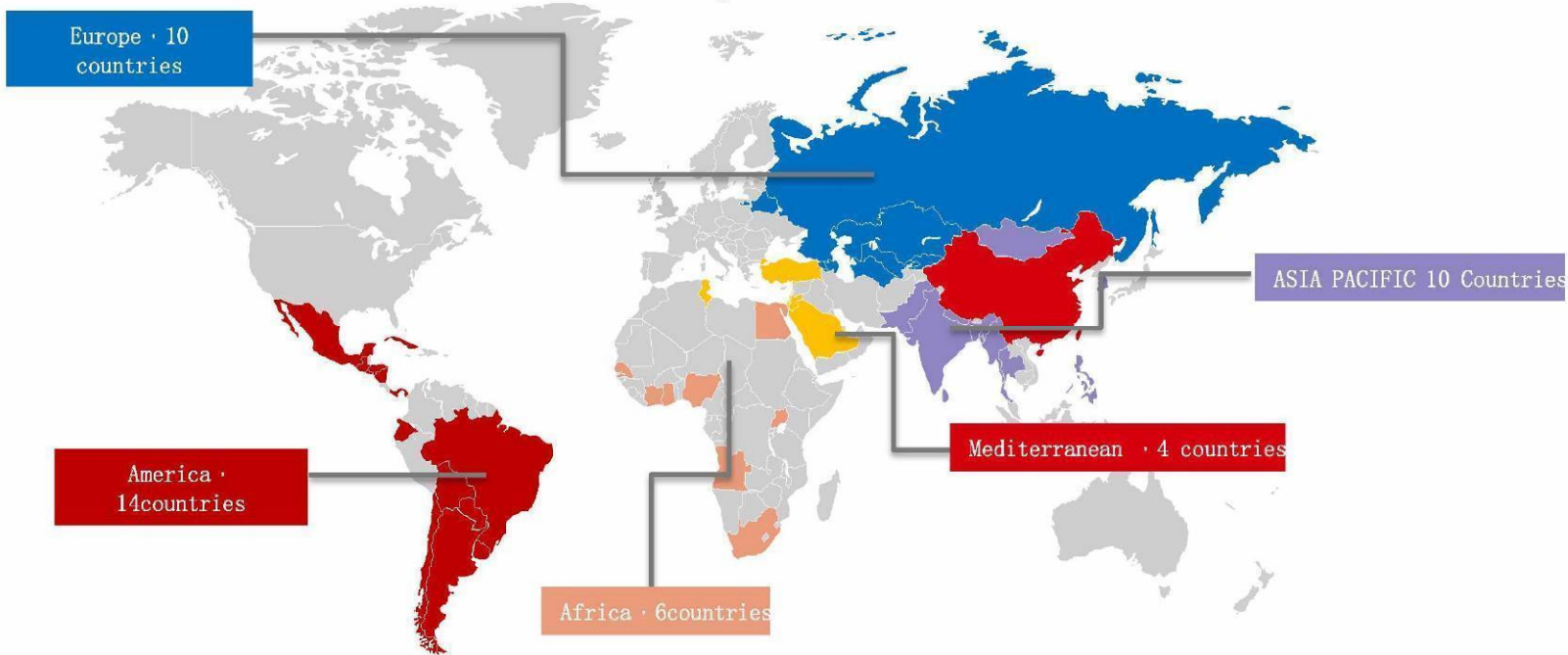
Sars-Cov-2

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- Beijing(Haidian, Changping, Daxing sites ), and Dalian site. 4 sites in total
- Total Capacity: More than 400 million doses per year for more than 10 vaccines
- Total area:192,000m<sup>2</sup> Total floorage:136,000m<sup>2</sup>
- SARS-COV-2 Vaccine Capacity: **300 million doses per year**

# Worldwide Market & Footprint

- ▶ The cumulative global sales are nearly 160 million doses. In 2019, an average of 112 people per minute were vaccinated with Sinovac's vaccines to obtain immune protection.
- ▶ Sinovac's vaccine has been sold in 22 countries around the world, has been registered in 17 countries, and is being registered in 26 countries, covering 3.25 billion people 68 million newborns
- ▶ The hepatitis A vaccine Healive® is the first HepA vaccine in China to pass WHO-PQ, and is being exported to more than 10 "Belt and Road" countries and international organizations such as UNICEF and PAHO.



# Quality Accreditation



China



Kazakhstan



Nepal



Nigeria



**MINISTÉRIO DA SAÚDE**  
**AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA**  
**CERTIFICADO DE BOAS PRÁTICAS DE FABRICAÇÃO DE MEDICAMENTOS**  
**LINHA DE INSUMOS FARMACÉUTICOS ATIVOS BIOLÓGICOS**

A Agência Nacional de Vigilância Sanitária - ANVISA, por meio da Resolução RE nº 2.221, de 01.07.2020, publicada em Diário Oficial da União (DOU) na data de 06.07.2020, certifica que a empresa abaixo é periodicamente inspecionada e monitorada pelo Sistema Nacional de Vigilância Sanitária e que cumpre com as diretrizes de Boas Práticas de Fabricação dadas pela legislação brasileira, a qual está em consonância com as recomendações da Organização Mundial de Saúde.

Fabricante: Sinovac Biotech CO. LTD.  
Endereço: Nº 39, Shangdi Xi Road, Haidian District, 100085, Beijing (Pequim)  
País: República Popular da China Código Único: A.1404  
Solicitante: Bio Medicamentos Ltda CNPJ: 15.268.466/0001-40  
Autorização de Funcionamento: 1.14.586-7 Expediente(s): 0115791/20-5  
Certificado de Boas Práticas de Fabricação de Medicamentos:  
Insumos farmacêuticos ativos biológicos: vacina adsorvida hepatite A (inativada).


A presente certificação é válida até o dia 06/07/2022 e poderá ser cancelada, caso seja comprovado, pela autoridade sanitária competente, o não cumprimento dos requisitos preconizados pelas normas vigentes de Boas Práticas.

Documento assinado eletronicamente por **Ronaldo Lucio Ponciano Gomes, Gerente-Geral de Inspeção e Fiscalização Sanitária**, em 03/07/2020, às 09:36, conforme horário oficial de Brasília, com fundamento no art. 6º, § 1º, do Decreto nº 8.539, de 8 de outubro de 2015 [http://www.planalto.gov.br/ccivil\\_03/\\_Ato2015-2018/2015/Decreto/D8539.html](http://www.planalto.gov.br/ccivil_03/_Ato2015-2018/2015/Decreto/D8539.html).

A autenticidade deste documento pode ser conferida no site <https://se.anvisa.gov.br/autenticidade>, informando o código verificador **1073069** e o código CRC **AF531C91**.





Brazil



Reference: 311.1 20/202017  
Hepatitis A (Human Digid Cell), Inactivated (Adult)  
HEALIVE

**Product Overview:**

Type:	Hepatitis A (Human Digid Cell), Inactivated (Adult)	
Commercial Name:	HEALIVE	
Manufacturer:	Sinovac Biotech Co. Ltd	
Country:	People's Republic of China	
URL:		
Responsible NRA:	State Food and Drug Administration	
Country:	People's Republic of China	
URL:		
Bulk Supplier:	Not applicable	

**Prequalification:**

Prequalification Status: Current  
Effective Date (dd/mm/yyyy):

**Product Description:**

Pharmaceutical Form:	Liquid ready to use
Presentation:	Vial
Number of Doses:	1
Diluent:	Not Applicable
Route of Administration:	Intramuscular
Shelf Life:	at storage temperature: 2-8°C
Vaccine Vial Monitor:	Type 30
Secondary Packaging:	Single dose carton [Dimensions 2.5 x 2.5 x 5.5 cm]
Tertiary Packaging:	Box of 40 wrapped packages with 10 single dose cartons (400 doses/400 vials) [Dimensions: 47 x 39 x 38 cm]
Cold Chain Volume:	3.3 cm <sup>3</sup> /dose (in secondary packaging)

المنظومة الصحية العالمية • 全球卫生健康  
Organizacine mondiale de la Sante • Romonesca organoza pe sanitate • Organizacine Mundial de la Sante

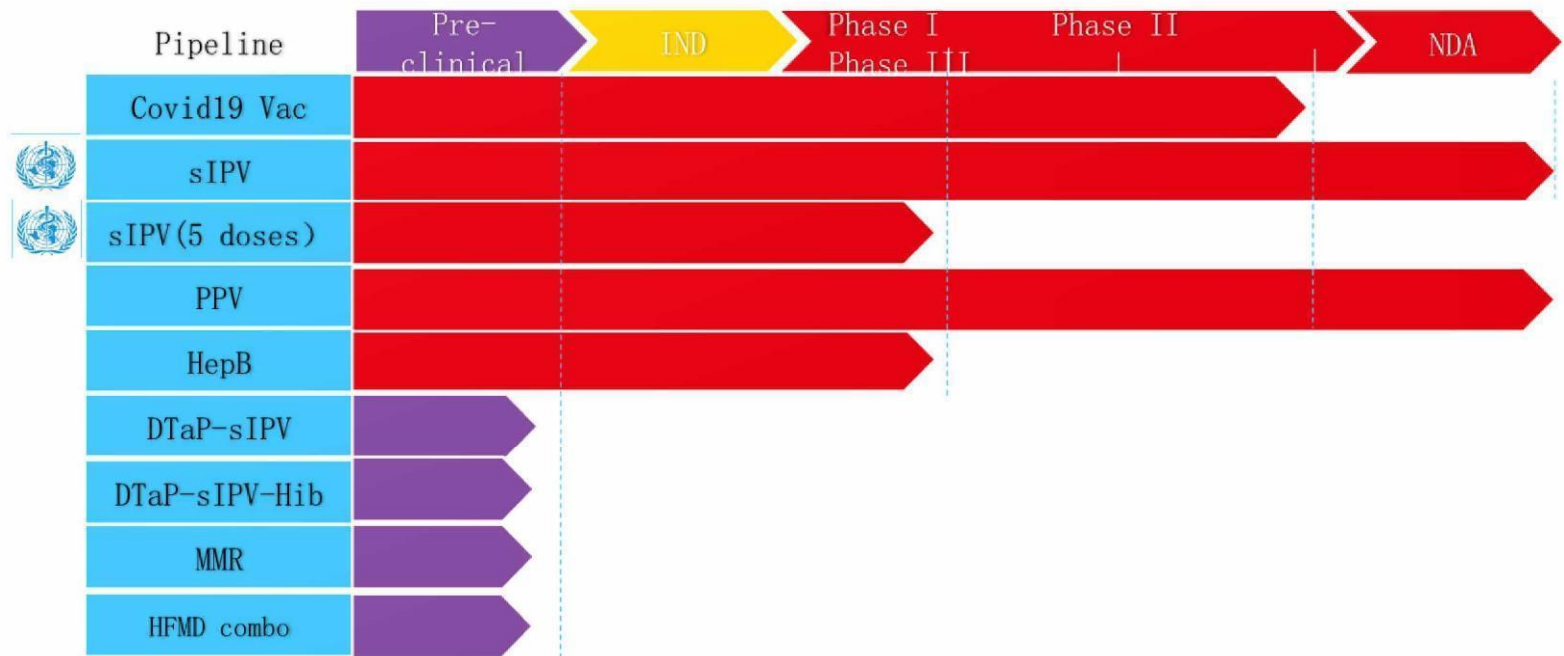
WHO PQ

Total GMPs: 11 Certificates

Total MAs : 33 product

# Our Pipeline

Leveraging Our Proven Track Record in Vaccine Development,  
SINOVAC's Future Growth is Driven by Advancement of Our Pipeline Product.



Total R&D: 9 projects

# International Coordination



Developing Countries Vaccine  
Manufacturers Network

&

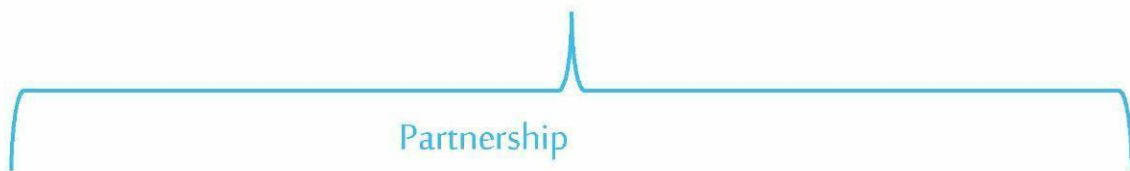


IFPMA

International Federation  
of Pharmaceutical  
Manufacturers & Associations

[ Member ]

**SINO**VAC



Partnership

**PAHO**



Pan American  
Health  
Organization



World Health  
Organization

REGIONAL OFFICE FOR THE Americas

unicef  for every child

# SARS-COV-2 VACCINE (VERO CELL), INACTIVATED

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# PRECLINICAL STUDIES

## Summary of the studies

Studies performed by GLP compliant lab, results presented in the following slides.

### Study design

	Item	Animal
Efficacy	Immunogenicity	Mice, Rat
	Virus Challenge*	Machaca Rhesus
	Cross-protection test	Mice, Guinea Pig, Rabbit, Rat, Sheep
Safety	Singe dose Toxicity/ Acute Toxicity	Rat
	Active Systemic Anaphylaxis	Guinea Pig
	Repeat Doses Toxicity (inc. local irritation)	Rat, Machaca Fascicularis

\*. An animal model which has been successfully developed for COVID-19 vaccine evaluation, including hCAE2 mice and Rhesus is employed  
<https://www.biorxiv.org/content/10.1101/2020.02.07.939389v3>

### GLP compliance

#### Virus Challenge test:

Institute of Laboratory Animal Sciences, Chinese Academy of Medical Sciences

➤ National Institution

#### Other safety tests:

JOINN Laboratories (Beijing)

- CFDA GLP Certified
- U. S. FDA GLP Inspected
- AAALAC Accredited
- OECD GLP Certified
- Korean MFDS GLP Inspected
- <http://www.joinn-lab.com/>

# PRECLINICAL STUDIES

EFFICACY DATA PRESENTING - Design of Virus Challenge test

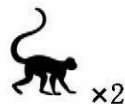
## Focus of study

Vaccine group VS.  
Model group

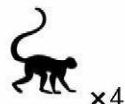
- (1) Routine observation
- (2) Virus load for throat swab.
- (3) Virus load for anal swab.
- (4) Virus load on each lung.
- (5) Pathology of lung tissue.
- (6) Correlation between neutralizing antibody and efficacy.

## Design

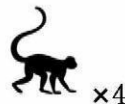
Model group  
(control)



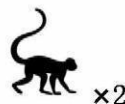
High dose  
group  
1200SU/dose



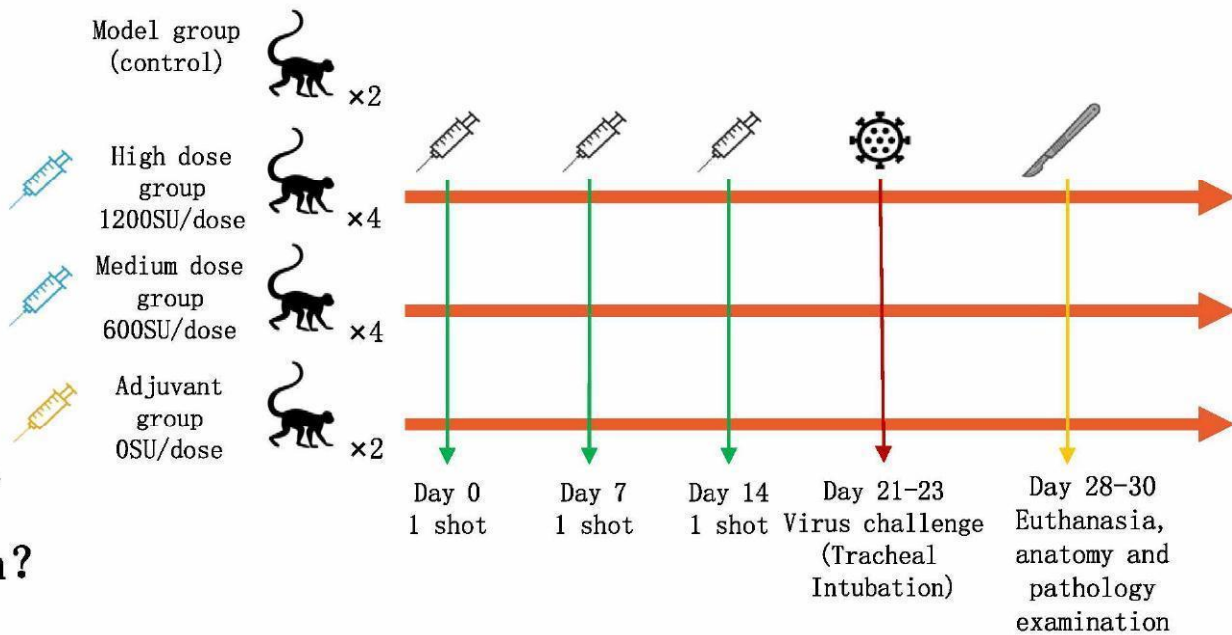
Medium dose  
group  
600SU/dose



Adjuvant  
group  
0SU/dose

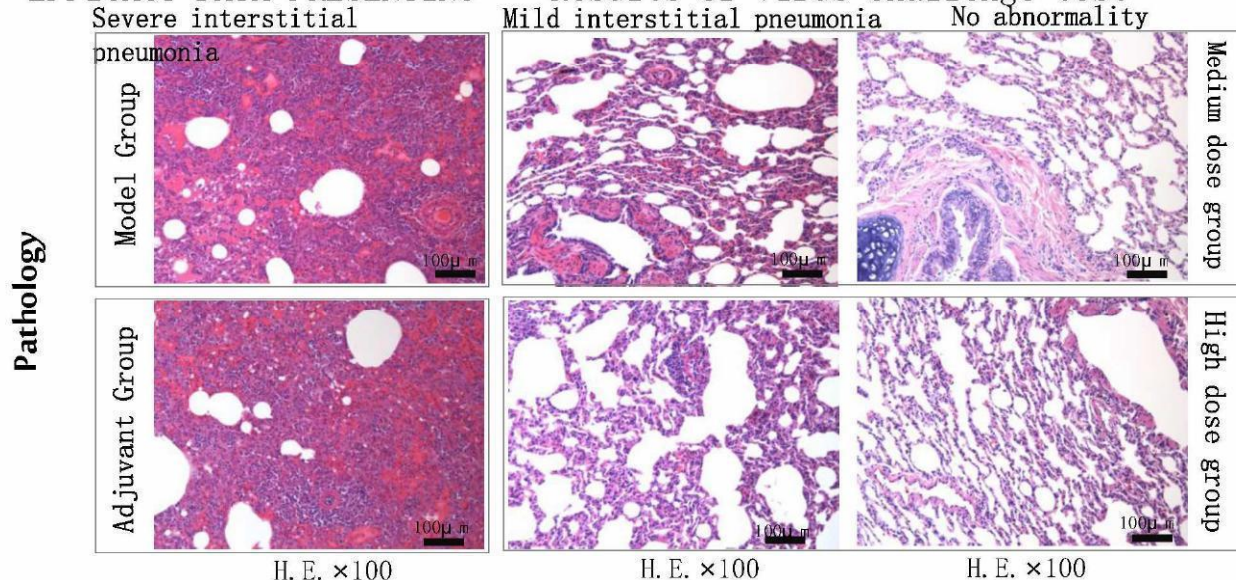


## Three dose schedule (0, 7, 14)



# PRECLINICAL STUDIES

## EFFICACY DATA PRESENTING - Results of Virus Challenge test



Significant protective effect observed for medium dose vaccination

Significant protective effect observed for high dose vaccination

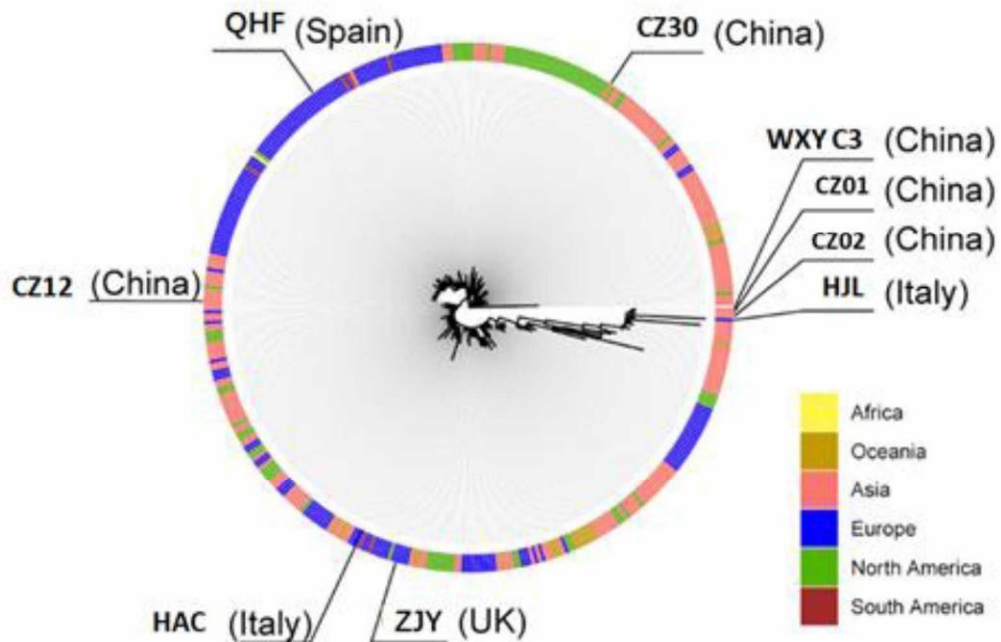
- Model:** 2 cases (2/2) showed severe interstitial pneumonia with Vascular and peribranchial inflammatory cells infiltrate
- Adjuvant:** 1 case (1/2) showed mild interstitial pneumonia; 1 case (1/2) showed Severe interstitial pneumonia with Vascular and peribranchial inflammatory cells infiltrate
- High dose group:** 4 cases (4/4) showed mild interstitial pneumonia; Compare with model group and adjuvant group, the pulmonary pathological change of vaccine groups has been significantly reduced.
- Medium dose group:** 4 cases (4/4) showed mild interstitial pneumonia; Compare with model group and adjuvant group, the pulmonary pathological change of vaccine groups has been significantly reduced.

# PRECLINICAL STUDIES

## EFFICACY DATA PRESENTING - Cross-protection test

### Source of the strains

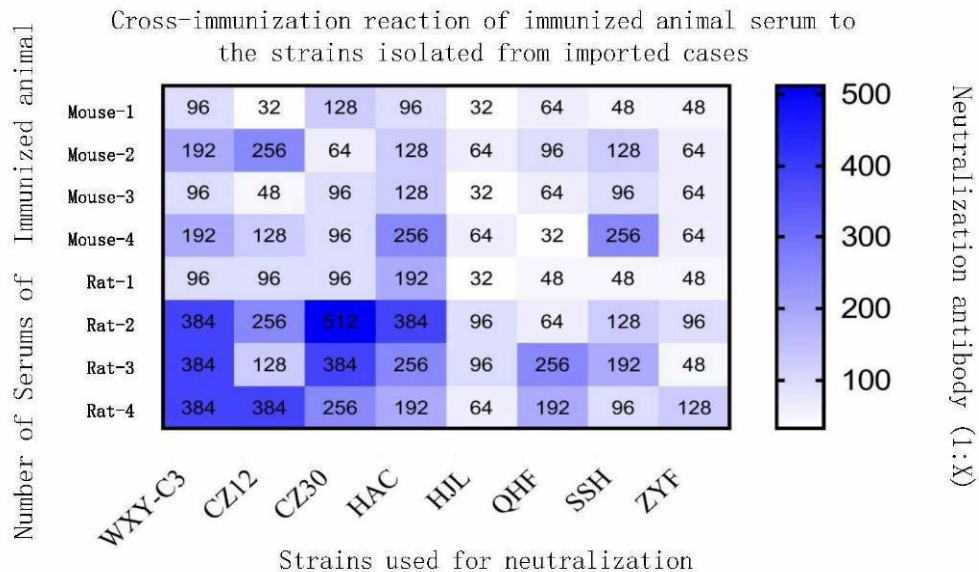
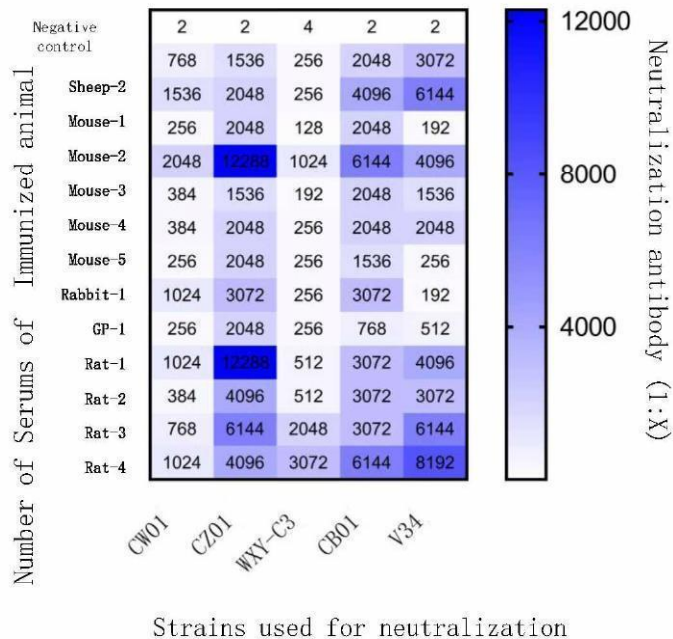
Name	Source
CW01	Wuhan, China
WXY-C3	Zhejiang, China
CZ01	Zhejiang, China
CB01	AS-IV, China
V34	Chinese military academy of science, China
CZ12	Zhejiang, China
CZ30	Zhejiang, China
HAC	Imported from Italy
HJL	Imported from Italy
QHF	Imported from Spain
SSH	Imported from Switzerland
ZYF	Imported from Italy



# PRECLINICAL STUDIES

## EFFICACY DATA PRESENTING - Cross-protection test

Cross-immunization reaction of immunized animal serum to the strains isolated in China



**Volunteer Subjects:** Phase I/II clinical trials in Healthy Adult  
Aged 18-59

**Trial Design:** Typical double blinded, randomized, placebo control

Schedule/ No. Volunteers	Phase I	Phase II
0, 14 day	72	300
0, 28 day	72	300
<b>Total</b>	<b>144</b>	<b>600</b>

Studies on elderlies are being carried on;

Studies on adolescents and pediatric groups are going to commence;

# CLINICAL STUDY RESULT-Phase III Plan

- ❑ Phase III trials have been approved in Brazil, Indonesia, Turkey and Bangladesh
- ❑ Trials have commenced in Brazil and Indonesia
- ❑ Other phase III trials will be initiated in September
- ❑ Approximately 30,000 subjects will be enrolled in these phase III trials

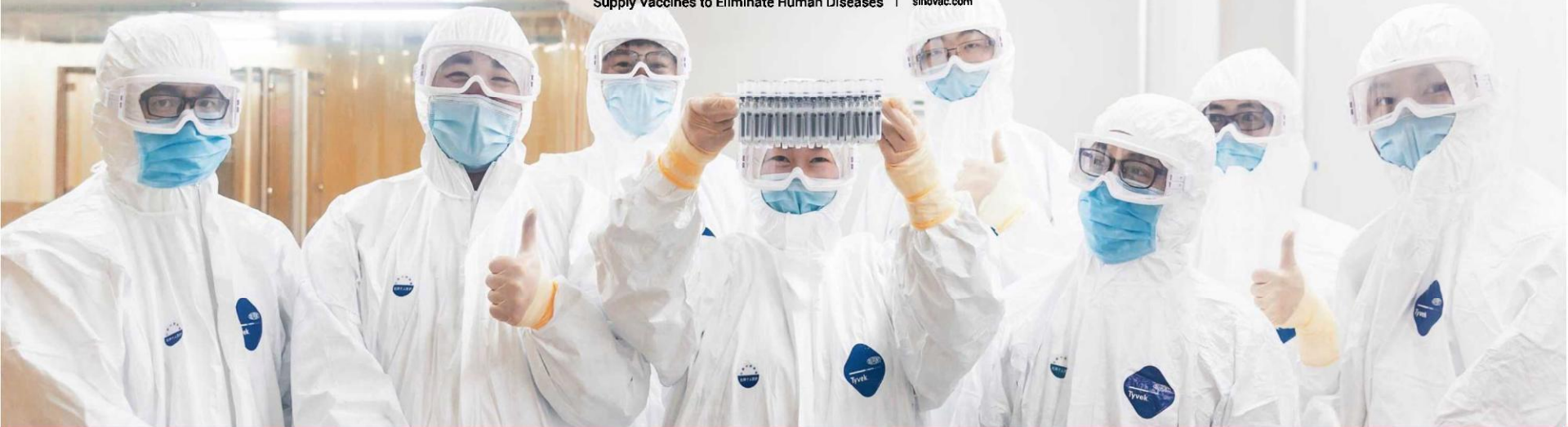
# SINOVAC

Supply Vaccines to Eliminate Human Diseases



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721970



**SINOVAC : Supply Vaccines to Eliminate Human Diseases**



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