Cross-continent Vaccine Collaboration against COVID-19
Company Introduction
Our History & Products

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

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

- Beijing (Shang Di, Chang Ping, Da Xing sites), and Dalian site. 4 sites in total.
- Total Capacity: More than 400 million doses per year for more than 10 vaccines
- SARS-CoV-2 Vaccine Capacity: more than 300 million doses per year

- Area: 22264.21 m²
  - Floorage: 14200.38 m²
  - HepA
  - Influenza
  - HepA&B combo
  - PPV23

- Area: 95685.6 m²
  - Floorage: 20000 m²
  - Mumps
  - Varicella

- Area: 29021 m²
  - Floorage: 32322 m²
  - EV71
  - Sabin-IPV

- Area: 45523 m²
  - Floorage: 69124.5 m²
  - SARS-CoV-2
  - Influenza
Development of SARS-CoV-2 Vaccine (Vero Cell), Inactivated
Development Process

Initial R&D of COVID-19 vaccine on Jan 28, 2020

Phase I and II trials were approved by NMPA on April 13, 2020

Phase I and II commenced on April 16, and May 3, 2020

Efficacy result on rhesus model published in *Science* on May 6, 2020

Phase III was approved by Brazil authority on July 3, and has started on July 21, 2020.

Started in Indonesia on August 11, 2020.

Also started in Turkey and Chile.
### Clinical Study Protocol

#### Phase I clinical trial in Healthy Adults Aged 18-59

<table>
<thead>
<tr>
<th>Schedule (Day)</th>
<th>Medium dose</th>
<th>High dose</th>
<th>Placebo</th>
<th>Total</th>
<th>Blood collection (Day)</th>
<th>Antibody detection/ T cell response (Day)</th>
<th>Lab index/ Inflammatory factors (Day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0,14</td>
<td>24</td>
<td>12</td>
<td>36</td>
<td>0(-14),7,14,21,28,194</td>
<td>0(-14),7,14*,21,28*,194</td>
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<td>12</td>
<td>36</td>
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<td>0(-14),28, 35,42*,56,208</td>
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<tr>
<td>Total</td>
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<td>48</td>
<td>48</td>
<td>144</td>
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</table>

#### Phase II clinical trial in Healthy Adults Aged 18-59

<table>
<thead>
<tr>
<th>Vaccination schedule (Day)</th>
<th>Medium Dose</th>
<th>High Dose</th>
<th>Placebo</th>
<th>Total</th>
<th>Antibody detection (Day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0,14</td>
<td>120</td>
<td>120</td>
<td>60</td>
<td>300</td>
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<tr>
<td>0,28</td>
<td>120</td>
<td>120</td>
<td>60</td>
<td>300</td>
<td>0,28,56,208</td>
</tr>
<tr>
<td>Total</td>
<td>240</td>
<td>240</td>
<td>120</td>
<td>600</td>
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</tr>
</tbody>
</table>
Phase I/II Clinical Study Results - Safety & Immunogenicity

Safety

0, 14 Days Schedule

ADR with highest incidence:
- Pain at the injection site (19.35%)

Second highest:
- Fatigue (5.91%)

0, 28 Days Schedule

ADR with highest incidence:
- Pain at the injection site (10.78%)

Second highest:
- Fatigue (4.31%)

Immunogenicity

Sero-positive rate (≥1:4)

- 0-14 days/14 days after second dose: 95.76%
- 0-28 days/28 days after second dose: 99.16%

Sero-positive rate (≥1:8)

- 0-14 days/14 days after second dose: 92.37%
- 0-28 days/28 days after second dose: 98.32%
Difficulties in Further Development

Active COVID-19 Cases in China

Few COVID-19 Cases in China  Limited Production Capacity

Collaboration
Collaboration on SARS-CoV-2 Vaccine (Vero Cell), Inactivated
How to choose our partners?

Considerations in choosing a partner

<table>
<thead>
<tr>
<th>COVID-19 cases</th>
<th>Population</th>
<th>Experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>The country must have enough active COVID-19 cases.</td>
<td>The country should have a huge population.</td>
<td>The company should have experience on vaccines.</td>
</tr>
</tbody>
</table>

Our partners

- In Brazil
  - Biofarma

- In Indonesia
  - Instituto Butantan
Introduction to Instituto Butantan

➢ Instituto Butantan is located in São Paulo, Brazil.

➢ It supplies the Brazilian public health system with 90% of the sera and 65% of all vaccines distributed in the country.

➢ Instituto Butantan manufactures 100% of the influenza vaccine doses used by the Brazilian Ministry of Health.

➢ It is set to be a global player in the development and manufacturing of the most advanced and needed biological products.
Introduction to Bio Farma

➢ Bio Farma is a state-owned company based in Bandung and the only local vaccine manufacturer in Indonesia.

➢ Bio Farma provides a wide range of vaccines, including virus vaccines (against measles, polio, Hepatitis B) and bacterial vaccines (DTP, DT, TT, BCG vaccine).
Strategic collaboration between Sinovac and Butantan

Timeline for collaboration

Clinical development collaboration agreement signed
2020.06.28

Phase III clinical trial approved
2020.07.03

Phase III clinical trial started
2020.07.21

Product registration and distribution agreement signed
2020.09.30

Local manufacturing agreement signed
2020.10.09

Discussion initiated
2020.05

Clinical trial
➢ A phase III double-blind, randomized, placebo-controlled clinical trial for the evaluation of efficacy and safety in health professionals
➢ 13,000 subjects in 22 sites, 0, 14 days schedule

Vaccine supply and technology transfer
➢ Sinovac will supply to Butantan 46 million doses of ready-to-fill bulk and finished product
Strategic collaboration between Sinovac and Bio Farma

Timeline for collaboration

- Clinical development collaboration agreement signed: 2020.07.14
- Phase III clinical trial started: 2020.08.10
- Local manufacturing agreement signed: 2020.09.29

Discussion initiated: 2020.06
Phase III clinical trial approved: 2020.07.27
Ready-to-fill bulk distribution agreement signed: 2020.08.20

Clinical trial
- Observer-blind, randomized, placebo-controlled two arms parallel groups, prospective intervention study
- 1,620 subjects, 0, 14 days schedule.

Technology transfer
- Sinovac will supply to Bio Farma 50 million doses of ready-to-fill bulk and finished product
Collaboration within dcvmn

The collaboration is between dcvmn members.

Complementary advantages

Butantan: strong clinical study experience and production capacity.

Bio Farma: the only vaccine company in Indonesia.

Pandemic control

China, Brazil and Indonesia constitute 24% of world population.

The collaboration serves to control the pandemic around the world.
SINOVAC：Supply Vaccines to Eliminate Human Diseases