Updated safety & immunogenicity of 3rd dose CoronaVac®

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WHO R&D BLUEPRINT CONSULTATION MEETING
October 25, 2021
01 Safety of the 3\textsuperscript{rd} dose of CoronaVac\textsuperscript{®}
Safety:
3rd dose of CoronaVac® after 6-8 months of primary immunization performed well in safety;

**AEFI did not increased after the 3rd dose**

A 3rd dose after 6 months of 2-dose (0,28) vaccination, the incidence of adverse reactions (grade 2 or above) within 28 days

<table>
<thead>
<tr>
<th>Dose</th>
<th>N</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>300</td>
<td>2.50%</td>
</tr>
<tr>
<td>2</td>
<td>296</td>
<td>3.57%</td>
</tr>
<tr>
<td>3</td>
<td>130</td>
<td>1.92%</td>
</tr>
</tbody>
</table>

Grade 2 was the highest level of adverse reactions for CoronaVac®
Grade 3 or above was not noticed.

Pan HX, et al. “Immunogenicity and safety of a third dose, and immune persistence of CoronaVac vaccine in healthy adults aged 18-59 years: interim results from a double-blind, randomized, placebo-controlled phase 2 clinical trial” medRxiv (2021) Li M, et al. “A booster dose is immunogenic and will be needed for older adults who have completed two doses vaccination with CoronaVac: a randomized, double-blind, placebo-controlled, phase 1/2 clinical trial” medRxiv (2021)
Two doses of CoronaVac induced higher antibody response among previously Covid-19 infected HCWs

- Median Ig G titer: **1,220 AU/ml** (range: 202–10328 AU/mL) in previously infected HCWs vs **913 AU/ml** (range: 2.8–15547 AU/mL) in uninfected HCWs
- Seropositivity rate (≥ 50 AU/ml): 98% in all tested HCWs

Ahmet Soysal et al. Comparison of immunogenicity and reactogenicity of inactivated SARS-CoV-2 vaccine (CoronaVac) in previously SARS-CoV-2 infected and uninfected health care workers; Human Vaccines & Immunotherapeutics. (2021)
02 Immunogenicity, timing, and immune persistence of the 3rd dose of CoronaVac®
Pan HX, et al. "Immunogenicity and safety of a third dose, and immune persistence of CoronaVac vaccine in healthy adults aged 18-59 years: interim results from a double-blind, randomized, placebo-controlled phase 2 clinical trial" medRxiv (2021) Li M, et al. "A booster dose is immunogenic and will be needed for older adults who have completed two doses vaccination with CoronaVac: a randomized, double-blind, placebo-controlled, phase 1/2 clinical trial" medRxiv (2021)
6-12 Months interval between 2\textsuperscript{nd} - 3\textsuperscript{rd} dose produce better immune response after 3\textsuperscript{rd} dose

**Participents**

<table>
<thead>
<tr>
<th>Schedule</th>
<th>18-59 years old</th>
</tr>
</thead>
</table>

**Sample size**

<table>
<thead>
<tr>
<th>Sample size</th>
<th>Mon-3</th>
<th>Mon-6</th>
<th>Mon-9</th>
<th>Mon-12</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>

| Total       | 400   |

**Schedule**

Day 0, Day 28, Day 28+Mon 3/6/9/12

**Sample size**

<table>
<thead>
<tr>
<th>Sample size</th>
<th>Mon-3</th>
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</tbody>
</table>

| Total       | 400   |

**Interval 3/6/9/12 Mo**

Day 0 → Day 28 → 14 days after the third dose

**GMT of the third dose with different interval**

- **Beta variant**
- **Delta variant**

When the interval time is 6/9/12-mon between the second dose and the third dose, the GMT to the variants is higher than that of 3-mon.
Good immune persistence at 6 months after the 3\textsuperscript{rd} dose

GMT: 6m after 3\textsuperscript{rd} dose higher than the peak of 2 doses

Seropositivity remained high 6m after 3\textsuperscript{rd} dose

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Summary

- Homologous vaccine with a 3rd dose of CoronaVac® is safe.
- Effective in recalling a SARS-CoV-2 specific immune response if given 6-8m after the 2nd dose.
- China is scaling up the 3rd dose inactivated vaccination campaign.
- More data are needed on cell immunity, effectiveness evaluation for the 3rd dose etc.
- Heterologous vaccine is under research.
SINOVAC: Supply Vaccines to Eliminate Human Diseases

Thank you!