Vaxine’s recombinant COVID-19 spike protein vaccine (Covax-19)

- COVID-19 virus isolated and sequenced
- Spike protein gene cloned into baculovirus
- Insect cell expression
- Preparation for large scale cell culture and protein purification through manufacturing partners

Formulation with Advax adjuvant

Animal studies confirm high immunogenicity with Advax for adjuvant
COVAX-19 vaccine efficacy studies

Hamster challenges
Key outcomes
• Neutralizing antibody
• Lung protection
• Prevention nasal viral shedding
• Prevention of transmission?

Ferret challenge
Subjects: 30
Key outcomes:
• Neutralizing antibody
• Lung protection
• Prevention nasal virus shedding

Human Phase 1 trial
Subjects: 40
Key outcomes:
• Safe, well-tolerated, minimal AE

Human Phase 2 trial
Subjects: 400
Key outcomes to date:
• Safe, well-tolerated, minimal AE
• Positive neutralising antibody responses

Human Phase 3 trial
Subjects: 17,800 subjects
Types of neutralisation assays

Mice

\[ y = 4.183x + 386.0 \]

\[ P = 0.0226 \]

\[ R^2 = 0.1721 \]
Ferrets: impact on nasal immunity

**Anti-RBD antibody (ELISA)**

<table>
<thead>
<tr>
<th>Groups</th>
<th>Day 28 IgG RBD Titer</th>
<th>Day 3 nasal virus isolation (nu. pos in gp)</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 ug/mL Adj - Boosted</td>
<td>10000</td>
<td>0/6 (0%)</td>
</tr>
<tr>
<td>25 ug/mL Adj - Boosted</td>
<td>35100</td>
<td>0/6 (0%)</td>
</tr>
<tr>
<td>12.5ug/mL Adj - Boosted</td>
<td>27900</td>
<td>1/6 (16%)</td>
</tr>
<tr>
<td>Single dose and mock vaccinated</td>
<td>0 - 9950</td>
<td>6/12 (50%)</td>
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</tbody>
</table>

Nasal washes

Yoshikazu-Honda et al, Vaccine, in press
Transmission blocking?

**Post challenge weight (3 animals/group)**
- G/W (Spike) 5 mcg
- Control (10-4 TCID50)
- Alum (RBD) 5 mcg
- G/W (RBD) 5 mcg
- NP-CpG (RBD) 5 mcg
- NP (RBD) 5 mcg

**Virus titer 3 d post challenge**
- NP (RBD) 5 mcg
- NP-CpG (RBD) 5 mcg
- G/W (RBD) 5 mcg
- Alum (RBD) 5 mcg
- Control (10-4 TCID50)
- G/W (Spike) 5 mcg

**Lung Histology Analysis**
- NP (RBD) 5 mcg
- NP-CpG (RBD) 5 mcg
- G/W (RBD) 5 mcg
- Alum (RBD) 5 mcg
- Control (10-4 TCID50)
- G/W (Spike) 5 mcg

Vaccinated and challenged

Naïve animal placed in same cage day 2 post challenge

Day 7 post challenge

Contact Animal

**Spike protein vaccine**

**Control unimmunised**

Confidential information of Vaxine Pty Ltd
Monkey study Covax-19

Unimmunised monkey

Covax-19 Immunised

Left caudal lobe several gray foci (arrows to two) of potential Pneumonia

Viral Titer:

![Graph showing viral titers for Day 3 and Day 7 for Control, COVAX-19, Control, and COVAX-19.]

- Day 3:
  - Control: 3/3 (100%)
  - COVAX-19: 1*/4 (25%)
  - Control: 2/2 (100%)
  - COVAX-19: 0/5 (0%)

Number of animals with detectable virus:

*single very elderly 19 year old female with absence of clinical signs had low levels recoverable virus at Day 3

Lower Lung Virus Detection
Trial samples – no correlation between assays?

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<th>WT vnt3</th>
<th>Pseudo neut</th>
<th>svnt3 binding inhibition</th>
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</table>
Vaxine’s multivariant Covid-19 vaccine equally neutralises all variants

Original Wuhan strain

- SP V12
- SP V13 (day 7 post TV)

UK variant

- SP V12
- SP V13 (day 7 post TV)

South African variant

- SP V12
- SP V13 (day 7 post TV)

Brazil variant

- SP V12
- SP V13 (day 7 post TV)
Global Network of Partner Organisations

vaxine
University of Georgia
Colorado State University
The University of Sydney
Flinders University
Kirby Institute
UNSW
La Trobe University
Mercatus Center
Royal Adelaide Hospital
National Institute of Allergy and Infectious Diseases
INN
Danaher
Cytiva
Apc
Australian Respiratory and Sleep Medicine Institute
Sypharma
Oracle
Microsoft
CinnaGen
Pall
Innovate UK
Waters

MERCK MILLIPORE