WHO COVID-19
VACCINE RESEARCH
Dec 06th, 2021
PRESENTED BY: ALLEN LIEN M.D., DrPH
MEDIGEN VACCINE BIOLOGICS CORP
DISCLAIMER:

By their very nature, forward-looking statements for a development process involve inherent risks and uncertainties, both general and specific. Thus there is no assurance or guarantee that any predictions, forecasts, projections and other forward-looking statements will be achieved.

Given the unprecedented circumstances of the COVID-19 pandemic, regulatory uncertainty, funding and rapid production development schedule, all numbers presented as well as schedule must be subject to adaptations and change.
COVID-19
SARS-CoV-2 CHALLENGE STUDY IN NHP - PROTEIN/ADJUVANT VACCINE STUDY 870.2

Goals of Study:
(1) Determine if spike S-2P protein expressed in CHO cells (VRC) induces neutralising antibodies and protection in NHP
(2) Compare immune responses and protection with three different adjuvants using a dose of 15 mcg of protein.

Animals:
- Rhesus macaques
- 4-8 years old
- 6/group, 30 total

Time Points:
- Prime: Aug. 4, 2020
- Boost: Aug. 25, 2020
- Challenge: Apr. 19, 2021

Vaccines:
- A: Spike-S-2P 15 mcg + CpG/Alum
- B: Spike-S-2P 15 mcg + CpG
- C: Spike-S-2P 15 mcg no adjuvant
- D: CpG/alum no antigen

Challenge
B.1.351
Dose: 5 x 10⁶ PFU
Route: IN (1 ml) + IT (3 ml)

Primary Endpoint: BAL Viral Load-Days 2, 4, 7
Secondary Endpoint: Nasal Viral Loads- Day 1, 2, 4, 7
Histo/Path, Viral Load-Lung tissue- Day 7, 8, 9

Source: U.S. NIH
CHALLENGE OF RHESUS MACAQUE WITH BETA VARIANT (8 MONTHS AFTER IMMUNIZATION)

Days Post B.1.351 Challenge

sgRNA_E in BAL

sgRNA_N in BAL

Source: U.S. NIH
COVID-19

CHALLENGE OF RHESUS MACAQUE WITH BETA VARIANT (8 MONTHS AFTER IMMUNIZATION)

Source: U.S. NIH
THE DOSE-DEPENDENT NEUTRALIZING ANTIBODIES AGAINST VOCs

Chia-En Lien et al. Evaluating the Neutralizing Ability of a CpG-Adjuvanted S-2P Subunit Vaccine Against Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Variants of Concern, Clinical Infectious Diseases, 2021, ciab711, https://doi.org/10.1093/cid/ciab711
THIRD BOOSTER DOSE BASED ON BETA STRAIN CONSTRUCT RENDERS WIDER BREADTH OF COVERAGE

Average NT fold reduction over WT

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https://www.biorxiv.org/content/biorxiv/early/2021/10/15/2021.09.29.462344.full.pdf
## TIMELINE FOR STABLE CLONE DEVELOPMENT

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<tr>
<td>1</td>
<td>Plasmid construction</td>
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<tr>
<td>2</td>
<td><strong>Transient expression:</strong> Production of S-2P protein from ExpICHO cells</td>
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<tr>
<td>3</td>
<td><strong>Cell pool expression:</strong> Production of S-2P protein from stable pool of CHO cells (2 L bioreactor)</td>
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<tr>
<td>4</td>
<td><strong>Stable clone expression:</strong> Production of S-2P protein from stable clone of CHO cells</td>
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<td><strong>Cell line development – Single clone Screening</strong></td>
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<td><strong>Cell line development – Single clone development and RCB production</strong></td>
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## COVID-19
### DEVELOPMENT OF VARIANT VACCINE

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THANK YOU

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