SpikoGen Clinical Trial

Dr Saghar Barati

Clinical Pharmacist

CinnaGen Company

vaxine

SpikoGen®
COVID-19 Vaccine

شرکت سینا ژن
CinnaGen

A rapidly growing Australian biotechnology company

Vaxine Pty Ltd

- A rapidly growing Australian biotechnology company based in Adelaide.
- Specialize in pandemic vaccine development and development of 12 human vaccines
- Focusses on the development of innovative vaccine technologies.
- Involved in SARS and MERS vaccine development
- Vaxine's human candidates:

i.	**COVID-19**	V.	West Nile Virus
ii.	Seasonal and pandemic influenza	VI.	Malaria
iii.	Hepatitis B	VII.	Rabies
iv.	Japanese encephalitis	VIII.	Allergy

Flinders UNIVERSITY

Vaxine Pty Ltd

Much of its vaccine development is conducted in collaboration with global collaborators including:

i. The National Institutes of Health (NIH)

ii. The United States Agency for International Development (USAID)

iii. Other vaccine companies and academic research groups

Vaxine Pty Ltd

- First Australian company authorized by TGA to commence phase I clinical trial in Australia

In Australia, the primary approval is given by

The Institutional Human Research Ethics Committee

The Institutional Research Governance Committee

The Therapeutic Good Administration (TGA) is then notified of the decision and the TGA can then put a clinical hold on the trial if they see an issue with the approval or they let it proceed.

Human Research Ethics Committee Approval

Government of South Australia | Health
Central Adelaide Local Health Network

Central Adelaide Local Health Network
Human Research Ethics Committee

North Terrace
Adelaide, SA, 5000

RAH Tel 08 7117 222
TQEH/BHI Tel 08 8222 684

Health.CALHNResearchEthics@
www.health.sa.gov.au

ABN: 96 269 526 412

Approval Date: 30 June 2020

Prof David Gordon
Infectious Diseases Department
FLINDERS MEDICAL CENTRE

Dear Prof Gordon

CALHN Reference Number: R20200601

Project Title: A randomised, controlled, Phase 1 study to evaluate the safety and immunogenicity c candidate adjuvanted recombinant protein SARS-COV-2 vaccine in healthy adult subjects.

Human Research Ethics Committee APPROVAL

Thank you for submitting the above project for ethical and scientific review. The application was first considered by the Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC) at its meeting held 11 June 2020.

The CALHN HREC has reviewed all responses, and I am pleased to advise that the application has be granted full ethics approval. The project meets the requirements of the *National Statement on Ethical Conduct in Human Research (2007)* updated 2018.

The documents reviewed and approved include:

Document	Version	Date
HREA Application – AU/1/835B312	N/A	02 June 2020
Cover Letter	N/A	02 June 2020
Protocol	1.3	24 June 2020
Investigator Brochure	1.1	19 June 2020
Participant Information and Consent Form	3.0	24 June 2020
Supporting Documents: • Participant Diary Card, v1, 02 June 2020 • Participant Symptoms Diary Card, v1, 02 June 2020 • Ethics Cover Letter, 01 June 2020 • Ethics Cover Letter, 19 June 2020 • Supporting Letter - Dr P Hissaria, 24 June 2020 • Supporting Letter – Prof D Gordon, 24 June 2020 • Supporting Letter – Dr P Rolan, 25 June 2020		
Response to request for further information - email	-	19 June 2020
Response to request for further information - email	-	24 June 2020
Response to request for further information - email	-	30 June 2020

Sites covered by this approval:

Site	State	Investigator
PARC Clinical Research	SA	CPI: Prof David Gord
PARC Clinical Research	SA	CPI: Dr Pravin Hissa

CALHN HREC approval is valid for 5 years from: **30 June 2020 to 30 June 2025.**

GENERAL TERMS AND CONDITIONS OF ETHICAL APPROVAL:

1. For all clinical trials, the project must be registered in a publicly accessible trials registry prior to enrolment of the first participant.
2. The CALHN HREC is certified by the NHMRC for National Mutual Acceptance of Single Ethical an Scientific Review. The CALHN HREC is the reviewing HREC for the purpose of this ethics approv Any project sites that are not listed on this letter are not covered by this ethics approval. Any proje

sites that wish to be added must contact the CPI, who must formally request the additional sites to be added by CALHN HREC.

3. Researchers must notify the CALHN HREC of any events which might warrant review of the approval or which warrant new information being presented to research participants, including:
   a) adverse events which warrant protocol change or notification to research participants;
   b) changes to the protocol;
   c) changes to the safety or efficacy of the investigational product, device or method;
   d) premature termination of the project.
4. All clinical trials approved by the CALHN HREC must comply with the NHMRC Guidance on *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (November 2016)*. https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018.
5. The CALHN HREC must be notified within 72 hours of any Urgent Safety Measures (USMs) occurring at this or any approved sites.
6. Confidentiality of the research participants must be maintained at all times as required by law.
7. Adequate record keeping is important and must be maintained in accordance with Good Clinical Practice, NHMRC and state and national guidelines. If the project involves signed consent, researchers must retain the completed Consent Forms which relate to this project and a list of all those participating in the project to enable contact with them in the future if necessary. The duration of record retention for all clinical research data is 15 years from completion of the project.
8. Approval is valid for **5 years** from the date of this letter after which an extension must be applied for.
9. **Annual Progress Reports must be submitted to the CALHN HREC, every 12 months on the anniversary of the above approval date**. In accordance with the National Human and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research 2007 (updated 2018), it is the researchers' responsibility to provide reports of the progress of approved research projects at least annually, and related to the degree of risk to participants, to the reviewing Human Research Ethics Committee (HREC). This report must be completed by the Coordinating Principal Investigator (CPI) for all multi-site projects or the Principal Investigator (PI) for single site projects for all research projects approved under the Central Adelaide Local Health Network (CALHN) HREC. The report is due on the anniversary of HREC approval. Continuation of ethical approval and local governance authorisation is contingent on submission of this report, due within 2 weeks of the approval anniversary. Failure to comply may result in suspension of the project
10. **A Final Report must be submitted to the CALHN HREC on completion of the project and for all site closures.** In accordance with the National Human and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research 2007 (updated 2018), it is the researchers' responsibility to provide a final report of the outcome for completed research projects and for all site closures to the reviewing Human Research Ethics Committee (HREC). This report must be completed by the Coordinating Principal Investigator (CPI) for all multi-site research projects or the Principal Investigator (PI) for single site research projects approved under the Central Adelaide Local Health Network (CALHN) HREC.

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at any site until separate authorisation from the Chief Executive or delegate of that site has been obtained. For any queries, please contact the CALHN Governance Office: Health.CALHNResearchGovernance@sa.gov.au

The CALHN HREC is constituted in accordance with the NHMRC's *National Statement on the Ethical Conduct of Human Research (2007)* incorporating all updates.

Should you have any queries about the CALHN HREC's consideration of your project, please contact the CALHN HREC Support Officer on 08 7117 2229, or Health.CALHNResearchEthics@sa.gov.au.

The CALHN HREC wishes you every success in your research.

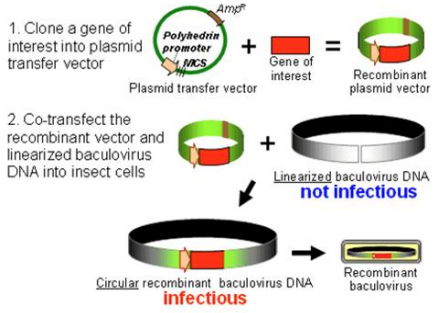
Yours sincerely,

Vaccine Formulation

a protein subunit vaccine against COVID-19 produced in insect cells

SpikoGen® COVID-19 Vaccine - a protein subunit vaccine against COVID-19 produced in insect cells

Spike Protein gene cloned into baculovirus	Optimization of Insect Cell Expression System	Large scale bioreactor cell culture and protein purification



- Robust protein expression platform (also used for Cervarix, Flublok, Provenge)

Avecia · cytiva · PALL Pall Corporation · apc · Expression Systems · Merck Millipore · Oxford Expression Technologies · sypharma · Waters The Science of What's Possible.

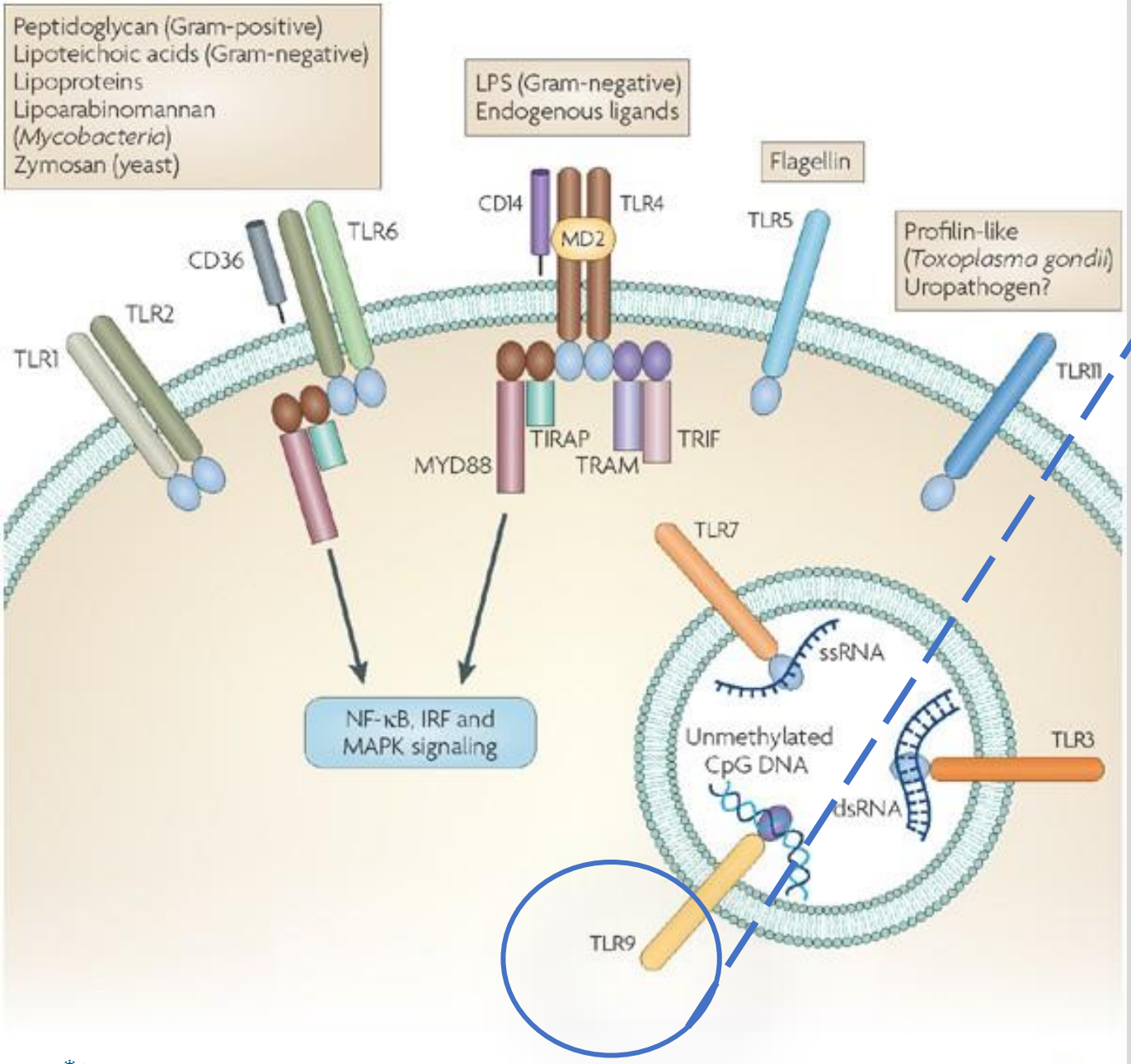
Investigational Product

SARS-CoV-2-S protein

Advax delta inulin suspension

CpG55.2

These ingredients are then mixed together in the final syringe by a pharmacist.



Toll-like receptor (TLR)-9 innate immune receptors are expressed on immune cells and are used to initiate innate immune responses in response to viral and other pathogens

CPG binds and activates TLR9, resulting in innate immune activation. By inducing DCs to produce IL-12, CpG results in Th1 polarization of the immune response.

CpGs activate TLR9 thereby stimulate Th1 T cells and production of Th1 cytokines including TNFα and IFNγ

38 Clinical Trials

SpikoGen®
COVID-19 Vaccine

CPG

No	Clinical Trial	Registered Code
1	A Controlled Phase 2/3 Study of Adjuvanted Recombinant SARS-CoV-2 Trimeric S-protein Vaccine (SCB-2019) for the Prevention of COVID-19 (SCB-2019)	NCT04672395
2	VELOCITY: An Anthrax Vaccine Clinical Study	NCT03877926
3	Flublok or Fluzone With Advax-CpG	NCT03945825
4	HepB-CpG Series for Healthcare Workers Who Are Hepatitis B Vaccine Nonresponders	NCT04456504
5	Vaccine Therapy in Treating Patients With Stage IIC-IV Melanoma	NCT00085189
6	KBP-201 COVID-19 Vaccine Trial in Healthy Volunteers	NCT04473690
7	Immunotherapy of Stage III/IV Melanoma Patients	NCT00112242
8	A CpG-methylation-based Assay for Stratifying Stage III Clear Cell Renal Cell Carcinoma of Receiving Adjuvant Treatment	NCT02688491
9	Safety of and Immune Response to a Malaria Vaccine (MSP1 42-C1) With or Without CPG Adjuvant	NCT00320658
10	Safety and Immunogenicity Study of Na-GST-1 With or Without CpG	NCT02143518
11	Na-GST-1/Alhydrogel With or Without CpG 10104 in Gabonese Adults	NCT03373214
12	Vaccine Therapy in Treating Patients With Recurrent Stage III or Stage IV Melanoma That Cannot Be Removed by Surgery	NCT00471471
13	NY-ESO-1 Protein With Montanide and CpG 7909 as Cancer Vaccine in Several Tumors	NCT00299728
14	Safety and Immunogenicity of Malaria Vaccines AdCh63 AMA1, MVA AMA1 and AMA1-C1/Alhydrogel®+/- CPG 7909	NCT01351948
15	BARDA Securing Anthrax Immunity For the Elderly (B-SAFE)	NCT03518125
16	SCB-2019 as COVID-19 Vaccine	NCT04405908
17	Phase I Study of AMA1-C1/Alhydrogel® (Registered Trademark) + CPG 7909 Malaria Vaccine	NCT00427167

CPG

No	Clinical Trial	Registered Code
18	A Controlled Phase 2/3 Study of Adjuvanted Recombinant SARS-CoV-2 Trimeric S-protein Vaccine (SCB-2019) for the Prevention of COVID-19 (SCB-2019)	NCT04672395
19	VELOCITY: An Anthrax Vaccine Clinical Study	NCT03877926
20	Flublok or Fluzone With Advax-CpG	NCT03945825
21	HepB-CpG Series for Healthcare Workers Who Are Hepatitis B Vaccine Nonresponders	NCT04456504
22	Vaccine Therapy in Treating Patients With Stage IIC-IV Melanoma	NCT00085189
23	KBP-201 COVID-19 Vaccine Trial in Healthy Volunteers	NCT04473690
24	Immunotherapy of Stage III/IV Melanoma Patients	NCT00112242
25	A CpG-methylation-based Assay for Stratifying Stage III Clear Cell Renal Cell Carcinoma of Receiving Adjuvant Treatment	NCT02688491
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CPG

No	Clinical Trial	Registered Code
35	A Controlled Phase 2/3 Study of Adjuvanted Recombinant SARS-CoV-2 Trimeric S-protein Vaccine (SCB-2019) for the Prevention of COVID-19 (SCB-2019)	NCT04672395
36	VELOCITY: An Anthrax Vaccine Clinical Study	NCT03877926
37	Flublok or Fluzone With Advax-CpG	NCT03945825
38	HepB-CpG Series for Healthcare Workers Who Are Hepatitis B Vaccine Nonresponders	NCT04456504

Advax™

1) Attract additional monocytes to the site of antigen administration

2) Upregulates surface molecules involved in antigen presentation, T- and B- cell co-stimulation and chemotaxis including MHC class I and II, CD11c, CD80, and CD86

3) Enhanced ability to present antigen to and activate B cell and CD4 and CD8 T-cells in the draining lymph node, with resultant memory T cell and plasma cell generation

19 Clinical Trial

Advax™

No	Clinical Trial	Registered Code
1	Flublok or Fluzone With Advax-CpG	NCT03945825
2	Safety and Immunogenicity of TBC-M4, a MVA HIV Vaccine Alone or in a Prime-Boost Regimen With ADVAX DNA HIV Vaccine	NCT00902824
3	A Phase 1 Study to Evaluate the Immunogenicity and Safety of a Pandemic Avian Influenza Vaccine in Adults (FLU003)	NCT02335164
4	Study of Sting Challenge and Serological Responses to Jack Jumper Venom Immunotherapy With Inulin as Adjuvant (Jumpvax) (Jumpvax)	NCT03066986
5	Safety and Efficacy Study of Adjuvanted Prophylactic Hepatitis B Vaccine	NCT01951677
6	Recombinant H7 Hemagglutinin Influenza Vaccine Trial (FLU007)	NCT03038776
7	Randomized controlled trial demonstrating the benefits of delta inulin adjuvanted immunotherapy in patients with bee venom allergy	PMID: 31300280
8	A study in healthy adults of a randomised, controlled vaccine intervention study evaluating the safety and immunogenicity of a Hepatitis B vaccine containing Advax adjuvant (HBV001)	ACTRN 12607000598482

Advax™

No	Clinical Trial	Registered Code
9	A randomised, controlled Phase 1/2 study in healthy adults of a seasonal influenza vaccine containing an inulin-based adjuvant to evaluate safety and immunogenicity (FLU001)	ACTRN 12607000599471
10	Randomized, controlled Phase 1/2 study to evaluate the safety and effectiveness of an enhanced potency adjuvanted seasonal influenza vaccine in patients with chronic disease and the elderly (FLU002)	ACTRN 12608000364370
11	A randomised, controlled Phase 1/2 study in healthy adults to evaluate the safety and immunogenicity of an inulin-adjuvanted seasonal trivalent inactivated influenza vaccine (FLU004)	ACTRN 12608000350325
12	A randomised, controlled Phase 1/2 study of adults with bee venom allergy to evaluate the safety and efficacy of an Advax-adjuvanted bee venom desensitization regime (BEE001)	ACTRN 12608000379314
13	A randomised, controlled, study in healthy adults to evaluate the safety and immunogenicity of an adjuvanted recombinant 2009 H1N1 pandemic swine influenza vaccine (FLU005)	ACTRN 12609000674235
14	A randomised controlled trial to evaluate the immune response to an adjuvanted 2012 seasonal trivalent inactivated influenza vaccine in adults delivered via needle and syringe or jet injector device (FLU006)	ACTRN 12612000709842
15	Safety, Tolerability and Immunogenicity of Two Different Formulations of an Influenza A Vaccine (FP-01.1_CS_02)	NCT01677676
16	Influenza A Vaccine (FP-01.1) Formulated With and Without Adjuvant, in the Presence or Absence of a Single Administration of a Trivalent Inactivated Influenza Virus Vaccine in Older Adults (FP-01.1_CS_03)	NCT01701752
17	Single-center, randomized, controlled, blinded Phase 1/2 study to compare the safety and effectiveness of Hepatitis B vaccine (HBV002)	NCT01951677
18	A Phase 1 clinical study of a jumper jack ant venom allergy desensitisation vaccine including Advax delta inulin adjuvant.	NCT03066986
19	A Phase 1b/2 dose ranging study to evaluate the safety and immunogenicity of Covax-19, a candidate recombinant protein COVID-19 vaccine	NCT04453852

Advax-CpG murine influenza studies

The co-formulation of Advax with CpG resulted in enhanced production of all IgG subtypes in immunized mice, resulting in the highest overall anti-influenza IgG levels in immunized mice.

Advax-CpG ferret influenza studies

Advax-CpG adjuvant with inactivated H5N1 influenza vaccine in the ferret model provided complete protection from lethal challenge with avian influenza, and markedly diminished all measures of morbidity following challenge.

Advax-CpG non-human primate studies

Both Advax and CpG used as single adjuvants enhanced the IgG response to HBsAg over antigen alone, but the combination of both adjuvants gave the highest overall IgG levels.

Studies in Special Populations

1. Neonates

Inactivated influenza vaccine (iH1N1) combined with Advax™ adjuvant administered as a single immunization to 7-day-old mouse pups significantly enhanced serum influenza- specific IgM, IgG1, IgG2a and IgG2b levels in association with a 3-4 fold increase in the frequency of splenic influenza specific IgM and IgG antibody secreting cells versus pups immunized with iH1N1 alone.

2. Pregnancy

Advax-CpG adjuvant was tested in mice with a RSV prefusion F protein vaccine administered to pregnant dams where it was safe and enhanced RSV neutralizing antibody production, thereby providing enhanced protection of pups via transfer of anti-RSV antibodies in the breast. No adverse effects were observed on the pregnant dams or their subsequent litters from immunization with vaccine formulated with Advax-CpG.

3. Reproductive toxicology

Vaccination of female mice with influenza vaccine formulations containing Advax-CpG adjuvant had no effect on fertility.

COVAX-19™

Pre-clinical and

Clinical Studies

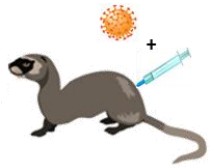
COVAX-19TM
4 major studies to date

Murine study

Key outcomes

- Vaccine was well tolerated
- Induction of neutralizing antibodies
- Strong Th1 T-Cell Immunity

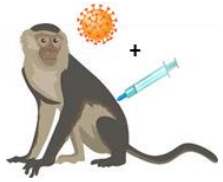
Ferret challenge study



Key outcomes:

- Protection against nasal virus shedding (sterilizing immunity)

Monkey challenge study



Key outcomes:

- Vaccine was well tolerated
- Protection against viral pneumonia
- Prevention lung virus replication (Sterilizing immunity)

Human Phase 1 trial

Subjects: 40

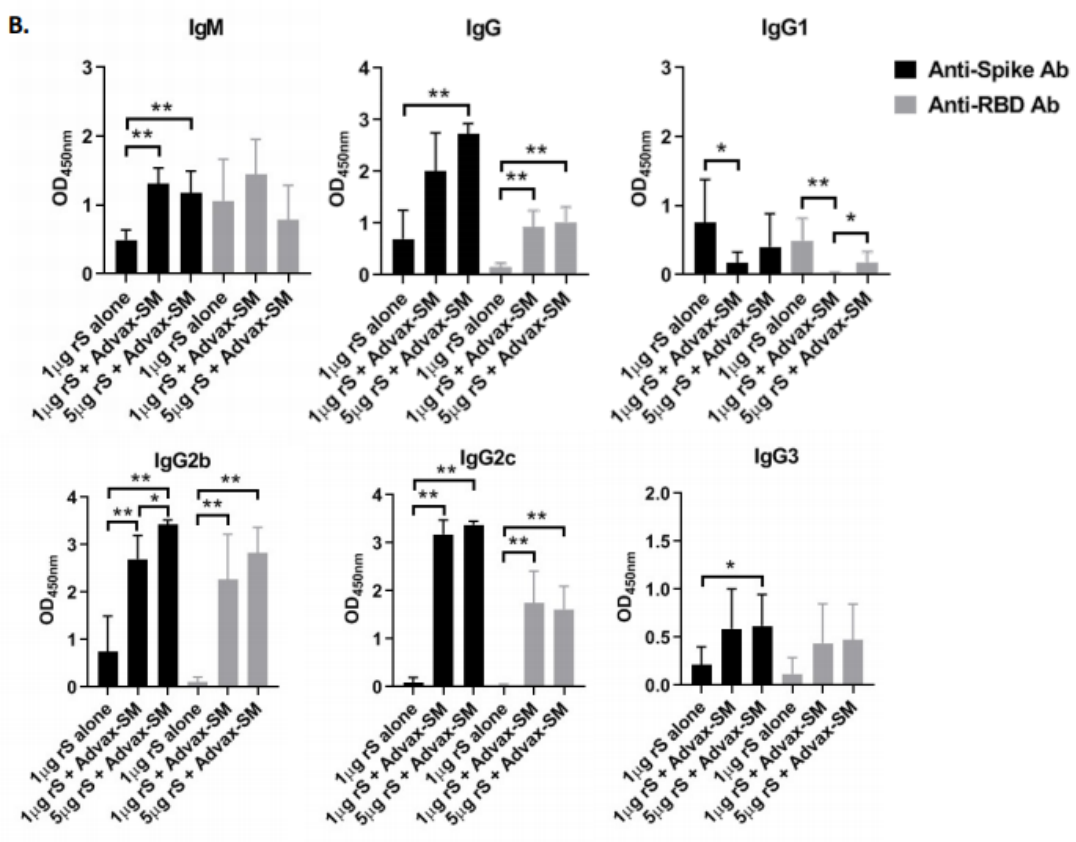
Completion: Sept 2020 -analysis ongoing

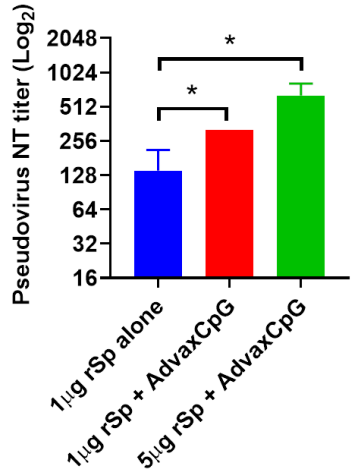
Key outcomes:

- Well tolerated, no safety issues

Mice Study Results of COVAX-19™

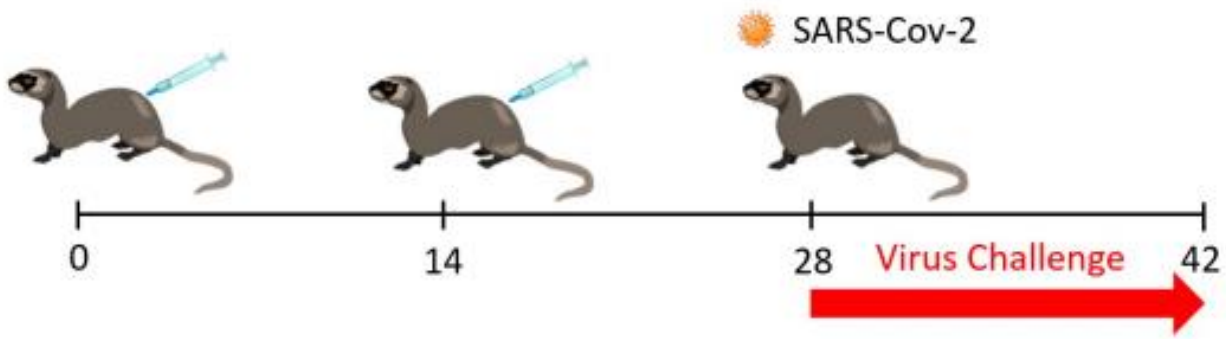
Mice testing: COVAX-19™ immunogenicity
Enhanced Antibody and T Cell Response

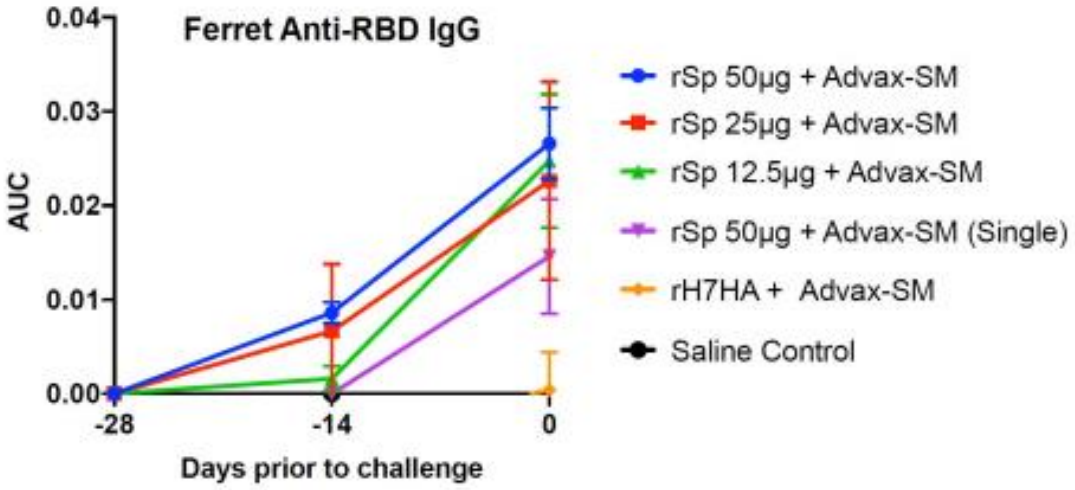




5 times higher neutralization activity

Ferret Study Results of COVAX-19™

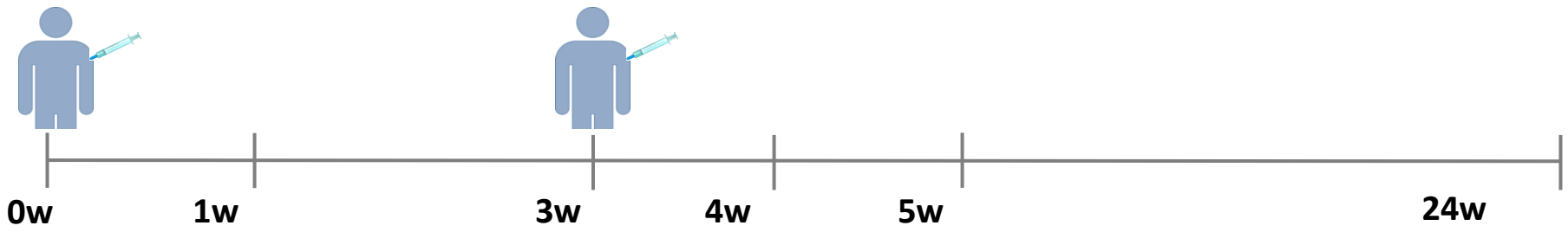




Phase I Clinical Trial of **COVAX-19™**

First Australian COVID-19 Vaccine to commence Phase 1 Human Clinical Trials

- Phase I Human Clinical Trial (NCT04453852) commenced July 2, 2020
- Healthy participants 18-65 years. Forty subjects (30 Covax-19, 10 saline)
- Received two doses vaccine 3 weeks apart. Blood sera was collected pre and post-immunization.
- No reports of serious adverse events



Phase I Human Clinical Trial: Local AEs

Covax-19 vaccine Group						
	First Immunization			Second Immunization		
	Mild	Moderate	Severe	Mild	Moderate	Severe
Pain	24	3	2	14	3	1
Swelling	6	2	0	6	1	0
Redness	3	0	0	4	1	0
Itching	2	0	0	2	1	0

	Vaccine Group		Saline Group	
Systemic AEs	Total No. of events	No. of subjects experiencing an event	Total No. of events	No. of subjects experiencing an event
Headache/Migraine	27	14	4	2
Muscle ache	15	9	0	0
Fatigue	14	9	2	2
Dizziness	8	6	1	1
Nausea	6	4	1	1
Joint pain	4	3	0	0
Coryzal-like symptoms	2	2	0	0
Skin rash	2	2	0	0
Shivering	2	2	0	0
Diarrhea	2	1	0	0
Dysgeusia	2	1	0	0
Nasal congestion	2	1	0	0
Upper respiratory tract infection	1	1	0	0
Back pain	1	1	1	1
Palpitation	1	1	0	0
Positive IGRA test	1	1	0	0
Bursitis, Knee	1	1	0	0
Skin lump	1	1	0	0
Diaphoresis	1	1	0	0
Herpes simplex lesion	0	0	1	1
Otitis externa	0	0	1	1
Sore throat	0	0	1	1
Allergy symptoms	0	0	1	1
Rhinorrhoea	0	0	1	1

Phase I Human Clinical Trial: Antibody against S1/S2

	Vaccine (n/total gp size (%))	Saline Control (n/total gp size (%))
Seropositive at baseline	4/30 (13.3%)	2/9 (22.2%)
Seropositive at Visit 5	18/28 (64.2%)	3/9 (33.3%)
Increase in Seropositive frequency from Visit 1 to Visit 5	15/25 (60.0%)	2/7 (28.5%)

Immunogenicity results
Antibody Produced by memory B cells (CELISA)

19 subjects in vaccine group VS, 1 subject in saline group, had memory B cells secreting IgG against SARS-CoV-2 spike protein 1 week after second immunization

Immunogenicity results
Antibody Produced by memory B cells (CELISA)

19 subjects in vaccine group VS, 1 subject in saline group, had memory B cells secreting IgG against SARS-CoV-2 spike protein 1 week after second immunization

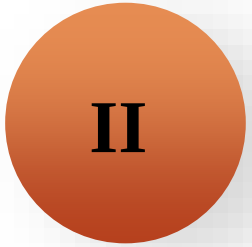
Phase II study

Study Endpoints

The main purpose of this phase II study was to evaluate the adverse events of Solicited up to 7 days after each dose and the adverse events of Unsolicited up to 28 days after each dose of Vaccine.

- The primary immunogenicity objectives of this phase II study were to evaluate seroconversion against S protein

Phase II study design



Phase of study

Randomized

Ratio

Double-blind

Placebo control

Intervention details

Vaccine:

- Vial (injection solution) of the vaccine at a dose of 25 mcg, of which 2 doses are given 21 days apart.
- This injection is given IM in the deltoid muscle (nondominant arm).
- The vaccine is a recombinant S protein from the SARS-CoV-2 virus that is injected with the Advax-CpG adjuvant.
- The vaccine is offered as a sterile solution for injection and is white in appearance.
- The concentration of the vaccine is 0.05 mg/ml in PBS buffer and contains 0.01% tween 80%.
- Placebo: 0.9% normal saline

Secondary Endpoints

- Evaluation and comparison of individuals who developed seroconversion for bAb against protein RBD on days 21 and 35.
- GMC measurement for Binding Ab(bAb) against RBD virus on days 0, 21, 35
- GMFR measurement for Binding Ab against RBD on days 21,35
- GMC measurement for neutralizing antibody (nAb) against SARS-CoV-2 virus on days 0, 21, 35
- GMFR measurement for neutralizing antibody (nAb) against SARS-CoV-2 virus on days 21, 35
- Evaluation and comparison of individuals who developed seroconversion for neutralizing antibody (nAb) against SARS-CoV-2 virus on days 21 and 35.
- GMC measurement for IgA against S virus on days 0, 21, 35
- GMFR measurement for IgA against S on days 21,35
- Evaluation and comparison of individuals who developed seroconversion for IgA against RBD and S on days 21 and 35
- Evaluation of neutralizing antibodies via conventional virus neutralizing test
- Evaluation of cellular immunity by examining the percentage of proliferation (CD4/ CD8) and interferon gamma release on days 0, 21, 35
- Occurrence of serious adverse and suspicious unexpected events within 6 months after second immunization

Phase III study

Primary Endpoints

Evaluation of COVID-19 disease from 14 days after the second dose injection.

Secondary Endpoints

Evaluation of severe cases of COVID-19 disease from 14 days after the second dose injection and evaluation of adverse events

SpikoGen®
COVID-19 Vaccine

Manufacturing Capacity

Production Yield:
~100 doses/Lit Cell Culture Volume

CinnaGen Potential Production Capacity:
11000 Lit Culture eq. to
>1 million doses/lot

3 to 4 lots/month leading to
3 to 4 millions doses/month

All Together
Towards Science

Because All Lives Matter