FREQUENTLY ASKED QUESTIONS (FAQ) ABOUT CONVIDECIA™ RECOMBINANT NOVEL CORONAVIRUS VACCINE (ADENOVIRUS TYPE 5 VECTOR) SOLUTION FOR INJECTION

Q1: Which COVID-19 vaccine and what indication(s) is being registered?

A1: The Drug Control Authority (DCA) in its 359th meeting has granted **Convidecia (Trade Mark) Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector) Solution for Injection** (Product Registration Holder: Solution Biologics Sdn. Bhd.; Manufacturer: CanSino Biologics Inc. China) a CONDITIONAL REGISTRATION on 15th June 2021.

Each vial of Convidecia Vaccine contains 0.5ml (single dose) or three doses per vial (1.5 ml per vial, 0.5 ml per dose) filled in a 2ml glass vial.

Each dose (0.5ml) of Convidecia Vaccine not less than 4×10^{10} viral particles of replication-defective recombinant human Type 5 Adenovirus expressing S protein of SARS-CoV-2.

On 6th January 2022, the DCA in its 368th meeting concluded that a booster dose of Convidecia may be administered at least 3-6 months after the first single dose in individuals aged 18 years and above.

Q2: What are the conditions of the registration?

A2: Since the registration application is via "Conditional Registration of Pharmaceutical Products during Disaster", the approval is based on rolling submission of the latest data, the Product Registration Holder (PRH) will need to ensure all outstanding documents are to be submitted and deemed satisfactory by NPRA according to the timeline given.

Apart from that, the PRH is required to monitor the safety profile of the registered vaccine and inform NPRA soonest possible of any untoward events. The PRH is also required to conduct all activities planned under the Risk Management Plan (RMP) as well as submit a Monthly Safety Summary Report to NPRA.

The validity of this conditional approval is one (1) year. During this period, the DCA will periodically be updated with all necessary information related to the quality, safety and efficacy of this vaccine. The conditional registration can be revoked if the conditions are not fulfilled by the PRH or if the benefit over risk of the vaccine is no longer deemed beneficial.

Q3: Why is Convidecia granted conditional registration?

A3: Clinical studies for Convidecia Vaccine are currently still ongoing. The current interim analysis provided shows a positive benefit over risk and hence making this available to the nation. However, further monitoring of the efficacy and safety will be needed in order to ensure that the benefit-risk balance of this vaccine remains positive.

Q4: Who can be given Convidecia?

A4: Convidecia Vaccine is indicated for the active immunization to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals **18 years of age and older**. The use of this vaccine should be in accordance with the recommendations by the Ministry of Health Malaysia.

Q5: Who can't be given Convidecia?

A5: Convidecia Vaccine should not be given to

a) People who are known to have allergic reactions to any of the ingredients in the vaccine [*Mannitol, sucrose, sodium chloride, magnesium chloride, magnesium chloride, polysobate 80, glycerine, N-(2-Hydrxyethyl) piperazine-N'-(2-ethanesulfonic acid)(HEPES) and Water for Injection*].
b) People who have experienced severe allergic reactions to vaccines in the past (such as acute allergic reactions, angioedema, dyspnea, etc).
c) People with uncontrolled epilepsy and other progressive neurological diseases, and a history of Guillain-Barré syndrome.
d) Pregnant and lactating women

Q6: Can immune-compromised populations receive Convidecia?

A6: At the moment, there is insufficient clinical evidence to support vaccination in this population: Impaired immune function (patients with a malignant tumour, nephrotic syndrome, AIDS) including those receiving immunosuppressant therapy. Use of Convidecia in these individuals should be in consideration of a potentially lowered immune response. Human immunoglobulin injections should be given at least one-month interval before or after the administration of the vaccine to avoid lowered immune response.

However, these recommendations may change as more clinical data is obtained. Please speak to your doctor to identify if you may be a suitable candidate to receive the vaccine.

Q7: If I have the following conditions, or receiving or have received these treatments, can I receive the vaccine?

A7: Please consult your doctor if;

a) You are suffering from acute diseases, acute-outbreak period of chronic diseases, severe chronic diseases, allergies and fever. If necessary, the vaccination shall be delayed after the doctor's evaluation.
b) You have diabetes, history of asthma, history of convulsions, epilepsy, encephalopathy, mental illness or family history of mental illness.
c) You have thrombocytopenia or any coagulation dysfunction since intramuscular injection of this vaccine may cause bleeding.
d) You had a previous history of COVID-19 infection, had previously received another COVID-19 vaccine (whether during an immunisation program or was

involved as a subject in a COVID-19 clinical study) or previously received passive antibodies therapy for COVID-19.

You may receive the vaccine even if you have the above conditions. However, please speak with your doctor before deciding if you are a suitable candidate.

Q8: How is Convidecia given?
A8: Convidecia should be injected into the deltoid muscle of the upper arm as a course of a SINGLE dose (0.5mL one dose). A booster dose of Convidecia may be given approximately 3-6 months after the first single dose in individuals aged 18 years and above. The need for when and whom to be given the booster dose will be determined by the local recommendation.

Q9: How well does Convidecia prevent COVID-19?
A9: Based on the interim analysis of Phase III clinical trial, the vaccine was 65.28% (95%CI: 45.73-77.79) effective in preventing symptomatic COVID-19 disease 28 days after the single dose of the vaccine. This fulfilled the efficacy standard as recommended by WHO, where the primary efficacy endpoint point estimate for a placebo-controlled efficacy trial should be at least 50%, and the lower bound of confidence interval (CI) should be >30%.

The protective efficacy in severe cases was 90.07% (95%CI: 22.41, 98.73) from the interim analysis. More data is expected from the ongoing Phase III trial.

Q10: How long will Convidecia provide protection?
A10: As the clinical trial is still currently ongoing, no data is available on the duration of protection that the vaccine will provide. This however will be made known once updated data is available.

Q11: Can people who have already had COVID-19 get Convidecia?
A11: There is no evidence of the efficacy & safety of Convidecia for people with COVID-19 infection history at this point of time. Since previously infected individuals can be at risk of COVID-19 (i.e. reinfection), vaccination may be offered to them. However, please speak with your doctor before deciding if you are a suitable candidate.

Q12: Can elderly receive Convidecia?
A12: The vaccine is indicated for people aged 18 years and above. However, based on the current available clinical data, there is limited number of subjects aged 60 years and above recruited and analysed therefore the data in this population are limited. Based on early phase data, administration of Convidecia to individuals aged 60 years and above has shown lowered neutralizing antibodies titres as compared to younger adults. At present, it is recommended that vaccination for people aged 60

and above should be cautiously considered, its necessity should be evaluated based on their health condition and exposure risk.

Q13: Can children receive Convidecia?
A13: Currently in Malaysia, the vaccine is indicated for individuals 18 years and above. This is because there is not enough data yet to determine the effectiveness and safety of this vaccine in those under 18 years old. Hence children below the age of 18 should not take the vaccine until further data is made available.

Q14: What are the side effects of Convidecia?
A14: Convidecia can cause the following side effects:

- Very common side effects (may affect more than 1 in 10 people): injection site pain, fever, headache, fatigue, muscle pain, drowsiness, nausea, and diarrhea.
- Common side effects (may affect up to 1 in 10 people): injection site swelling, itch, redness, hardening, joint pain, cough, sore throat, vomiting, loss of appetite, dizziness, and itchiness (non-injection site).
- Uncommon side effects (may affect up to 1 in 100 people): injection site bleeding, rash, cellulitis (skin infection), loss of sensation, gastrointestinal disorder, joint swelling, fainting, difficulty in breathing and acute allergic reaction.

Recipient will be monitored 15-30 minutes after the administration of this vaccine at the vaccination centre.

The overall incidence of adverse reactions after booster vaccination is found to be similar to that of the first dose.

During marketing of Convidecia in Malaysia, NPRA will monitor its use to ensure effectiveness and safety. Please inform your healthcare providers or report any side effects to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers > Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Q15: Can Convidecia cause thromboembolic events (blood clots) following vaccination?
A15: Based on the known clinical data, thromboembolic events are not among the known or typical side effects of Convidecia.

Please seek immediate medical attention if you develop shortness of breath, chest pain, leg swelling, or persistent abdominal pain following vaccination.
Also, please seek immediate medical attention if you experience after a few days severe and/or persistent headaches or blurred vision after vaccination, or experience

skin bruising or pinpoint round spots beyond the site of vaccination that appears after a few days.

Q16: What should I do after I am vaccinated?
A15: All individuals should continue to follow the country's SOP. Practice the 3Ws (**Wash**, **Wear**, **Warn**) and avoid the 3Cs (**Crowded** space, **Confined** space, **Close** conversation).

For further information regarding **Convidecia (Trade Mark) Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector) Solution for Injection***, please refer to the Package Insert and Patient Information Leaflet.*
(https://quest3plus.bpfk.gov.my/pmo2/detail.php?type=product&id=MAL21066050AZ)

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