

# SARS-CoV-2 mRNA Vaccine

## Indo-made thermostable Covid-19 mRNA vaccine

Stable at 2-8°C for as long as 12 months, easy storage and distribution, administrable without freeze-thaw procedure

The 1<sup>st</sup> Halal mRNA vaccine in the world

The 1<sup>st</sup> locally produced mRNA vaccine

Easily scalable with short manufacturing time to ensure responsiveness to emerging outbreaks



Non-clinical research published in *Cell*



Phase I clinical research published in *The Lancet Microbe*



Heterologous boosting research published in *Cell*



### SARS-CoV-2 mRNA Vaccine

#### Product Description

An mRNA-based vaccine encoding the receptor-binding domain (RBD) of spike glycoprotein (S protein) of SARS-CoV-2

#### Indication

To prevent COVID-19 caused by the infection of SARS-CoV-2 in adults 18 years of age and above

#### Presentation

Pre-filled syringe, 1×0.5 mL single human dose, 1 dose per package

#### Immunization Schedule

- As primary series: 2 dose (28 days apart)
- As a heterologous booster: 1 dose (≥ 6 months after complete regimen of inactivated Covid-19 vaccines)

### Better Performance in Stability



Based on currently available long-term stability study data<sup>[1]</sup>, quality of SARS-CoV-2 mRNA Vaccine complies with specification after stability test for **12 months at 2-8°C**



Our mRNA Vaccine  
2°C to 8°C



Other mRNA Vaccines  
-70°C to -20°C

SARS-CoV-2 mRNA Vaccine does not require ultra-cold storage, dry ice or other special conditions that might be more difficult in the distribution<sup>[2]</sup>

### Made in, and Made for Indonesia

#### The 1<sup>st</sup> Halal mRNA Vaccine Certified by LPPOM-MUI

Indonesian Supreme Court issued an decision (31 P/HUM/2022) that requires the Government to use only Halal vaccines for the public



Halal Certificate Number : ID00410000248600522

#### Aimed for future vaccine security and self-reliance



Local production complies with Domestic Content Level (TKDN) policy implementation emphasized by the president of Indonesia



Indonesia through PT Etana Biotechnology already has the capability for mRNA technology



Ensuring sufficient supply for mass vaccination

### A Safe and Effective Covid-19 mRNA Vaccine

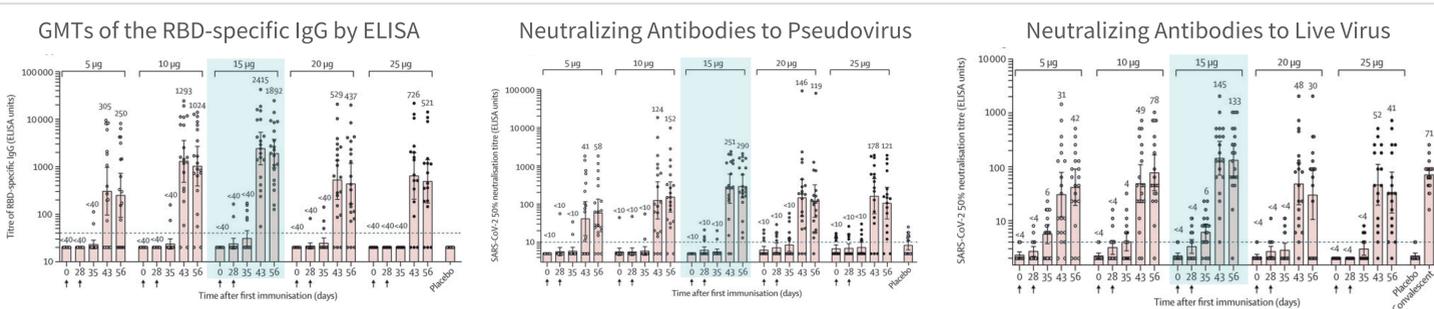
#### Acceptable Safety Profile as Both 2-dose Series and Single Heterologous Booster Dose

The safety profile with the 2-dose regimen has been well characterized by common local (injection-site pain, redness, swelling, etc.) and systemic adverse reactions (fever, headache, fatigue/weakness, myalgia, etc.) which are similar to marketed mRNA vaccines post immunization, with the severity being generally mild to moderate

Following a heterologous booster dose of SARS-CoV-2 mRNA vaccine, common adverse reactions of fever, headache, and injection-site pain were observed, showing an acceptable safety profile<sup>[3]</sup>

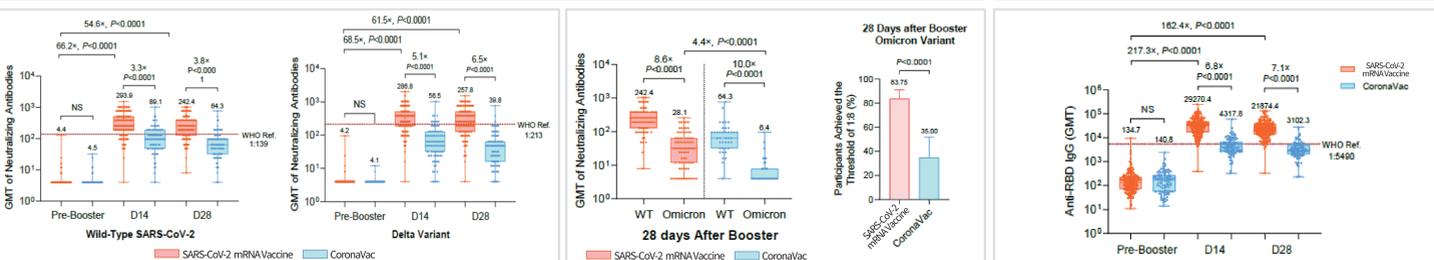
#### Robust Immunogenicity Profile as Both 2-dose Series and Single Heterologous Booster Dose

Potent immunogenicity elicited following 2-dose series administered 28 days apart<sup>[4]</sup>



Marked increase in GMT of neutralizing antibodies to live WT SARS-CoV-2 (66.2x), Delta variant (68.5x), and Omicron variant (4.4x vs inactivated Covid-19 vaccine)<sup>[3]</sup>

Dramatic increase of GMT of anti-RBD IgG antibodies to WT SARS-CoV-2. Dramatic increase in GMT of anti-RBD IgG antibodies to WT SARS-CoV-2 (217.3x) after heterologous booster dose<sup>[3]</sup>



#### References

- ZHAO H, WANG T-C, LI X-F, et al. Long-term stability and protection efficacy of the RBD-targeting COVID-19 mRNA vaccine in nonhuman primates [J]. *Signal Transduction and Targeted Therapy*, 2021, 6(1): 438.
- ZHANG N-N, LI X-F, DENG Y-Q, et al. A Thermostable mRNA Vaccine against COVID-19 [J]. *Cell*, 2020, 182(5): 1271-83.e16.
- Liu, X., Li, Y., Wang, Z. et al. Safety and superior immunogenicity of heterologous boosting with an RBD-based SARS-CoV-2 mRNA vaccine in Chinese adults. *Cell Res* 32, 777-780 (2022). <https://doi.org/10.1038/s41422-022-00681-3>
- CHEN G-L, LI X-F, DAI X-H, et al. Safety and immunogenicity of the SARS-CoV-2 ARCoV mRNA vaccine in Chinese adults: a randomised, double-blind, placebo-controlled, phase 1 trial [J]. *The Lancet Microbe*, 2022.