

**Sayı:** 17812098-TİM.AKİB.GSK.SAN.2022/564-5251  
**Konu:** Endonezyalı Aşı/İlaç Firmasının İşbirliği Talebi Hk.

Mersin, 9/11/2022

**Sayın Üyemiz,**

Ticaret Bakanlığından iletilen yazıda, Endonezya’da kanser ve Covid-19’a karşı aşı ve ilaç geliştirme çalışmaları yürüten PT Etana Biotechnologies Indonesia (“Etana”) firmasının yatırım ve ürün tedariki konusunda firmalarımızın iş birliği taleplerine açık olduğu ifade edildiği belirtilmektedir.

Bilgilerini rica ederim.

**Mehmet Ali ERKAN**  
**Genel Sekreter**

**Ek**

- 1- Ek2-ETANA firma tanıtımı.pdf
- 2- Ek3\_Corona MRna Aşısı Broşürü.pdf
- 3- Ek4-ETANA firma yazısı.pdf





# PT Etana Biotechnologies Indonesia

Jakarta, September 2022

5070 sayılı kanun gereğince güvenli elektronik imza ile imzalanmıştır. ID:3976281262022119978. Bu kod ile <http://evrak.akib.org.tr/> adresinden doğrulayabilirsiniz.

PT Etana Biotechnologies Indonesia is engaged in manufacturing and sales of biopharmaceutical products. PT Etana already built a PIC/S compliance state-of-the-art biopharmaceutical facility in Jakarta and develop strong collaboration with leaders of biopharmaceutical industries



PTEBI Manufacturing Facility

### Finished product:

- Erythropoietin
- Bevacizumab
- Covid-19 Vaccine
- Covid-19 Drugs



VISION	DIVISION	MISSION
To become ASEAN most valuable biopharmaceutical company with extensive Biopharmaceutical's portfolio	<ul style="list-style-type: none"> <li>• Oncology Division (MAB, Chemicals)</li> <li>• Anti Infectious (Vaccine, Drugs)</li> <li>• Others</li> </ul>	Providing high quality, affordable and innovative biopharmaceutical for ASEAN and Muslim countries

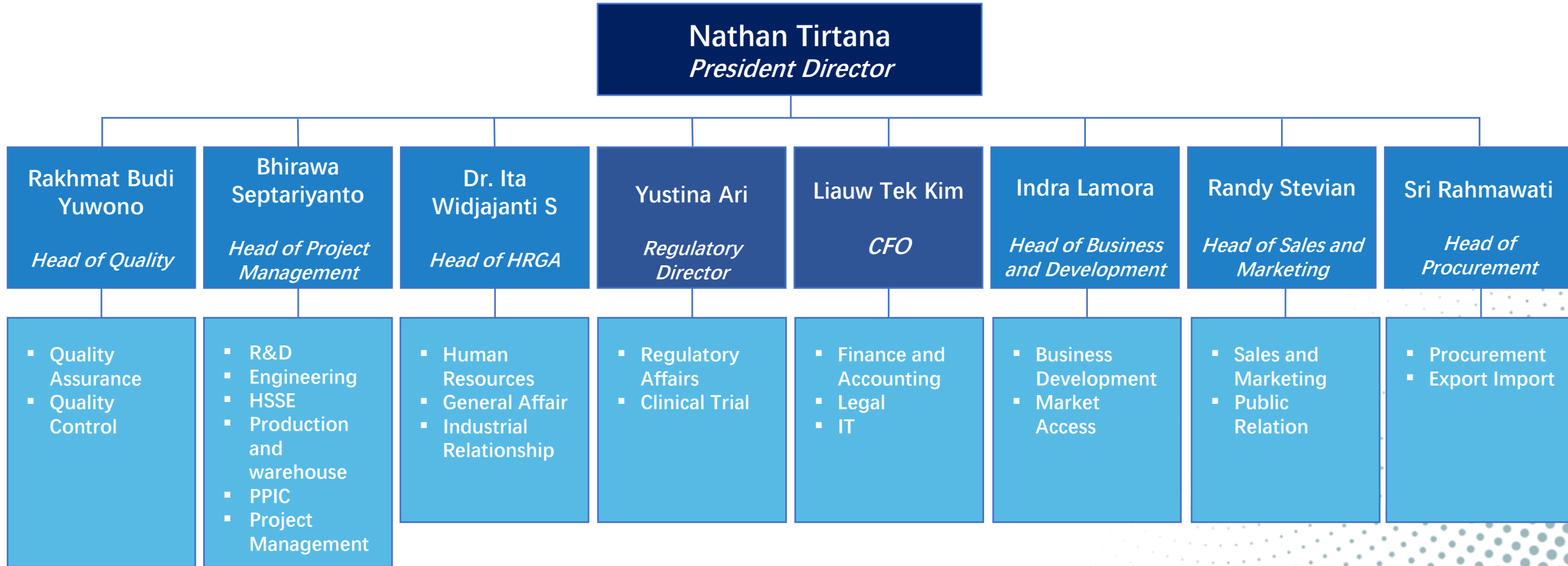
# Etana means “ Strength in Purpose”

**Our Purpose: Serve patients by providing high quality, affordable and innovative biopharmaceutical products**

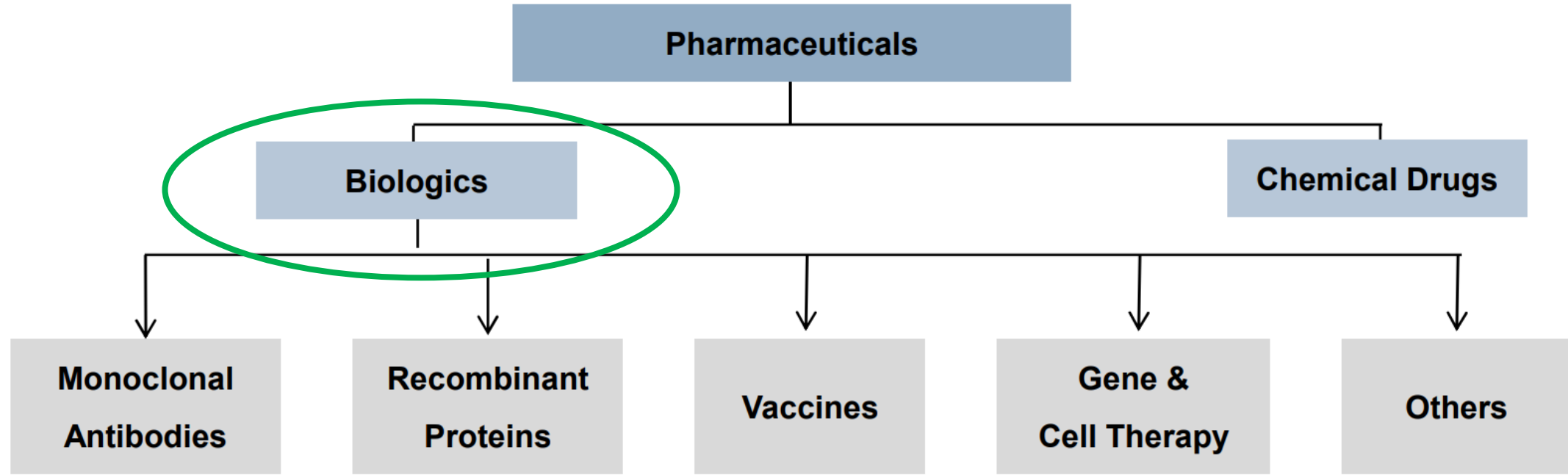
## **Our Values: 3C ETANA**

- › **Commit**
- › **Care**
- › **Collaborate**
- › **Empower and Excel**
- › **Trust**
- › **Agile**
- › **Nurture**
- › **Acknowledge**

# 2022 Etana Organizational Structure



# Market Segmentation



**Definition:** The FDA is defining Biologics as a products that includes a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues. Biologics are isolated from a variety of natural sources - human, animal, or microorganism - and may be produced by biotechnology methods and other cutting-edge technologies. Gene-based and cellular biologics, for example, often are at the forefront of biomedical research, and may be used to treat a variety of medical conditions for which no other treatments are available.

# Core Competence: Ready to use Manufacturing System, one of the largest GMP factory in Indonesia

## GMP Compliance

- PIC/S guideline
- BPOM guideline

## Future Expansions

- Additional PFS / Vial filling line
- Upstream API manufacturing

## Strategic Location

- Jakarta Industrial Estate Pulogadung (JIEP), East Jakarta



## Highlights

Build ing	Description	Size
A	Warehouse	1,000 m <sup>2</sup>
B	Production	3,600 m <sup>2</sup>
C	Animal House (new)	476 m <sup>2</sup>
D	Central Utility (new)	600 m <sup>2</sup>
E	QC, QA, and R&D	795 m <sup>2</sup>
<b>TOTAL</b>		<b>6,471 m<sup>2</sup></b>

## Facility Capabilities

- Level 1 Fill Finish and Packaging
- Level 2 Fermentation and Purification
- Annual Capacity PFS 100 million doses
- Annual Capacity Vial 120 million doses

- **Technology Support from Top Tier Biotech Companies worldwide**

# Core Competency: Establish strong BD capability through Cooperation with Strong investors and Pharmaceutical Companies

## INVESTOR



## PARTNER





# Bevacizumab

## Gold standard treatment for various cancer



### Indication:

**Bevacizumab** is indicated for the treatment of various cancers, such as:

1. Metastatic Colorectal Cancer
2. Advanced, metastatic or recurrent non-squamous Non-Small Cell Lung Cancer (NSCLC)
3. Glioblastoma, Peritoneal, Merkel Cell Carcinoma
4. Renal Cell Carcinoma, Ovarian Cancer, Cervical Cancer

### Eminence:

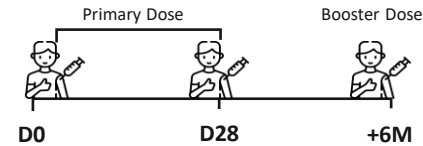
**Bevacizumab** is a drug available for a variety of solid tumors.

**Bevacizumab** has changed the treatment paradigm and is becoming the standard of care in the treatment of advanced cancer.

## Product Information

**InaRNAVac** is a mRNA-based vaccine encoding the receptor-binding domain (RBD of spike glycoprotein (S protein) of SARS-CoV-2 to prevent COVID-19 caused by the infection of SARS-CoV-2 in adults 18 years of age and above. Packaging Pre-filled syringe, 1x0.5 mL single human dose, 1 dose per package.

### IMMUNIZATION SCHEDULE



The "New Coronavirus mRNA Vaccine" (ARCoV) developed by **Abogen**, the **Military Medical Research Institute of the Chinese Academy of Military Sciences**, and **Walvax**<sup>[1]</sup>



**Stable at 2<sup>o</sup>-8<sup>o</sup> 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 and locally produced mRNA vaccine

Halal Certificate Number ID0041000248600522



### Clinical Trial



Non-clinical research published in *Cell*



Phase I clinical research published in *The Lancet Microbe*



Heterologous boosting research published in *Cell*

### 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 – **15<sup>th</sup> June 2022**

### 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

# Erythropoietin Alfa



Renogen is the 1<sup>st</sup> Erythropoietin Alfa in Indonesia conduct the clinical trial compared to innovator: with equal efficacy and safety.

Publication in Acta Medica Indonesia  
Vol. 51 No. 3 July 2019

## Indication

Patients with anemia caused by renal insufficiency, including patients with hemodialysis and non-hemodialysis due to chronic renal failure.

Patients with anemia caused by non-myeloid malignancy applied chemotherapy, other than those with anemia caused by other factors in the treatment of cancer patients (e.g., iron or folate deficiency, hemolysis or intestinal tract bleeding).

## Presentation/Packing

Injection (pre-filled syringe, sterile, clear, colourless, buffered parenteral solution)

2,000 IU/mL, 3,000 IU/mL, 4,000 IU/mL

# Product Profile of PCV-13

13-valent Pneumococcal Polysaccharide Conjugate Vaccine: Prevention of invasive diseases caused by 13 serotypes of *Streptococcus pneumoniae* for infants and children 6 weeks through 5 years of age

- Launched on 31 December 2019 in China
- The **Second PCV13** in the World
- Expected to submit PQ application in 2022

<b>Serotypes</b>	■ 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F
<b>Presentation</b>	■ single-dose vial/pre-filled syringe, 0.5mL/dose
<b>Carrier Protein</b>	■ tetanus toxoid
<b>Storage</b>	■ 2°C to 8°C
<b>Shelf Life</b>	■ 24 months
<b>Schedule</b>	■ 2-6 months: 3 primary doses + 1 booster dose 7-11 months: 2 primary doses + 1 booster dose 12-23 months: 2 doses ≥ 24 months: 1 dose



# Product Profile of HPV-2

Recombinant Bivalent Human Papillomavirus Vaccine (Types 16/18) (*Pichia pastoris*) : For the prevention of cervical cancers and precancerous lesions caused by human papillomavirus types 16/18

- Strict quality standards applied, with a total of 1920 quality control points in the production process, and 5 more quality control points compared with European Pharmacopoeia standards
- Good safety and immunogenicity demonstrated by the first multi-center phase III HPV vaccine clinical trial with the largest sample size ever conducted in China

<b>Composition</b>	40 µg HPV 16L1, 20 µg HPV 18L1 and 225 µg aluminum phosphate
<b>Indicated Population</b>	Females 9 to 30 years of age
<b>Presentation/ Formulation</b>	Single-dose vial (0.5 mL) and single-dose pre-filled syringe (0.5 mL) in liquid suspension formulation
<b>Shelf-life &amp; Storage</b>	36 months, storage at 2-8°C and protection from light
<b>Schedule</b>	3-dose regimen: 0, 2, 6 months 2-dose regimen*: 0, 6 months for age 9-14



# Halal Assurance System PT Etana Biotechnologies Indonesia

mRNA Covid-19 Vaccine

  
REPUBLIC INDONESIA  
(REPUBLIC OF INDONESIA)  
جمهورية إندونيسيا  
SERTIFIKAT HALAL  
(HALAL CERTIFICATE)  
**شهادة الحلال**

Nomor Sertifikat / Certificate Number: ID00410000248600522      رقم الشهادة

Berdasarkan keputusan penetapan halal produk Majelis Ulama Indonesia nomor :  
Based on the decree to stipulating halal products of the Indonesian Council of Ulama :  
استنادا على قرار مجلس العلماء الإندونيسي عن تحديد الحلال للمنتجات :  
LPPOM-00140147470622 Tanggal 15 Juni 2022

Jenis Produk / Type of Product	Produk biologi	نوع المنتج
Nama Produk / Name of Product	-Terlampir / As Attached-	اسم المنتج
Nama Pelaku Usaha / Name of Company	YUXI WALVAX BIOTECHNOLOGY CO., LTD.	اسم الشركة
Alamat Pelaku Usaha / Company's Address	NO.83 SOUTH DONGFENG ROAD, HIGH & NEW TECHNOLOGY INDUSTRIES DEVELOPMENT ZONE, YUXI, YUNNAN, 653100, P.R. CHINA	عنوان الشركة
Diterbitkan di Jakarta pada / Issued in Jakarta on	16 Juni 2022	أصدرت الشهادة بجكرتا في
Berlaku sampai dengan / Valid until	16 Juni 2026	سارية المفعول حتى

telah memenuhi ketentuan perundang-undangan  
Has complied with the provision of laws and regulations  
قد استوفت أحكام التشريع

KEPALA  
BADAN PENYELENGGARA JAMINAN PRODUK HALAL  
HEAD OF HALAL PRODUCT ASSURANCE BODY  
رئيس وكالة ضمان المنتجات الحلال

  
Muhammad Aqil Irham

 Majelis Ulama Indonesia

  
LEMBAGA PENGKAJIAN PANGAN OBAT-OBATAN DAN KOSMETIKA  
MAJELIS ULAMA INDONESIA (LPPOM-MUI)  
THE ASSESSMENT INSTITUTE FOR FOODS, DRUGS, AND COSMETICS  
THE INDOONESIAN COUNCIL OF ULAMA (LPPOM-MUI)

**HALAL ASSURANCE SYSTEM STATUS**  
保证哈拉系统的状态  
NO. HS1A24933/112021/ETN

**إِسْمُ اللَّهِ الرَّحْمَنِ الرَّحِيمِ**

Berdasarkan pemeriksaan dokumen dan audit implementasi Sistem Jaminan Halal, Lembaga Pengkajian Pangan, Obat - obatan dan Kosmetika - Majelis Ulama Indonesia (LPPOM-MUI) menyatakan bahwa :  
Based on the on-desk appraisal and implementation audit of Halal Assurance System, The Assessment Institute for Foods, Drugs and Cosmetics - The Indonesian Council of Ulama (LPPOM-MUI) states that :  
按照审查文件和审计哈拉保证系统, LPPOM-MUI 宣布:

Nama Perusahaan ( 公司名称 ) : **PT Etana Biotechnologies Indonesia**  
Name of Company  
Alamat Perusahaan/Pabrik ( 公司地址 ) : PT CKD Otto Pharmaceutical  
Kawasan Industri Delta Silicon 3/ Jl. Kapuk Timur Blok F23-17, Lippo Cikarang,  
Bekasi, Jawa Barat, Indonesia  
Jakarta, 12 NOVEMBER 2021  
Direktur Eksekutif,  
Executive Director,  
Ir. Hj. Muti Arintawati, M.Si.

dinilai telah menerapkan Sistem Jaminan Halal  
has been implementing Halal Assurance System  
已贯彻执行哈拉保证系统

dengan kategori/with category/ 评分 :  
**SANGAT BAIK / EXCELLENT**

Berlaku sampai dengan / Valid until / 有效期: 11 NOVEMBER 2025      Lembar ini bukan merupakan Sertifikat S.H/H This is not HAS Certificate

  
REPUBLIC INDONESIA  
(REPUBLIC OF INDONESIA)  
جمهورية إندونيسيا  
LAMPIRAN SERTIFIKAT HALAL  
(THE ATTACHMENT OF HALAL CERTIFICATE)  
**مرافقة لشهادة الحلال**

Nomor Sertifikat / Certificate Number: ID00410000248600522      رقم الشهادة

Nama Pelaku Usaha / Name of Company	YUXI WALVAX BIOTECHNOLOGY CO., LTD.	اسم الشركة
Jenis Produk / Type of Product	Produk biologi	نوع المنتج
Alamat Pabrik / Factory's Address	YUXI WALVAX BIOTECHNOLOGY CO., LTD. NO.83 SOUTH DONGFENG ROAD, HIGH & NEW TECHNOLOGY INDUSTRIES DEVELOPMENT ZONE YUXI 653100 YUNNAN	عنوان المصنع

Daftar Produk / Product Name

No	Nama Produk / Product Name
1	SARS-CoV-2 mRNA Vaccine (AWceorna)

Hal: 1 / Total Produk: 1

Diterbitkan di Jakarta pada / Issued in Jakarta on	16 Juni 2022	أصدرت الشهادة بجكرتا في
Berlaku sampai dengan / Valid until	16 Juni 2026	سارية المفعول حتى

KEPALA  
BADAN PENYELENGGARA JAMINAN PRODUK HALAL  
HEAD OF HALAL PRODUCT ASSURANCE BODY  
رئيس وكالة ضمان المنتجات

  
Muhammad Aqil Irham

 Majelis Ulama Indonesia

# Thank You



PT Etana Biotechnologies  
Indonesia



Jl. Rawa Gelam V Blok L, Kav.11 – 13  
Kawasan Industri Pulogadung,  
Jakarta Timur  
Indonesia 13930



<https://www.id.etanabiotech.com/>

# 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

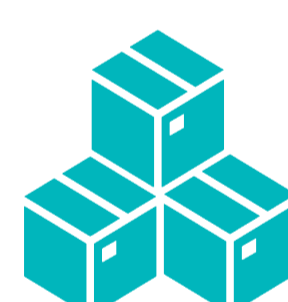
#### Aimed for future vaccine security and self-reliance



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

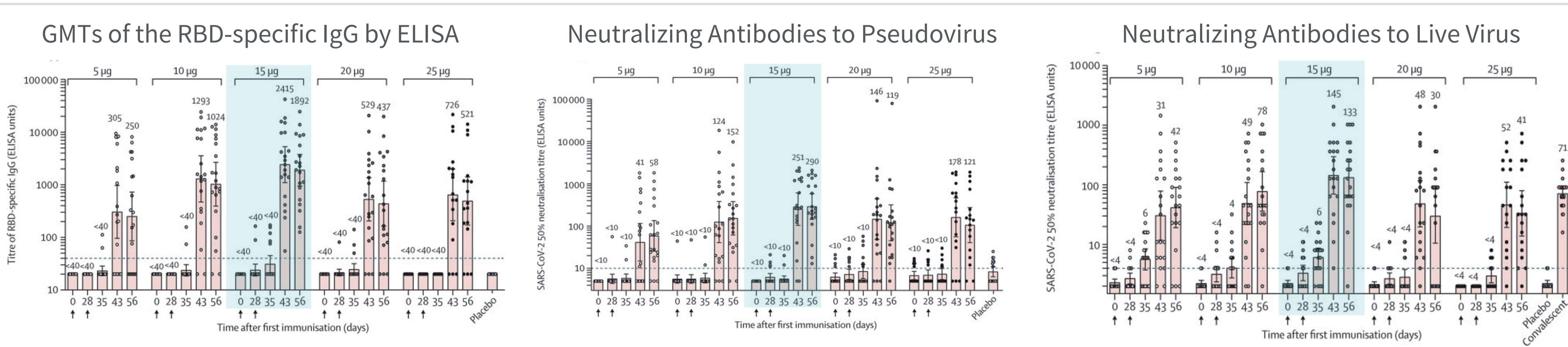
#### Acceptable Safety Profile as Both 2-dose Series and Single Heterologous Booster Dose

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>

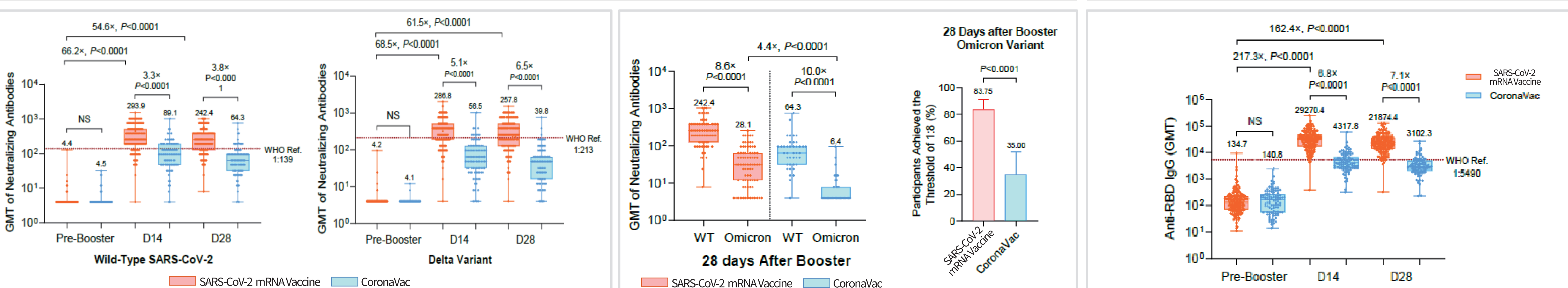
#### Robust Immunogenicity Profile as Both 2-dose Series and Single Heterologous Booster Dose

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.



October 10<sup>th</sup>, 2022

**Mr. Erkan Kiper**

**Chief Commercial Counsellor, Embassy of Türkiye**

Jl. HR. Rasuna Said Kav. 1 Kuningan Timur Setiabudi

Jakarta Selatan DKI Jakarta, RT.5/RW.4, Kuningan Tim.,

Kecamatan Setiabudi, Kota Jakarta Selatan, Daerah Khusus Ibukota Jakarta 12950

Dear Mr. Erkan Kiper,

I am reaching out on behalf of PT Etana Biotechnologies Indonesia. We would like to thank you for your visit last Wednesday (October 12<sup>nd</sup>, 2022).

We are writing this letter in relation with our discussion we had in context of business partnership,

PT Etana Biotechnologies Indonesia ("Etana") is an emerging producer of high-quality, affordable and innovative biopharmaceuticals to treat a range of metabolic, autoimmune and other major life-threatening diseases, including cancer. In order to best serve patients, Etana has established a network of strategic alliances and partnerships with international pharmaceutical producers with a strong track record in researching and developing safe and efficacious pharmaceuticals, enabling Etana to offer new treatments to the Indonesian market and global market.

We would like to offer you a cooperation to supply COVID-19 Vaccine platform mRNA to Turkey. AWcorn is the first Halal mRNA vaccine in the world and have excellent stability, it can be stored and distributed under 2-8°C. You can refer to the product brochure to see the details of the product.

We also looking for opportunity to cooperate such as investation or another product to supply, we also enclosed our company's profile for your reference. We eagerly look forward for positive response from you. Thank you.

Sincerely,



**Indra Lamora**

Head of Business Development

**PT. Etana Biotechnologies Indonesia**

Head Office:

Kawasan Industri Pulogadung

Jl. Rawa Gelam V, Blok. L, Kav. 11-13

Jakarta – 13930

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