

## **PRESS STATEMENT**

### **IMBCAMS PHASE 3 CLINICAL TRIAL EXTENDED CROSSOVER AND BOOSTER STUDY**

This press statement is to update the Phase 3 Clinical Trial of the SARS-CoV-2 Vaccine, Inactivated (Vero Cell) for COVID-19 which involved the enrolment of 3,000 participants and the whole-course immunization were successfully completed in May 2021. This was the first and largest Phase 3 Clinical Trial of COVID-19 vaccine as well as the on-going extended crossover and booster vaccine study carrying out in Malaysia involves participants of all gender, race, religious and ethnic backgrounds. The Malaysia Research & Ethics Committee (MREC) and National Pharmaceutical Regulatory Agency (NPRA) of Malaysia had granted approval for the clinical trial in January 2021. The Phase 3 Clinical Trial was conducted by the Institute of Clinical Research (ICR), Ministry of Health Malaysia (MOH) in collaboration with the Institute of Medical Biology Chinese Academy of Medical Sciences (IMBCAMS) as the study sponsor and Toppharma Marketing (M) Sdn Bhd (TOPPHARMA) as the Exclusive Agent and Sole Distributor in Malaysia.

In view of recent surge of COVID-19 cases in the country and due to emergence of the new virus variants and the dynamic changing of pandemic situation in Malaysia, we are obliged and responsible to ensure all our study participants are safe and better protected from COVID-19 virus infection. We are now embarking on the second part of the vaccine Phase 3 Clinical Trial by introducing an "Extended Crossover and Booster Study", which is a booster dose and 2 doses of vaccination to the study participants of vaccine arm and placebo arm respectively. This decision is in-line with the approval issued by MREC to IMBCAMS in July 2021. We anticipate with this pro-active action taken by the study's sponsor IMBCAMS and clinical investigators of ICR would benefit all the participants while maintaining the vaccine's efficacy and safety all the time during study period. The extended clinical study is expected to be completed before end of the year 2021 and the final report will be submitted to NPRA.

#### **About Toppharma Marketing (M) Sdn. Bhd.**

TOPPHARMA is a pharmaceutical service and marketing company having an international network of pharmaceutical companies with experience in collaboration to do multi-centre clinical trial study, warehousing and distribution of vaccines, biological and medical products to private and public sectors. In line with the company's commitment to excellence and sustainable relationship in the healthcare industry, we will continue to be innovative in our pharmaceutical services and continuous assurance in providing safe and quality products to our clients and consumers. TOPPHARMA and IMBCAMS have entered into an Exclusive Agency Agreement to authorize TOPPHARMA as the Exclusive Agent and Sole Distributor and Product Registration Holder in Malaysia.