Phase 3 Clinical Trial of Bio Farma's Covid-19 Vaccine Commencing Soon, Indonesia Will Be Independent in Making Covid-19 Vaccine

Menteri BUMN RI Erick Thohir (ketiga dari kiri), Wakil Menteri Kesehatan RI, Dante Saksono Harbuwono (kedua dari kanan), Kepala BPOM Penny Lukito (kedua dari kiri), Direktur Utama Bio Farma, Honesti Basyir (paling kiri) dan Peneliti Utama Center Semarang dr Yetty Movieta Nency, Sp.A(K) dalam kesempatan Konferensi Pers Kick Off Uji Klinis Fase 3 Vaksin Covid-19 BUMN, di Lab Sentral RSND FK Undip Semarang, pada tanggal 9 Juni 2022.

(Semarang 9/6) The Holding Holding Company for Pharmaceuticals, Bio Farma, will soon carry out Phase 3 Clinical Trial of BUMN Vaccine to prevent Covid19 at the beginning of June 2022. The declaration was marked by a Kick-off which was held at the Faculty of Medicine, Diponegoro University (FK UNDIP), on June 9, 2022.

The kick-off activity was attended by the Minister of SOEs, Erick Thohir, Deputy Minister of Health of the Republic of Indonesia Dante Saksono Harbuwono, Head of BPOM Penny Lukito, Chancellor of UNDIP represented by Vice Chancellor IV, Prof. Dr. Ir. Ambariyanto, M.Sc, Dean of Medical Faculty UNDIP Dr. dr. Dwi Pudjonarko, M.Kes., Sp.S(K), President Director of Bio Farma, Honesti Basyir along with the Board of Executives of Bio Farma and President Commissioner of Bio Farma Tanri Abeng.

The BUMN vaccine is the result of a global collaboration between Bio Farma and Baylor College of

Medicine, USA, which has been registered in the WHO Covid-19 vaccine candidate development stage since June 2021. The BUMN vaccine uses Recombinant Protein Subunit (protein *Receptor Binding Domain* / RBD) technology, which is made in Indonesia and will be used as a primary vaccine, after obtaining an Emergency Use Authorization (EUA) from the POM Agency at the end of July 2022.

Implementation of clinical trials Phase 3 was carried out after Bio Farma obtained the Approval for the Implementation of Clinical Trials (PPUK) for Phase 3 Clinical Trials, which was signed by the Head of the POM RI Penny K Lukito, on June 6, 2022. Besides being carried out in Semarang, Phase 3 Clinical Trials were also carried out in the city of Jakarta in collaboration with the Faculty of Medicine, University of Indonesia, Padang in collaboration with the Faculty of Medicine, Andalas University, and Makassar in collaboration with the Faculty of Medicine, Hasanuddin University.

Penny K Lukito said this Covid-19 vaccine was the first vaccine whose development from upstream to downstream was developed in Indonesia by Bio Farma.

"This is a big step for us towards drug and vaccine independence, to fulfill Presidential Instruction No. 6 of 2016, so we certainly thank the industry that has followed the standards of the POM because we want what is developed in Indonesia are products that are indeed globally competitive, especially with the credibility of Bio Farma, which has been around for more than 130 years, both at the international and regional levels," said Penny

Bio Farma is again a vaccine that meets GMP (Good Manufacturing Practices) standards to become a commercial vaccine. This is also a process of strengthening our science in the field of vaccine development and of course increasing the capacity of the pharmaceutical industry in the field of vaccines in Indonesia.

Meanwhile, Dante Saksono said that one of the capitals for making new breakthroughs in handling Covid-19 is the manufacture of vaccines. The vaccine, which was initiated by this BUMN, is one of the projects that will be included in Phase 3 Clinical Trial

. used. I hope this vaccine will not stop using primary vaccines in clinical trials, but should also be used for booster vaccines," said Dante.

Dante continued that we do not know when this Pandemic will end. Therefore, several things are needed, which must support that this pandemic will remain under control, one of which is providing support for booster vaccines.

"We support and support Bio Farma so that the BUMN Covid-19 vaccine can be used for booster vaccine activities, especially in the future," concluded Dante,

the President Director of Bio Farma, Honesti Basyir, thanked all parties for supporting research and the development of this BUMN vaccine, which is a manifestation of the independence of the Indonesian nation during the Covid-19 pandemic.

Honesti also added that this phase 3 clinical trial is a major milestone, especially for the Health Industry in Indonesia, where we will kick off the phase 3 clinical trial of the BUMN COvid-19 vaccine, whose upstream to the downstream production process is carried out in Indonesia.

"The BUMN vaccine is one of the works of the nation's children because starting from the development of working vaccine seeds/vaccine seeds, it is carried out in Indonesia and carried out by experts from Indonesia, of course, we hope, this phase 3 clinical trial can run smoothly as planned and provide optimal results," said Honesti.

He added, that in the future, if this phase 3 clinical trial runs smoothly, Bio Farma will apply for an Emergency Use Authorization (EUA) to the POM no later than the end of July 2022 and will be registered for Emergency Use Listing (EUL) with the World Health Organization. , for the purposes of exporting Covid-19 vaccines.

In his closing remarks, Erick Thohir encouraged Bio Farma to be more competitive to transform into a modern health industry through collaboration, to reduce dependence on medicinal raw materials, and we are also encouraging how herbs can be an alternative to reduce dependence on medicinal raw materials.

"We want the Indonesian nation to be sovereign for health. This Covid-19 proves how burdensome our dependence is, therefore we must collaborate so that we can be sovereign in our health as a nation," said Erick.

Erick closed the Ministry of SOEs continuing to encourage and one of them we can start phase 3 clinical trials, then we also encourage the use of booster vaccines, and furthermore, we will also encourage the implementation of other technologies such as mRNA and viral vectors as well as upgrading production facilities at Bio Farma.

Clinical Trial 3 was carried out after the results of Clinical Trials 1 and 2 gave satisfactory results. starting in February 2021 for three months. Phase 1 Clinical Trials provide safe results in volunteers and provide a significant increase in the body's immune response up to 28 days after the second vaccination. This clinical trial 1 involved 175 subjects aged 18 years and over after the second dose.

The second Clinical Trial was carried out to evaluate and select the best vaccine formula to proceed to phase 3, involving 360 subjects aged 18 years and over, starting April 13, 2022. Currently entering a long-term safety monitoring period up to 6 months after dose second.

This BUMN Vaccine Phase 3 Clinical Trial, serves to evaluate the safety and immunogenicity of the vaccine compared to the comparison vaccine by involving 4,050 volunteers, aged 18-70 years, whose recruitment begins in the first week of June 2022. Each volunteer will be given two doses. with a span of 28 days between the first and second doses, and will continue to be monitored for up to 1 year after the second dose.

For Bio Farma, this clinical trial is not the first time. It is noted that Bio Farma has conducted clinical trials more than 30 times, both domestically and abroad. For the Covid-19 vaccine itself, Bio Farma was involved in the implementation of Phase 3 clinical trial of the Covid-19 vaccine from Sinovac, which was carried out in 2020.