IndoVac Productions Bio Farma to Strengthen Indonesia's Health Infrastructure



Jakarta, October 26, 2022 - Bio Farma as a Pharmaceutical BUMN Holding, is committed to supporting the government's steps and efforts in strengthening health infrastructure, one of which is through the independence of the Covid-19 vaccine. This concrete step is realized by Bio Farma through its success in producing the IndoVac Vaccine which was officially launched by President Joko Widodo on October 13, 2022.

“WHO says that the Covid-19 pandemic is not over yet. Especially after the emergence of a new variant of the Covid-19 virus, XBB which has been detected in several countries, including Indonesia. We all still need to be vigilant and careful, prokes, and vaccinations, especially *booster*, based on data from the Ministry of Health, there are still relatively many people who haven't had *boosters*. We continue to support the government's efforts to strengthen health infrastructure, one of which is through domestic vaccine production, namely IndoVac," said Director of Bio Farma Honesti Basyir at the Media Gathering event, Wednesday (26/10/2022).

Honesti explained, one of the steps taken by Bio Farma in strengthening health infrastructure in the country is through collaboration with various domestic universities in conducting clinical trials of IndoVac. In conducting IndoVac research and research, Bio Farma cooperates with seven medical faculties; namely from the University of Indonesia, Diponegoro University, Andalas University, and Hasanuddin University to carry out primary dose clinical trials, and Padjadjaran University and Udayana University for booster dose clinical trials. Three medical faculties, namely Gadjah Mada University, University of Indonesia, and Andalas University, are the centers for clinical trials of the IndoVac vaccine for children aged 12-17 years.

The IndoVac vaccine for primary vaccination (dose 1 & 2) for adults (18+) received an *emergency use authorization* (EUA) or emergency Agency Supervisory Drugs and Food (BPOM) on 28

September 2022. Bio Farma has started commercial production of *drug substances* (DS) and *drug products* (DP). In addition, this Pharmaceutical BUMN Holding is currently registering an *emergency use listing* (EUL) with the World Health Organization (WHO) so that it can be exported to various countries, especially *lower-middle-income countries*.

IndoVac for *Booster*

Pharmaceutical BUMN Holding has completed clinical trials of the IndoVac Vaccine for further/booster vaccination with temporary results of increasing antibody titers and Omicron neutralization but is still in the testing process to obtain emergency *use authorization*(EUA) from the Food and Drug Administration (BPOM).

Bio Farma has submitted the results of the clinical trial to BPOM on October 10, 2022. Based on a *booster* through clinical trials starting September 1, 2022, for *safety* and *immunogenicity* 14 days after the second injection, a *booster* can increase antibody titers and neutralize Omicron variants. The company targets the EUA for the adult IndoVac *booster* (18+) to be issued by the end of October 2022.

It doesn't stop there, Bio Farma continues to develop IndoVac so that it can be accepted as a Covid-19 vaccine for children aged 12-17 years. Bio Farma received approval for the implementation of clinical trials (PPUK) from BPOM on September 30, 2022. A *booster* can only be submitted after an interim report for the primary study is available. Clinical trials for that age group have been ongoing since October 6, 2022. BUMN Pharmaceutical Holding hopes that UAE IndoVac for vaccination of children (12-17 years) will be issued by BPOM in early December 2022.

Meanwhile, for primary and booster IndoVac children aged 6-11 years, clinical trials will only be conducted if there is a commitment from the Ministry of Health to the need for vaccinations for children 6-11 years old.

Honesti Basyir emphasized that IndoVac's portfolio is getting more comprehensive in order to reach all levels of Indonesian society in obtaining vaccines, both primary adult, *booster*, 12-17 years old, and vaccinations for children under 12 years old.

"From clinical trials, the result of collaboration between Bio Farma scientists working with researchers from various universities in Indonesia, it can be seen that IndoVac scientific data has good safety, has better effectiveness than comparison vaccines with efficacy above 80%, and is halal. Most importantly, as stated by President Jokowi at the launch of IndoVac, this is a domestic production made by the nation's best sons and daughters, especially young people. Furthermore, if necessary, we are ready to conduct clinical trials of vaccinations for children aged 11 and under, " he said.

IndoVac is a COVID-19 vaccine based on recombinant protein subunit technology that is used as an active immunization against COVID-19 caused by the SARS-CoV-2 virus. IndoVac has also obtained a halal fatwa and MUI and a halal certificate from BPJPH, the Ministry of Religion, and is a domestic product created by the nation's children with a domestic content level (TKDN) of around 90%.

During the launch of the IndoVac Vaccine, President Jokowi said that so far Bio Farma has produced various types of vaccines up to 3 billion doses which have been exported to 153 countries. The President said that Indonesia through Bio Farma is a vaccine producer that is in the top 5 in the world. Bio Farma produces various vaccines, such as polio, diphtheria, tetanus, hepatitis B, haemophilus influenzae type B, flu, measles, and finally the Covid-19 vaccine launched today, namely IndoVac. For the polio vaccine alone, 2/3 of the world's needs are supplied from Indonesia.

The President said that Bio Farma's success in producing IndoVac is the hard work of young human resources (HR). "Minister of SOEs, Minister of Health, continue to encourage Bio Farma to generate innovation and *revenue* for the country and we have independence."

Global Institutional Cooperation

At the IndoVac vaccine launch, Minister of State-Owned Enterprises (BUMN) Erick Thohir said he wanted Indonesia can become a hub for world vaccine production. He explained that the IndoVac vaccine is one of the results of cooperation between the pharmaceutical BUMN holding and the Baylor College of Medicine (BCM) of the United States.

Bio Farma as the holding parent of Indonesian pharmaceutical SOEs is indeed intensively conducting various collaborations with institutions week, Bio Farma announced four signings of cooperation with four global healthcare companies, on the sidelines of the G20 State-owned-Enterprise (SoE) International Conference & Expo 2022, which will be held on 17-18 October 2022 in Nusa Dua, Bali.

The cooperation carried out is, first, Bio Farma with Suzhou Ronnsi Pharm a Co., Ltd (Ronsi), for the development of a *Supply Agreement on Active Pharmaceutical Ingredients* (API) for Enoxaparin products from Ronsi, which will be formulated at Bio Farma. This product is targeted to be sold for the export market. The signing was carried out by the President Director of Bio Farma Honesti Basyir with the President Director Ronsi Yiming Yao.

The second signatory was Bio Farma with ConnectedLife Health Singapore, namely the commercialization of preventive care services in Indonesia, signed by the President Director of Bio Farma, Honesti Basyir, with ConnectedLife Health Singapore CEO Daryl Arnold.

The signing of the third MoU was between Bio Farma and InHealth Indonesia Life Insurance, which was carried out by Bio Farma's Director of Transformation and Digital Soleh Ayubi., Ph.D and Marketing Director Bugy Riagandhy. This MoU relates to the development of preventive care system services to monitor the health and physical activity of MANDIRI IN HEALTH participants using Medwell services and Homecare services that will be connected to all of Bio Farma's digital health platforms.

The fourth collaboration is between PT Kimia Farma Tbk as a member of Holding BUMN Pharmaceuticals, which signed an MoU with Pantai Premier Pathology Sdn Bhd Kimia Farma for cooperation in mentoring and technical knowledge support for the development of laboratory services. Through this collaboration, Kimia Farma can improve the quality and services of its laboratory.