Indonesian Pharmaceutical Company Bio Farma Ready to Produce ‘IndoVac’ Covid-19 Vaccines, a New Milestone for Indonesia’s Independence in the Pharmaceutical Sector

Illustration of vaccines in the making at Bio Farma's facilities

(Bandung, 6/9/2022) – PT Bio Farma, the holding company for state-owned pharmaceutical companies in Indonesia, announced a new milestone in the manufacturing process of IndoVac, a Covid-19 vaccine brand it has developed since November 2021.

Honesti Baasyir, the President Director of PT Bio Farma said the company collaborated with Baylor College of Medicine, a private, independent health sciences center in Houston, Texas, United States to develop IndoVac, a recombinant protein subunit vaccine produced from yeast.

PT Bio Farma has completed the Phase 1 and Phase 2 clinical trials and is currently in the Phase 3 stage to produce the primary series vaccines, or two vaccine doses for everyone ages 18 years and older.

“IndoVac uses vaccine technology platforms, which are compatible with our equipments and facilities within our factories. The technology platforms to produce protein recombinant vaccine also offer other benefits: they can be adapted into the new strains of Covid-19. Results from the Phase 1 and Phase 2 clinical trials showed that IndoVac vaccine offers good quality for its safety and efficacy. They are not less competitive with the other Covid-19 vaccines. Next, we are completing a report to wrap up the Phase **3** stage,” Honesti said on Wednesday (Sept. 7, 2022).

Honesti said, Bio Farma has made intense communication with the Indonesian Food and Drug

Authority (BPOM) since July 2022 to provide the necessary data, so that the regulator can release the Emergency Use Authorization (EUA) permit for IndoVac's primary series vaccines in near term.

The EUA, released by a country's regulator, is a permit for medical supplies (including vaccines) and medications during a public health emergency. In Indonesia, BPOM plays a key role as a regulatory gatekeeper of medicines and vaccines used in the country.

BPOM's head Penny K. Lukito, during a hearing with Commission IX at the Indonesian House of Representatives, has said that the regulator expects to release the EUA for IndoVac's primary series vaccines in mid-September 2022.

Bio Farma also has processed the *Halal* (or Shariah compliant) certification for the IndoVac's **primary series vaccines** to provide comforts to the Indonesian Muslim consumers. The vaccines have passed an audit from The Indonesian Ulema Council Food and Drug Analysis Agency (LPPOM MUI), which reviews the halal aspect of a product.

The certificate from the Halal Certification Agency (BPJPH) under the Religious Affairs Ministry is expected to be released in near-term after BPOM release the EUA for IndoVac.

After securing all the necessary permits, Bio Farma is ready to move on to the next stage, which is producing IndoVac's primary series vaccines massively. At the first stage, Bio Farma plans to produce a maximum of 20 million doses of primary series vaccines, before it can be further increased to 40 million doses in 2023, as the company expands its production facilities.

In 2024, the company may further increase the volume to 100 million doses per year, depending on the demands and needs in the markets.

Honesti said after the company has secured all the necessary permits, then IndoVac's primary series vaccines "can be massively used by the people aged 18 and above."

Booster vaccine and vaccine for children

At the same time, Bio Farma also has started clinical trials for its booster vaccine since September 1, 2022. "We have secured approval for a clinical trial (PPUK) from BPOM for IndoVac booster vaccine," Honesti said. Next, Bio Farma also plans to conduct clinical trials for vaccine for children after it secures PPUK from BPOM.

Bio Farma has conducted clinical trials for its booster vaccine at Hasan Sadikin General Hospital (The Faculty of Medicine of Padjajaran University in Bandung) and at the Dr. I.G.N.G Ngoerah General Hospital in Bali (The Children's Health Sciences Department of Udayana University). The clinical trials involved 900 subjects with ages of 18 and above to test IndoVac's booster vaccines.

BPOM requires vaccine manufacturers to conduct clinical trials to ensure to decide if a vaccine is safe and it can boost immunity against Covid-19 and to determine whether the vaccine offers good efficacy to help protect the subjects from heavy symptoms and risks of fatalities due to Covid-19 infection.

All Covid-19 vaccines made by Bio Farma, which include the primary series, the booster vaccines and vaccines for children, will be labeled IndoVac.

For Bio Farma, it is not the first time to embark on a clinical trial. The company has conducted more than 30 clinical trials in Indonesia. This includes the Phase 3 clinical trials for the Covid-19 vaccine. Bio Farma also has experiences in conducting clinical trials overseas for Pentabio and Novel Oral

Polio Vaccine type 2 (nOPV2) – (Check the fact sheet)

Bio Farma, Honesti said, has started the process of registering IndoVac as a brand name **for its Covid-19 vaccines** to the Directorate General of The Intellectual Property Right at the Indonesian Ministry of Law and Human Rights on July 29, 2022.

President Joko Widodo gave the name of Bio Farma-manufactured vaccine, IndoVac.

“We are in the process of announcing it. Should noone objects, then we will process it to the next stage until we secure IndoVac trade lisence and patent it as a product of Bio Farma from the ministry,” Honesti said.

“The process of registering to the Directorate General of The Intellectual Property Rights begins with an official request and then validations of paper works. Once all the paper works are validated, then there will be a public announcement (for the name use). If there was no one objects, then we will go into the substantial validations, before registering (the name) to secure the property rights certificate from the Ministry of Law and Human Rights,” he said.

MADE-IN INDONESIA PRODUCT

Honesti Basyir said IndoVac is special for Indonesia, because it is one of the few made-in Indonesia vaccine products. The vaccines (which include the primary series vaccines, the booster vaccines and vaccines for children) are developed and manufactured by children of the nation. Bio Farma handles the manufacturing processes from the upstream to downstream parts.

The local contents of IndoVac’s primary series vaccines, according to Bio Farma’s self-assessment will be around 80%.

"The Covid-19 (primary series) vaccines made by state-owned company Bio Farma offer nearly 80% local contents. This is one-step closer to achieving indepence in the health sector. With such high local contents, we expect to help reduce the nation’s dependency on imported vaccines. This will also impact possitively on saving foreign exchange reserves,” Honesti said.

He added that high level of local contents would affect possitively to the nation’s domestic economy, thanks to higher local workers absorbtion, the use of locally made raw materials, and domestik spending in the research and development stages, all of which will benefit the nation.

In the long-term, Bio Farma is also eyeing to capture the export markets with its IndoVac vaccines. “So, we will not only produce them (the three types of vaccines) to meet the domestic needs, but also targeting to supply the global markets,” he said.

“We have embarked the process to register the Emergency Use Listing with the World Health Organization (for the primary series), so that this vaccines can be used in other countries through the support Covax Facility (multilateral). Through its Covid-19 vaccines, Bio Farma expects to contribute possitively to the health industry, not just in Indonesia, but also to the world.”

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FACT SHEETS

BIO FARMA’S SUCCESS IN POLIO VACCINE

Honesti said, apart from manufacturing Covid-19 primary series vaccines, which currently is awaiting for the results of the Phase 3 clinical trials and the EUA, Bio Farma has previously proven itself that it manages to secure the EUA from BPOM and the EUL from the WHO for its novel Oral Polio Vaccine type 2 (nOPV2)

The EUL, which is released by the WHO, a procedure for assessing and listing vaccines during public health emergencies such as during disease outbreaks/the pandemics by non-vaccine-producing countries. As Indonesia never had any polio outbreaks since 2014, the country never used nOPV2. Bio Farma-manufactured vaccine, was however, used by countries in Africa, Europe and the Middle East.

Among the countries that have used Bio Farma's nOPV2's vaccine are Algeria, Cameroon, the Democratic Republic of Congo, Djibouti, Ethiopia, Gambia, Ghana, Nigeria, Senegal, and Uganda.

In Europe, the vaccine was used in Ukraine and in the Middle East, it was used in Israel, Egypt, Somalia and Yemen.

In the manufacturing of nOPV2 vaccine, Bio Farma collaborated with world-class research institutions like Bill and Melinda Gates Foundation (BMGF), PATH and the WHO. Bio Farma has become the main supplier for the polio vaccine in the world. The company currently contributes to 67 percent of the global supply of polio vaccines. It distributes the vaccines via bilateral or multilateral means (through UNICEF).

Apart from producing polio vaccines, Bio Farma's Laboratories have secured international acknowledgement as the reference labs to check samples of polioviruses.

The world was previously waiting for two countries, Afghanistan and Pakistan, to combat polio diseases, before a 'world-free polio' can be declared. However, during the wait, polio outbreaks occured in Africa and the Middle East.

The nOPV2 vaccine became important product to prevent further widespread of the polio disease. Bio Farma's success in producing and exporting nOPV2 vaccine means that the Indonesian state-owned company has contributed possitively to the world's health sector, apart from making sure it can provide the necessary polio vaccine for domestic use at home, in Indonesia.