

Vietnam welcomes two locally produced vaccines for seasonal and pandemic influenza

International collaboration announces successful clinical trial results with licensure expected in 2019

Media contacts:

- **Dr. Le Van Be | Director, Institute of Vaccines and Medical Biologicals | ivaclevanbe@gmail.com | +84 58 3 822 408, +84 58 3 818 898, +84 90350152**
- **Dr. Vu Minh Huong | Mekong Regional Technical Director, PATH | hvu@path.org | +84 4 3936 2215 ext. 118.**
- **Kate Davidson | PATH Media Relations | media@path.org**

Nha Trang, Vietnam, September 25 2018—The Institute of Vaccines and Medical Biologicals (IVAC), World Health Organization (WHO), international global health organization PATH, and the Biomedical Advanced Research and Development Authority (BARDA) within the US Department of Health and Human Services, today joined leaders from the Ministry of Health (MOH), the National Institute of Hygiene and Epidemiology (NIHE), and the Pasteur Institute in Ho Chi Minh City (PIHCM) to announce results from two different Phase 2/3 clinical trials of locally produced seasonal and pandemic influenza vaccine candidates. Overall results showed both vaccine candidates to be acceptably safe and capable of prompting an immune response in healthy adults.

The vaccine candidates include an inactivated trivalent seasonal influenza vaccine that targets three strains—A/H1N1, A/H3N2, and B—and an inactivated pre-pandemic influenza vaccine that targets A/H5N1, a type of avian influenza, that has sporadically infected human populations in recent years. They are expected to be licensed for distribution by 2019—the culmination of a successful nine-year partnership to improve Vietnam’s vaccine production capacity and pandemic preparedness.

“We are pleased to announce the successful completion of the Phase 3 clinical trials for two different influenza vaccines, which are both set to be licensed by 2019,” said Dr. Be, IVAC Director. “We are thrilled at the successful collaboration that has enabled IVAC to reach this exciting stage of vaccine development, and we thank our long standing colleagues at BARDA, WHO, and PATH who have all contributed much to the progression of influenza vaccine development capacity in Vietnam.”

Seasonal influenza—a viral disease that causes mild to severe respiratory illness and sometimes even death—is responsible for up to 650,000 deaths and between three and five million cases of severe disease worldwide each year, including more than one million cases of influenza-like illnesses in Vietnam.¹ Occasionally, extremely destructive influenza strains emerge and lead to widespread outbreaks called pandemics. The last major influenza pandemic to hit Vietnam was the A/H1N1 pandemic in 2009, which in 12 months, caused more than 284,000 deaths worldwide, including 78,000 in South East Asia.²

Vietnam has historically lacked a sustainable supply of influenza vaccine and has been forced to rely on foreign manufacturers. The best way to ensure Vietnam’s access to these lifesaving tools is through local production of affordable, seasonal influenza vaccine, which helps to maintain manufacturing capacity on an ongoing basis. This strengthens pandemic preparedness by facilitating a smooth transition from seasonal to pandemic production should the need arise.

Since 2010, PATH has worked with Vietnam’s MOH to create a long-term plan for influenza vaccine production and use, and guidelines for influenza vaccine clinical trials and licensure. Simultaneously, in collaboration with BARDA and WHO, PATH supported IVAC in the development of its egg-based seasonal and pre-pandemic

¹ World Health Organization. Influenza (Seasonal)[fact sheet no. 211]. WHO; April 2009. Available at www.who.int/mediacentre/factsheets/fs211/en/index.html. Accessed October 1, 2013.

² Dawood, F., Iuliano, A., Reed, C., Meltzer, M., Shay, D. et al. (2012). Estimated global mortality associated with the first 12 months of 2009 pandemic influenza A H1N1 virus circulation: A modelling study. *The Lancet infectious diseases*. June 26 2012; 12: 687–95. DOI: [https://doi.org/10.1016/S1473-3099\(12\)70121-4](https://doi.org/10.1016/S1473-3099(12)70121-4)

influenza vaccines, and the Company for Vaccine and Biological Production No. 1 (VABIOTECH) in the development of a new cell-based pre-pandemic inactivated A/H5N1 influenza vaccine.

Between 2017 and 2018, the Phase 2/3 clinical trials of IVAC's egg-based seasonal influenza vaccine, which targets three strains of influenza, and A/H5N1 influenza vaccine, were completed. This is the final clinical evaluation required before the vaccines can be licensed for production.

The clinical studies evaluated both the vaccine candidates' safety and ability to induce an immune response in healthy adults. The overall results showed the vaccine candidates to be well tolerated and capable of creating a protective immune response. Licensing applications for the seasonal and pre-pandemic influenza A/H5N1 vaccine candidates are underway, with both expected to be licensed in 2019.

"The past nine years have been a thrilling journey toward the successful development of high quality, safe, and effective vaccines for pandemic and seasonal influenza in Vietnam," said Nguyen Tuyet Nga, PATH's Vietnam Deputy Country Director. "As well as threatening the health of ourselves and our families, outbreaks of infectious diseases can quickly derail a country's growth and development. Ensuring global health security is therefore a major priority for PATH. I applaud the diligence and commitment of our colleagues at the MOH, IVAC, NIHE, PIHCM and also VABIOTECH for reducing the risk of future outbreaks, and thank BARDA for their support."

The remarkable progress made toward sustainable influenza vaccine production establishes Vietnam's position as a leader in vaccine production and development among low- and middle-income countries globally. IVAC's efforts to develop locally produced influenza vaccines will not only benefit the people of Vietnam, they will help increase regional and global influenza vaccine supplies. With the world's influenza vaccine development and production resources mostly concentrated among a limited number of manufacturers, current global vaccine production falls short of need and leaves many low- and middle-income countries without vaccine access. The participation of more influenza vaccine suppliers, like IVAC, is vital for sustainably addressing this gap.

About IVAC

IVAC, established in 1978 by Vietnam's MOH, plans and carries out the production of vaccines and serum for the Expanded Program on Immunization in Vietnam and the overall prevention and treatment of diseases. IVAC conducts research and applies technological advances in vaccine development and production in cooperation with organizations in country and abroad. IVAC's main facility is located in Nha Trang, Vietnam, with other facilities in Suoi Dau. www.ivac.com.vn.

About PATH

PATH is a global organization that works to accelerate health equity by bringing together public institutions, businesses, social enterprises, and investors to solve the world's most pressing health challenges. With expertise in science, health, economics, technology, advocacy, and dozens of other specialties, PATH develops and scales solutions—including vaccines, drugs, devices, diagnostics, and innovative approaches to strengthening health systems worldwide. Learn more at www.path.org.