Editorial

The Bharat Biotech's COVAXIN®Phase-3 Clinical trial report meets WHO's touchstone

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COVAXIN® is India's indigenous COVID-19 vaccine developed by Bharat Biotech Company in association with the Indian Council of Medical Research (ICMR) - National Institute of Virology (NIV). The vaccine is developed via Whole-Virion Inactivated Vero Cell technology. Inactivated vaccines fail to replicate and hence they are improbable to revert and root pathological effects. They comprise dead virus, inept of infecting people but still able to inculcate the immune system to escalate a defensive reaction counter to an infection. COVAXIN® is incorporated along with adjuvants, which are augmented to the vaccine to enhance and boost vaccine's immunogenicity. The course of vaccination consist of two doses of COVAXIN® administered 28 days apart.This vaccine does not claim for sub-zero storage conditions, stored in multi-dose vials and remain stable at2-8°C which is ready to use without any reconstitution.

Figure 1: Phase 3 Clinical trial data of COVAXIN®

Serum Institute of India's Covishield and Russia's Sputnik V are the other two Covid-19 vaccines that have been administered to Indian citizens so far. Notably, COVAXIN® has not enlisted in the Emergency-Use Listing (EUL) of World Health Organization (WHO) vaccines due to inadequate data of Phase 3 clinical trials. The lack of endorsement from WHO has been hampering travel plans for individuals as many countries are only accepting vaccines approved by the public health body. However, COVAXIN®

has been acknowledgedwith emergency use authorizations in 16 countries together with Brazil, the Philippines, Iran and Mexico.

Finally, the Bharat Biotech company shared the final phase-3 clinical trial pre-print data on medRxiv on 3, July, 2021. According to the data provided, the company recruited 25798 subjects between November 16, 2020 and January 7, 2021(Figure 1). These participants were randomized to BBV152 or placebo groups. The purpose of this study is to gauge the efficacy, safety, and immunogenicity of COVAXIN® in volunteers of and above 18 years. The prime outcome was laboratory-confirmed symptomatic COVID-19, befalling at least fourteen days after the second dose. Ancillary outcomes were efficacy in18≤ 60 years and ≥ 60 years sub-groups and in volunteers with previous stable medical circumstances. The company also assessed safety, reactogenicity and consistency of immune responses for three sequential manufacturing lots.

Out of 24419 participants, 12221 received two doses of BBV152 and 12198 received placebo. In a case-driven analysis, 130 cases of symptomatic COVID-19 were recounted in 16,973 (0·77%) participants with sequelnot less than two weeks after the second vaccination. Out of 130 cases, 24 befell in the vaccine group and 106 in placebo recipients showing an overall vaccine efficacy of 77·8%. Out of 16 cases, one vaccinee and 15 placebo recipients, met the severe symptomatic COVID-19 case characterization demonstrating a vaccine efficacy of 93·4%. Efficacy against asymptomatic COVID-19 was 63·6%. The vaccine conferred 65·2% protection against the SARS-CoV-2 Variant of Concern, B.1.617.2 (Delta) with nil cases of anaphylaxis or vaccine-related deaths. Safety analysis demonstrated that adverse events reported were similar to placebo, with 12% of subjects experiencing commonly known side effects and less than 0.5% of subjects feeling serious adverse events. The vaccine has confirmed to neutralize the variants - B.1.1.7 (Alpha) first isolated in UK, P.1-B.1.1.28 (Gamma) & P.2 - B.1.1.28 (Zeta) first isolated in Brazil, B.1.617 (Kappa) first isolated in India, B.1.351 & B.1.617.2 (Beta & Delta) first isolated in RSA & India.

Dr.Soumya Swaminathan (Figure 2), the chief scientist at WHO, revealed to CNBC TV-18 on July,8,2021 that the final phase-3 clinical trial data for COVAXIN® "looks good" and encounters the safety profile of the international public health agency so far. She remarked that although COVAXIN®'s efficacy against the Delta variant of Covid-19 is a bit low, it is still not bad, while the overall efficacy is "quite high." She said that WHO keeps a close watch on all the vaccines which are on the pipeline for emergency listing, adding that the agency is anticipating more data for a concluding say on the matter.

Figure 2: Dr.SoumyaSwamination, Chief Scientist at WHO

In the interview, she also affirmed that most parts of the world have seen an uptick in coronavirus cases with no reduction in the number of COVID-related deaths, except in America. She also added that India can take inspiration from countries like the United Kingdom and strive to boost their shots as they are. By the way, she uttered that the WHO still does not recommend booster shots, adding that every country's prime focus should remain on widening the scope of primary COVID-19 vaccinations.

While on the subject, she also stated that one of the major reasons behind the spike in the number of COVID-related death, in Africa and other nations, is the spread of the Delta variant of the SARS-COV-2 that was first found in India. Listing out the reason for worry, she said the original strain could infect three people, the Delta variant can infect 6-8 and added that the world could witness another surge in coronavirus cases if the virus mutates further.

Last of all, she emphasized the need for social distancing and the usage of face masks. She pronounced that even after 70 percent of a nation's population is vaccinated, the remaining 30 percent stay at rest. In the end, the WHO Chief Scientist, Soumya Swaminathan concluded that vaccines alone are not enough and the government needs to continue with the testing and tracking method.

After the pre-print submission, Dr. N. K. Arora, Chief of National Technical Advisory Group on Immunisation, India (NTAGI, India)(Figure 3), supposed that these results will aid the vaccine to get acknowledgement from the WHO and people who have been administered COVAXIN® in our country will be capable of travelling across the globe without any restraints.

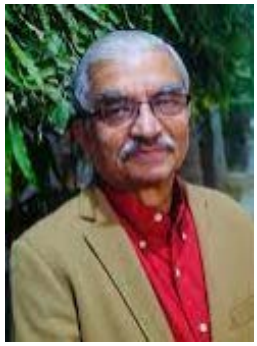

Figure 3: Dr. N. K. Arora, Chief of National Technical Advisory Group on Immunisation, India. (NTAGI, India)

Amidst unease over the lack of international recognition for locally manufactured COVAXIN®, the statement given by the Chief Scientist, Dr Soumya Swaminathan, emerge as a budding outbreath of liberation for students, officials and others who meant to travel abroad.

Sources:

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