All India Peoples Science Network (AIPSN) Statement

on Covaxin Interim Results from Phase 3 trials

7 Mar 2021

All India Peoples Science Network welcomes the first interim efficacy data from Phase-3 clinical trials as released by M/S Bharat Biotech for the indigenously developed Covid-19 vaccine "Covaxin". Based on the initial 43 cases of Covid-19 of which 39 were in the placebo arm and 7 were in the vaccinated arm of the phase 3 trial involving 25800 participants with 1:1 random allocation of vaccine and placebo, Bharat Biotech announced a point estimate of vaccine efficacy of 80.56% with two doses four weeks apart. The trial also showed protection from infection and severe disease across different segments of the population. Bharat Biotech has planned to release a second interim analysis at 87 cases, and a final analysis when 130 cases are reached in the near future. AIPSN looks forward to peer review and publication of all the data at the earliest.

Peer reviewed Phase-3 trial data should be submitted by Bharat Biotech to the Drug Controller General of India (DCGI) at the earliest so that the regulator may issue revised emergency use approval for Covaxin, doing away with the various conditions attached to it, notably the requirement of administering the vaccine in clinical trial, which were considered necessary by DCGI and its Subject Expert Committee because of the absence of Phase-3 trial data at that time. These steps would overcome the objections of a large section of the scientific community and civil society in India, who had raised their voice against premature approval to Covaxin without Phase-3 trial data.

Once approval is granted by DCGI to Covaxin on par with Covishield, Covaxin can justifiably join the global set of approved vaccines against the Covid-19 disease, enabling it to cater to the huge international demand for vaccines especially among developing countries. An indigenous Covid-19 vaccine, developed by the National Institute of Virology (NIV) under the Indian Council of Medical Research (ICMR), and manufactured by Bharat Biotech, legitimately gaining such acceptance internationally, would indeed be a matter of pride for Indian science and industry.

Statements by Government spokespersons claiming vindication of their support for the premature approval for Covaxin and its inclusion in the vaccination rollout, are entirely misplaced. As anticipated by those who strongly opposed both moves, including the AIPSN, the premature approval for Covaxin without Phase-3 data, clearly under Government pressure, has avoidably caused immense embarrassment at home and abroad, damaged the reputation of Indian science and regulatory institutions, and added to vaccine hesitancy in India. Little would have been lost if DCGI had waited for Phase-3 data now available. According to publicly available data, only about 10% of the approximately 16 million vaccination doses administered so far have been of Covaxin, a gap that could have easily been made up with Covishield.

AIPSN hopes that the nearly 81% efficacy shown by the first interim analysis of Covaxin phase 3 trials will now help dispel the earlier vaccine hesitancy due to hasty approval without data. AIPSN appeals to all eligible people to get vaccinated in order to protect themselves and prevent others who cannot be vaccinated from getting Covid-19. It is hoped that Bharat Biotech will now ramp up production to required levels and join the international battle against Covid-19 with full confidence. It is time the Government realizes that promotion of true self-reliance is not well-served by artificial support or false claims, but by promotion of quality R&D and products that can match the best in the world and compete globally on its own merits.

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