

Status of Development of COVID Vaccine in India

Posted On: 15 SEP 2020 2:58PM by PIB Delhi

While the Govt. and Industry are trying their best to make available a safe and effective vaccine for COVID-19 at the earliest, it is difficult to comment on the exact timelines in view of various complex pathways involved in vaccine development.

The Government has constituted a high-level National Expert Group on vaccine administration for COVID-19 which is chaired by Member, Niti Aayog and co-chaired by Secretary, Ministry of Health & Family Welfare. Other representatives are: Secretary, Ministry of External Affairs, Secretary, Department of Biotechnology, Secretary, Department of Health Research, Director General of Health Services, Ministry of Health & Family Welfare, Director, All India Institute of Medical Sciences, Head ECD, Indian Council of Medical Research, Director Jawaharlal Institute of Postgraduate Medical Education and Research (Member NTAGI) and Representatives from States & D/o Expenditure. The committee is addressing issues related to vaccine delivery, selection of suitable vaccines, procurement, prioritization of groups, logistics: Cold chain requirements, finance and National/International equity.

Central Drugs Standard Control Organisation (CDSCO) has granted test license permission for manufacture of COVID-19 Vaccine for preclinical test, examination and analysis to the following manufacturers in India.

1. M/s Serum Institute of India Pvt., Ltd., Pune
2. M/s Cadila Healthcare Ltd., Ahmadabad
3. M/s Bharat Biotech International Ltd., Hyderabad
4. Biological E Ltd., Hyderabad
5. M/s Reliance Life Sciences Pvt Ltd., Mumbai
6. M/s AurbindoPharma Limited, Hyderabad
7. M/s Genova Biopharmaceuticals Limited, Pune

The Indian Council of Medical Research (ICMR), an autonomous organisation under the Department of Health Research, has informed that the following companies are conducting clinical trials for COVID-19 vaccines in India:

(i) An inactivated whole virion candidate vaccine (BBV152) for SARS-CoV-2 has been developed by Bharat Biotech International Ltd (BBIL) using the virus isolate (NIV-2020-770) provided by ICMR-National Institute of Virology (NIV), Pune. Characterization of the vaccine candidate has been undertaken at ICMR-NIV followed by safety and tolerability studies in small animals like rats, mice and rabbits. Status of clinical trials is as follows:

- Phase I clinical trials alongwith parallel studies in large animals have been completed. The trial has revealed excellent safety of the candidate vaccine.

Immunogenicity testing is in progress.

- Phase II clinical trials are ongoing.

(ii) A DNA vaccine (ZyCov-D) has been developed by Cadila Healthcare Ltd. Pre-clinical toxicity studies were conducted in small animals: mice, rats, rabbits and guinea pigs. The vaccine has been found to be safe and immunogenic. Cadila has partnered with ICMR for conduct of parallel pre-clinical studies in large animals. Status of clinical trials is as follows:

- Phase I clinical trials have been completed. The trial has revealed excellent safety of the candidate vaccine. Immunogenicity testing is in progress.
- Phase II clinical trials are ongoing.

(iii) Serum Institute of India (SII) and ICMR have partnered for clinical development of two global vaccine candidates:

- ChAdOx1-S, which is a non-replicating viral vector vaccine developed by University of Oxford/AstraZeneca. This vaccine is undergoing phase III clinical trials in Brazil. Phase II/III bridging studies have been initiated by ICMR at 14 clinical trial sites. ICMR-National Institute for Research in Tuberculosis (NIRT), Chennai is the lead institution.
- ICMR and SII have also partnered for clinical development of a glycoprotein subunit nanoparticle adjuvanted vaccine developed by Novavax from USA. The trial will be initiated in second half of October after the vaccine is manufactured by SII. The trial is led by ICMR-National AIDS Research Institute (NARI), Pune.

As per details provided by Department of Biotechnology (DBT)/Department of Science and Technology(DST), more than 30 vaccine candidates have been supported which are in different stages of development.

The ICMR has allocated Rs.25.00 crore for various studies and other research activities pertaining to vaccine development.

The Science and Engineering Research Board (SERB), a statutory body under the Department of Science and Technology, has supported 03 projects under COVID-19 on vaccine research under Intensified Research in High Priority Areas (IRHPA) The sanctioned expenditure is Rs.22,27,579/- and the committed expenditure is Rs.3,20,78,161/-.

The Department of Biotechnology is also supporting 08 proposals by Industry and academia for candidate vaccine development and associated research resources at a total cost of Rs. 75 crore.

The Minister of State (Health and Family Welfare), Sh Ashwini Kumar Choubey stated this in a written reply in the Rajya Sabha here today.

MV

(Release ID: 1654450)