



(representative image) (Bloomberg)

'Excellent safety' of 2 indigenous Covid vaccines revealed during Phase-1 trials: Govt

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ICMR informs that the three companies are currently conducting clinical trials for COVID-19 vaccines in India and shares phase-wise update of these trials in the parliament. More than 30 vaccine candidates have been supported which are in different stages of development, the govt states.

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Amid the buzz to develop of potential vaccine against the novel coronavirus pandemic, the Indian government today shared that they in relation with the vaccine manufacturing industry are trying their best to make available a safe and effective Covid-19 vaccine at the earliest.

The Minister of State (Health and Family Welfare), Ashwini Kumar Choubey stated the report in a written reply in the Rajya Sabha today, during the second day of the Monsoon session in the Parliament.

Choubey also said that lockdown from March 25 to May 31 successfully controlled aggressive progression of COVID-19 in India but there has been steady rise in number of cases in post-lockdown phase.

He also said phase-I clinical trials have revealed "excellent safety" of the two candidate vaccines indigenously developed by Bharat Biotech in collaboration with ICMR and Cadila Healthcare Ltd and their immunogenicity testing is now in progress.

Mentioning the development progress of Covid-19 vaccines, he said that the Central Drugs Standard Control Organisation (CDSCO) has granted test license permission for manufacture of vaccine for pre-clinical test, examination and analysis to the following manufacturers in India:

- 1) Serum Institute of India Pvt., Ltd., Pune
- 2) Cadila Healthcare Ltd., Ahmadabad
- 3) Bharat Biotech International Ltd., Hyderabad
- 4) Biological E Ltd., Hyderabad
- 5) Reliance Life Sciences Pvt Ltd., Mumbai
- 6) AurobindoPharma Limited, Hyderabad
- 7) Gennova Biopharmaceuticals Limited, Pune

Moreover, the Indian Council of Medical Research (ICMR) has informed that the following companies are conducting clinical trials for COVID-19 vaccines in India:

- 1) 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 along with parallel studies in large animals have been completed. "The trial has revealed excellent safety of the candidate vaccine. Immunogenicity testing is in progress," said Choubey.

Phase II clinical trials are ongoing.

- 2) 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," he said. Immunogenicity testing is in progress.

Phase II clinical trials are ongoing.

- 3) 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 statement added.

The ICMR has allocated ₹25 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 three projects under Covid-19 on vaccine research under Intensified Research in High Priority Areas (IRIIPA). The sanctioned expenditure is Rs.22,27,579 and the committed expenditure is ₹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 ₹75 crore.

As per the World Health Organisation, 35 vaccine candidates are under clinical evaluation and 145 candidates are in pre-clinical evaluation stage as on September 9, Choubey said.

Centre 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," a statement read.

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.