India likely to get first mRNA vax by year-end

Emcure Pharma's arm Gennova completes Phase I trials

RUTAM VORA

Ahmedabad, August 4

India may get its first indigenous mRNA vaccine for Covid by the end of this year.

Gennova Biopharmaceuticals, a subsidiary of pharma major Emcure Pharmaceuticals, has completed the first phase of human trials for the vaccine – HGCO19 – company officials informed.

The first phase has established the safety of the two-dose vaccine for those aged 18 and above.

'No adverse reactions'

"The primary outcome of safety (of the vaccine) has been established. There has been no serious adverse events. Now, the independent body, Data and Safety Monitoring Board, is reviewing the data.

"The secondary outcome related to immunogenicity and efficacy results are being analysed at present," Samit Mehta, Gennova Chief Operating Officer, told *BusinessLine*.

"Our endeavour is to deliver the committed 6 crore doses of the vaccine to the government by the end of the year. And we expect to complete the Phase II and Phase III trials by that time and launch the vaccine by December-end. The government is providing all support and handholding us for the earliest launch," he added.

The first phase of trials took about 60 days and were conducted at three sites with 120 volunteers.

Once the data is accepted, the company will seek a combined approval for Phase II and Phase III trials. The two-dose vaccine is to be administered with the first dose on Day 1 and second on Day 29.

Grant provided

The Centre has provided Gennova ₹25 crore grant for the development of the vaccine. The company plans to produce the vaccine at its plant at Hingewadi near Pune.

The Phase II and Phase III trials will be much larger and will be carried out at about 20 centers all over the country, including the north-eastern, southern and northern parts of the country.

Unlike other mRNA vaccines by global majors, which require refrigeration of (minus) - 80 degrees Celsius, the vaccine from Emcure's stable can be stored and transported at 2-8 degrees Celsius, making it much convenient to supply it to the rural and interior areas of the country.