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INDIA AIMS TO PRODUCE MRNA COVID-19 VACCINE THIS YEAR

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Effort could boost nation’s pharmaceutical industry and ease the global distribution

NEW DELHI : India is preparing to produce its own mRNA-based Covid-19 vaccine by the end of the year, in what would be a scientific breakthrough for the country’s growing pharmaceutical industry and help expand the range of global production hubs for the shots.

A host of companies across the world are pushing to bring their own vaccines using the mRNA technology to market following the success of the Pfizer Inc. and Moderna Inc. shots. Indian firms, urged on in part by Prime Minister Narendra Modi, aim to be significant players in the new sector, with Gennova Pharmaceuticals Ltd. hoping to be the first.

Gennova’s candidate, known as HGCO19, is funded in part by the government and is being developed in conjunction with Seattle-based HDT Bio Corp. The vaccine’s key feature, Chief Executive Sanjay Singh, said, is that it can be stored between 2 degrees Celsius and 8 degrees Celsius (35.6 degrees to 46.4 degrees Fahrenheit), making it more manageable for easy distribution in low-and middle-income countries where storage and logistics can be a challenge. The mRNA vaccines developed by Moderna and by Pfizer with Germany’s BioNTech SE have to be stored at supercooled temperatures.

Developing a new vaccine could be a significant step forward for India’s pharmaceutical industry, which has huge production capacities and has largely evolved by manufacturing medications developed elsewhere, including a version of U.K.-based AstraZeneca PLC’s Covid-19 vaccine.

“India endeavors to establish a significant vaccine capacity using the mRNA technology platform not only for Covid-19 vaccines, but also for pre-existing and emergent ones," said V.K. Paul, who leads the health team at the National Institution for Transforming India, a government think tank that has helped lead India’s vaccination drive.

Unlike conventional vaccines, which use a live virus to trigger an immune response in humans, those made using messenger ribonucleic acid, mRNA, carry genetic instructions that generate a spike protein to develop antibodies against infections.

Gennova’s HGCO19 is designed to be simpler to manufacture than existing mRNA shots. Using a process called freeze-drying or lyophilization, the company would make the vaccine in powder form, making it more stable and easy to be shipped in addition to being stored at moderate temperatures. The powder can be reconstituted by dissolving with a diluent before vaccination.

Pfizer and BioNTech have also initiated a study to evaluate a lyophilized formulation for their Covid-19 vaccine, and the results are expected later this year, according to information on the company’s website.

Another differentiating characteristic is that Gennova’s candidate uses self-amplifying mRNA instead of non-replicating mRNA. This helps in administering smaller doses while having the same effect, reducing side effects, Mr. Singh said.

The Indian drug regulator approved Gennova's vaccine candidate last month for second- and third-phase trials after the shot was found to be safe and effective in an early-stage study.

The company began the Phase 2 trial this month and hopes to start the third phase from around mid-October at sites across the country. Around 4,400 volunteers will be enrolled in both the phases.

The company aims to get HGCO19 approved for emergency use by Indian authorities this year and manufacture up to 60 million doses by the end of December, mostly for distribution in the government's vaccination program, said Gennova's chairman, Satish Mehta.

Gennova has begun preparing to expand production capacity to become a significant part of India's own vaccination drive for adults and children, and as a booster for other vaccines in India and in other emerging markets.

The company is also hoping to play a role through the World Health Organization in supplying vaccines and sharing the technology to make the vaccine elsewhere. The WHO's Chief Scientist Soumya Swaminathan visited Gennova's facility in the western Indian city of Pune to discuss the vaccine last week.

Some manufacturers, notably French healthcare company Sanofi SA, are halting development of mRNA Covid-19 vaccines, noting that the market is already crowded. The WHO, however, is seeking to expand the capacity of low- and middle-income countries to produce Covid-19 vaccines, some of which would be distributed through its Covax facility.

Gennova's mRNA-based vaccine candidate "looks very promising in terms of immunogenicity and safety in its Phase 1 trial, though more results from the Phase 2 and 3 trials are awaited," Ms. Swaminathan said.

"It's a completely new platform for India and should be seen as investing in the future," said Shahid Jameel, one of India's top virologists and a visiting professor at Ashoka University.

India has so far authorized emergency use for two locally developed Covid-19 vaccines, made by Bharat Biotech International Ltd. and Zydus Cadila.

The Serum Institute of India is also collaborating with the U.K.'s AstraZeneca in making a vaccine, while the Russian vaccine Sputnik V is being produced in small quantities by some Indian manufacturers.

India's drug regulator granted emergency use to Moderna's vaccine in June, but the government hasn't yet guaranteed indemnity against prosecution in case of adverse reactions, slowing its rollout.

Pfizer had also planned to supply an initial 50 million doses to the Indian government this year, but with the rise in locally made vaccine stocks, Indian policy makers are moving slowly in providing the legal framework for that to happen, said a senior government official.

A spokeswoman for Pfizer in India said the company continues to be engaged with Indian government authorities to make the vaccine available for use in the country.

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