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Important to fast-track regulatory clearances for the COVID-19 vaccine: Adar Poonawalla

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At the forefront of discovering effective treatments and vaccines to combat the outbreak of COVID-19, coronavirus; Serum Institute of India Pvt. Ltd. (SIIPL), the world's largest vaccine manufacturer by number of doses produced and sold globally recently stated that the vaccine for COVID-19 will require fast-tracking of regulatory clearances, and a due diligence of ethics and safety standards for it to be market ready by 2022. Following the same, the development has now progressed to the pre-clinical test phase i.e. the animal trial phase, with results awaited to release in the next two months.

In a bid to generate a vaccine candidate at the earliest, the SII-Codagenix developed novel coronavirus virus-vaccine strain is pegged as the first in its form to progress to the pre-clinical trial phase.

Talking about the urgent need to formulate a robust way ahead to control the global pandemic, Adar Poonawalla, CEO, SIIPL said, “SII and Codagenix have been working with utmost diligence and meticulous effort to develop a preventive vaccine against the novel coronavirus. The vaccine-virus strain is identical to the original virus and can generate a robust immune response. At present we are the pre-clinical phase, i.e. the animal trial phase. In two- month time, we hope to get some results on the animal studies and then based on the regulatory path we take, and which countries allow for the most ethical and fastest approval clearance for the human trial phase; the way ahead will be determined.”

SIIPL seeks to do its clinical trials in India, while adhering to all the ethics and safety standards prescribed by the Government of India, however, the final decision is yet to be taken and will be dependent on varied factors. The vaccine-virus strain will be the fastest ‘Made in India’ vaccine to progress to the human trials phase within six months, if succeeded. The cost of the project has been estimated at INR 300 crores, SII aims to secure external funding for the project via various global partners.

Adding to the above, Mr. Poonawalla, said, “The company plans to do its clinical (human) trials in India, adhering to the ethics and safety standards. We have also been approached by other companies and things are in process. As the vaccine leaders of the world, we should step up and contribute towards combatting these kinds of pandemics.”

Highlighting on the manufacturing challenges he added, “This product will have to be handled under BSL 3 (biosafety level) conditions which basically is a very high containment level. I don't know how many facilities in the world have high volume manufacturing in BSL 3, we don't. We will have to see if this can be toned down. Even if you have the vaccine the main challenge will be to manufacture it at a large volume.”

Since the outbreak of COVID-19, coronavirus has claimed an estimated 3,300 lives worldwide while over 98,000 people have been infected by the virus. Recognized as a ‘global health emergency’ by the World Health Organization, proactive and urgent strides are being made by global institutions and drug-makers towards finding a viable cure in controlling the outbreak.

Marching towards generating a vaccine candidate, SIIPL had recently announced its partnership with American Biotechnology firm, Codagenix.