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By Vibha Ravi

SERUM INSTITUTE HAS STRUCK A PARTNERSHIP with Dynavax and Aurobindo Pharma with US-based company COVAXX for new vaccine candidates while Bharat Biotech has tied up with Ocugen to explore marketing of its existing contender, Covaxin, in the US.

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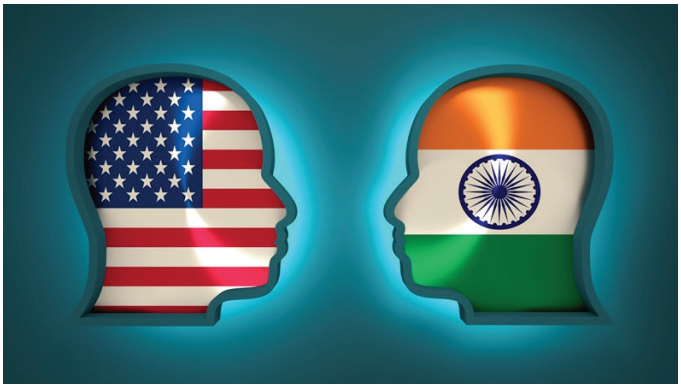

Adding more arrows to their quivers in the battle against COVID-19, two Indian companies are developing a new vaccine with partners in the US while a third is attempting to expand its reach in the country.

Serum Institute of India Pvt. Ltd. announced on 23 December a tie up with Dynavax Technologies Corporation, a commercial stage biopharmaceutical company developing and commercializing novel vaccines. Serum paired Dynavax's adjuvant CpG 1018 with an antigen developed in-house for the new COVID-19 vaccine candidate.

The company already has other vaccines in the works, with the University of Oxford/AstraZeneca PLC-partnered AZ1222, being in the most advanced stage. It's believed to be close to an accelerated approval in India as the country gets set to roll out its immunization program. (Also see "Coronavirus Update: Sanofi And GSK's Vaccine Suffers Setback" - Scrip, 11 Dec, 2020.)

Dynavax's adjuvant has been previously tried and tested in its first commercial product Heplisav-B, a recombinant Hepatitis B vaccine for adults, approved by the US Food and Drug Administration (FDA).

CpG 1018 provides a well-developed technology and a significant safety database, potentially accelerating the development and large-scale manufacturing of a COVID-19 vaccine. Dynavax is also advancing CpG 1018 as a premier vaccine adjuvant through research collaborations and partnerships focused on vaccines for COVID-19, pertussis and universal influenza.

Serum Institute said the first of the 39 healthy volunteers have been dosed in the Phase I part of the Phase I/II clinical trials. Post the completion of the study a decision will be taken regarding the dosing of up to 216 subjects in Phase II.

Adar Poonawalla, Serum Institute's CEO, said, " We are hopeful that delivering the CpG 1018 adjuvant in the vaccine will enhance the immune response of the candidate. Through this (alliance), we seek to provide our expertise and capability to produce large quantities of affordable vaccine to supply global needs."

Aurobindo Partners COVAXX

Meanwhile, Aurobindo Pharma Limited has joined hands with a US company, COVAXX, a name easily confused with the COVAX facility set up by Gavi, the Coalition for Epidemic Preparedness Innovations (CEPI) and the World Health Organization to ensure equitable access to COVID-19 vaccines.

COVAXX is a subsidiary of United Biomedical, Inc. Inc (UBI), founded in 1985, with headquarters in New York. The company manufactures and markets antibody blood diagnostic tests and veterinary vaccines.

On 24 December, Aurobindo announced an exclusive agreement with COVAXX to develop, commercialize and manufacture UB-612, the first synthetic peptide-based vaccine against SARS-CoV-2 for India and the United Nations Children's Fund (UNICEF). It will also have non-exclusive rights to market UB-612 in other select emerging and developing markets.

Preclinical studies have shown that UB-612 generated high titers of neutralizing antibodies. COVAXX is currently conducting a Phase I clinical trial for the vaccine candidate while Phase II/III trials are expected to begin early in the first quarter of 2021 in Asia, Latin America and US.

N Govindarajan, managing director, Aurobindo Pharma said the vaccine candidate has "immense potential in eliminating shedding, and hence containing, the spread of the pandemic." Mei Mei Hu, co-founder and CEO of COVAXX said the company is committed to providing an equitable distribution of UB-612 by prioritizing emerging markets where the unmet need is greatest.

Aurobindo will manufacture the finished doses at its facilities in Hyderabad. The company can make 220 million multi-dose vials at this unit and is building additional manufacturing plants/lines to have a total capacity of nearly 480 million doses by June 2021.

Aside from this vaccine, Aurobindo is working on its own vaccine contender and collaborating with three government labs - Centre for Cellular and Molecular Biology in Hyderabad, Institute of Medical Technology in Chandigarh and Indian Institute of Chemical Biology in Kolkata – to develop COVID-19 vaccine candidates using different technology platforms. (Also see "Aurobindo Enters Fray For COVID-19 Vaccine" - Scrip, 17 Aug, 2020.)

Bharat Biotech Plans US Inroads

In a partnership that switches the countries sitting on the two sides of the licensing table, Bharat Biotech will license its indigenously developed COVID-19 vaccine candidate, Covaxin, to US-based Ocugen Inc..

The whole-viron inactivated vaccine candidate, developed by Bharat Biotech developed in collaboration with the Indian Council of Medical Research's National Institute of Virology, is in Phase III trials in India. "The development and clinical evaluation of Covaxin marks a significant milestone for vaccinology in India. Covaxin has garnered interest from several countries worldwide for supplies and introduction," said Dr. Krishna Ella, chairman and managing director of Bharat Biotech.

Bharat Biotech recently has recruited 13,000 volunteers for the Phase III trial, which is set to be the largest clinical trial of a vaccine in India with a target of 26,000 participants. (Also see "Bharat Biotech Plans Coronavirus Vaccine" - Scrip, 20 Feb, 2020.)

Ocugen will have US rights to the vaccine candidate and, in collaboration with Bharat Biotech, will be responsible for clinical development, registration, and commercialization for the US market. The companies have begun collaborating and will finalize details of the definitive agreement over the next few weeks.

Ocugen has assembled a Vaccine Scientific Advisory Board featuring leading academic and industry experts to evaluate the clinical and regulatory path to approval in the US market. "Covaxin offers a vaccine candidate that is different from other options currently available in the US market with potentially broader coverage against multiple protein antigens of the virus," said Dr Harvey Rubin of the University of Pennsylvania, a member of Ocugen's Vaccine Scientific Advisory Board.

Dr. Shankar Musunuri, CEO, and co-founder of Ocugen said the company's management is "very pleased with the safety and immunogenicity demonstrated by the Phase I and Phase II trials of Covaxin and are encouraged with the progress of the Phase III trials in India."