DBT’s National Pharma Mission to fund a COVID-19 vaccine project

New Delhi, June 15: The current 2019 Novel Coronavirus (2019-nCoV or SARS-CoV-2) pandemic is unprecedented. The global response is drawing on the lessons learned from other disease outbreaks in the past. In the setting of a public health emergency, the development of a 2019-nCoV vaccine must balance manufacturing speed and technical feasibility with clinical safety and immunogenicity trial outcomes. Ultimately, the manufacturing must be scalable, and the delivery simple to reach the maximum number of people in the shortest possible period.

Considering all these requirements, Bharat Biotech International Ltd (BBIL), Hyderabad, and Thomas Jefferson University, USA have signed an agreement to develop a COVID-19 vaccine based on an inactivated Rabies virus platform. The Department of Biotechnology’s National Biopharma Mission will provide funding for the joint project under the DBT-BIRAC COVID-19 Research Consortia Initiative.

Thomas Jefferson University has developed a Rhabdovirus based vector that contains the S1 fragment of SARS-CoV-2 / COVID-19 spike glycoprotein. The recombinant rabies virus harboring SARS-CoV-2 S1 fragment will be further inactivated using beta-propiolactone.

The use of a Rhabdovirus vector for producing a vaccine is not new. It has been successfully used for many human vaccines. For instance, chemically inactivated Rabies Virus (RABV) vaccines are quite safe and are administered very widely to humans. The codon optimized foreign genes in general, introduced between RABV N and P genes have been found to be highly expressed and are stable. The same platform is being used to develop several vaccines against epidemic and pandemic causing viruses like Ebola virus, Nipah virus, and other coronaviruses like SARS, MERS-CoV, etc. The rabies vaccine has decades of safe use across diverse populations. A proof of concept was demonstrated by protecting animal models based on challenge studies with the related MERS-CoV in two mouse models and alpacas (camelid). Long-term protection is expected since the RABV vaccine often provides life-long protection.

Bharat Biotech International Ltd (BBIL), which is the world’s largest Rabies vaccine
manufacturer will take up complete development and commercialization of the vaccine into world markets. It will be involved in a full-fledged, end-to-end development of the COVID-19 vaccine candidate from laboratory scale work to full-scale GMP Manufacturing, pre-clinical evaluation of the safety of the vaccine and comprehensive clinical trials from Phase 1 to Phase 3, to achieve commercial licensure. Its vaccine facility has already received a Project Grant under BIRAC/DBT Scheme from the Govt. of India for this vaccine.

BBIL has so far commercialized 16 vaccines and has market authorization in over 65 countries. It is the major supplier of the Rotavirus (ROTAVAC®) and Oral polio vaccines (BIOPOLIO®) to India’s and World’s Expanded Program of Immunization (EPI). Globally, its products are registered in 33 countries and the products are being supplied to more than 115 countries. It has a track record of low-priced vaccines at a high supply.

**Long term Immunity against Covid-19 and Rabies by an established vaccine platform**

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