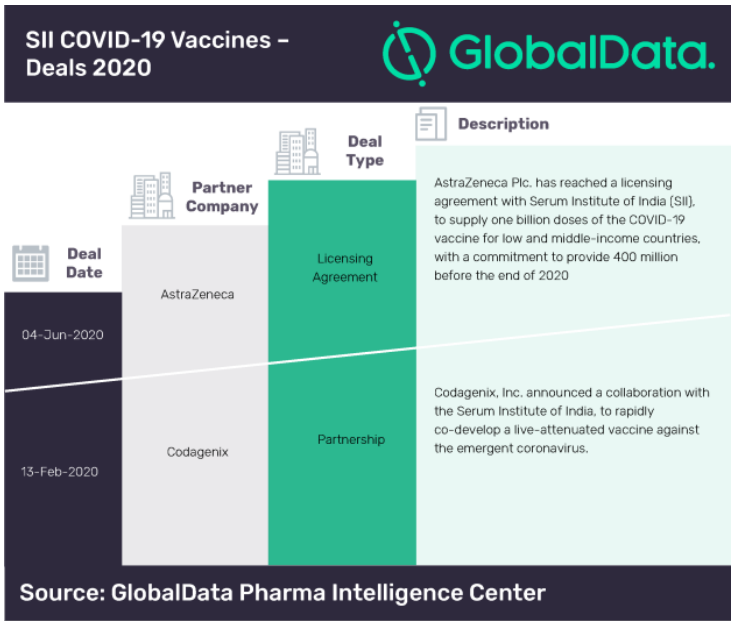
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India's Serum Institute to play pivotal role in COVID-19 vaccines

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"SII is currently working on three candidates for COVID-19, including the testing of its recombinant-BCG vaccine in Phase 3 clinical trials at several locations across India" reports GlobalData



Serum Institute of India (SII) is the world's largest vaccine producer in terms of volume. SII is currently working on three candidates for COVID-19, including the testing of its recombinant-BCG vaccine in Phase 3 clinical trials at several locations across India. With these, SII continues to play a pivotal role in the development and commercialization of COVID-19 vaccines, says GlobalData, a leading data and analytics company.

Krishna Srinivasaraghavan, Pharma Analyst at GlobalData, says: "Serum Institute of India has invested US$100m for setting up a COVID-19 vaccine manufacturing unit in India. SII is highly active on three fronts – development, partnerships and manufacturing capabilities to supply COVID-19 vaccines."

Earlier, New York Institute of Technology (NYIT) researchers highlighted that countries without universal policies of BCG vaccination have been more severely affected compared to countries with universal and long-standing BCG policies. It is important to note that BCG vaccination is part of the national immunization program in India and the majority of the Asian countries.

Vakzine Projekt Management GmbH (VKM), in which SII is the majority stake holder, has initiated a Phase 3 trial of VPM1002 (BCG vaccine) in May 2020, involving 1,200 healthcare professionals globally and around 6,000 high-risk subjects in India (NCT04387409 and CTRI/2020/04/024749). It is expected to be completed in April 2021.

According to GlobalData's Pharma Intelligence Center, overall, 19 trials are being conducted globally at various locations to test the use of BCG vaccine against COVID-19, especially focused on healthcare workers. These include a Phase 3 ongoing trial being conducted by Murdoch Children's Research Institute (BRACE trial) in Australia (NCT04327206), which is expected

to enrol around 10,000 subjects and complete by October 2020. Trials are also being planned in India by JIPMER (CTRI/2020/04/024833) in Phase III and Haffkine Institute (CTRI/2020/05/025013) to test a BCG vaccine in Phase II for COVID-19.

Srinivasaraghavan concludes: “BCG vaccinnation is already part of the compulsory schedule for children in India. If the BCG trials for COVID-19 are successful, the vaccine can be extended to a wider population in the fight against the pandemic effectively and save lives. Moreover, SII would be able to scale-up the production of BCG vaccine quickly in India.”