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US-based Akston Biosciences initiates Ph II trial of second-gen COVID-19 vaccine in India

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Akston Biosciences Corporation, based in the US, has announced that the first of 100 subjects were dosed in an open-label bridging study of AKS-452, its protein subunit COVID-19 vaccine candidate, in India.

AKS-452 is shelf-stable for at least six months at room temperatures (up to 25° Celsius or 77° Fahrenheit) and maintains its potency for one month at 37° Celsius (99° Fahrenheit).

Drug's Controller General of India (DCGI), Ministry of Health and Family Welfare, approved the open-label bridging study, being conducted by the Supe Heart & Diabetes Hospital and Research Centre, in Nashik, India along with four other sites in the state of Maharashtra. Veeda Clinical Research Ltd., a CRO with experience overseeing complex clinical trials, is managing the study.

In both studies, healthy volunteers will receive two 90 µg doses 28 days apart. Of the 1,500 participants in Phase II/III study, 1,150 will receive the two-dose regimen, while the remaining 350 will receive two placebo doses. The first dose will include AKS-452 and an adjuvant, which primes the body's immune response, with the second dose consisting only of AKS-452.

The AKS-452 is a protein sub-unit vaccine, a type of vaccine used safely and widely for decades. AKS-452 does not contain mRNA technology, viral vectors, or a weakened SARS-CoV-2 virus.