COVISHIELD™

VS

COVAXIN™

A Comparison Study

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VACCINE CANDIDATE NAME	SII-ChAdOx1 nCoV-19/AZD1222	BBV152
VACCINE DEVELOPMENT (STARTED)	January, 2020	April, 2020
TECHNOLOGY USED	• **New technology.** • Chimpanzee adenoviral vector, ChAdOx1 with SARS-CoV-2 structural surface glycoprotein antigen.	• **Proven, time-tested technology** • A whole-virion inactivated SARS-CoV-2 vaccine. • Vero-cell manufacturing platform with a 300 million doses safety track record.
ADJUVANTS	No	Adjuvanted: Algel + TLR 7/8 agonist

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DOSAGE SCHEDULE	0.5mL, Two-doses, 28 days apart	0.5mL, Two-doses, 28 days apart
VACCINE TYPE	Intramuscular	Intramuscular
DILUTION	No	No
AGE	≥18 years	≥18 years
STORAGE	2-8°C	2-8°C
OPEN VIAL POLICY (MULTI-DOSE VIALS)	Once opened to be used within 6 hrs.	Once opened to be used within 6 hrs.

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VACCINE VIAL MONITOR (VVM)	Not Available	VVM7: 7 days @ 37°C
WORKING MECHANISM	A single recombinant, replication-deficient ChAdOx1 vector encoding the S glycoprotein of SARS-CoV-2. ↓ Once administered, the S glycoprotein of SARS-CoV-2 expresses stimulating neutralizing antibody and cellular immune responses.	Consists of SARS-CoV-2 whole virus particles that have been killed or inactivated. ↓ The immune system learns to recognize the entire virus and attacks it with antibodies and T-cells.

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PRE-CLINICAL STUDY	• Studies conducted in non-human primates and Syrian Hamsters. • Monkey studies showed vaccination prevents virus replication only in the lower respiratory tract. Reference: https://www.nature.com/articles/s41586-020-2608-y	• Live viral challenge studies in Syrian Hamsters and Non-human Primates were conducted. • Vaccination in non-human primates prevented infection in both lower and upper respiratory tracts. References: https://www.researchsquare.com/article/rs-65715/v1 https://www.sciencedirect.com/science/article/pii/S2589004221000225

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HUMAN CLINICAL TRIALS (Phase I/II) (India)	• An acceptable safety profile was reported with induced strong humoral and cellular immune responses in phase1/2 study conducted in UK. • There is no Phase 1 study conducted representing Indian demographics. • A Phase 2/3 clinical trial with the enrolment of 1600 participants across different sites in India has commenced. References: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31604-4/fulltext http://ctri.nic.in/Clinicaltrials/showallp.php?mid1=46186&EncHid=&userName=covid-19%20vaccine	• Demonstrated tolerable safety outcomes and enhanced humoral and cell-mediated immune responses. • Phase 1 and 2 are conducted in India with active participation of 755 volunteers. References: https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30942-7/fulltext https://www.medrxiv.org/content/10.1101/2020.12.21.20248643v1

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EFFICACY	• In participants receiving ◆ 2 standard doses - 64.2% efficacy noted (Brazil study) ◆ low dose + standard dose - 90% efficacy noted (UK study) • Overall vaccine efficacy across 2 groups - 70.4%. • The variation in efficacy led to ambiguity of vaccine. • Moreover, the study pooled the results from differently designed trials in Britain and Brazil which is a break from the standard practice in reporting the results of any trials. Reference: https://www.nytimes.com/2020/11/25/business/coronavirus-vaccine-astrazeneca-oxford.html	• India's largest ever efficacy trials are being conducted with 25,800 volunteers. • Currently, second-dose of vaccine is being administered to all the volunteers. • The interim efficacy estimate will be generated by February, 2021. • The projected efficacy value will be >60% (expected). • Data reported from this study will truly reflect Indian population.

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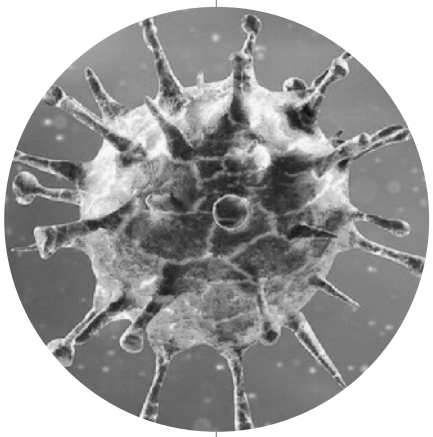
NEW STRAINS	Vaccine immunogenicity against mutant strain not reported.	• **Protective against UK variant strain** ◆ No Neutralization activity of vaccinated individual sera against variant as well as heterologous SARS-CoV-2 strains was noted. ◆ Importantly, sera from the vaccine recipients could neutralise the UK-variant strains discounting the uncertainty around potential escape. Reference: https://www.biorxiv.org/content/10.1101/2021.01.26.426986v2



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SIDE EFFECTS	• Fever, cough, shortness of breath, and anosmia or ageusia. • Percentage of side-effects reported by the study was 50-70%. Reference: The LANCET Journal* https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31604-4/fulltext	• The most common side effects included pain at the injection site, followed by headache, fatigue, and fever. • No severe or life threatening solicited adverse events were reported. • Percentage of all side-effects combined was 15% in vaccine recipients. Reference: The LANCET Journal* https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30942-7/fulltext

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MEDICAL INTERVENTION	Preventive use of paracetamol was administered before vaccination and participants were advised to continue 1g of paracetamol every 6h for 24h to reduce vaccine-associated reactions during phase 1/2 trials.	No medication was given to prevent any adverse effect during the trials.

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PUBLICATIONS	No Publications from Serum Institute. All the studies are from Oxford University, UK & AstraZeneca.	**6 Publications** from Bharat Biotech Already Published: 1. Phase 1 2. Syrian Hamsters study Accepted for Publication: 3. Rhesus macaques study 4. Phase 2 Under Advanced Review: 5. Animal models 6. UK Variant Strain

Regulatory Status: COVAXIN™ is approved for emergency use only in India, while COVISHIELD™ has been granted for emergency use in U.K, India, and other countries.