

## PRESS RELEASE

### South African Medical Research Council and National Department of Health announce Sisonke 2 or the Sisonke boost study for health workers

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**Sisonke early access study:** Between 17 February and 17 May this year, the SAMRC worked with the National Department of Health, Desmond Tutu Health Foundation, CAPRISA and Johnson and Johnson to provide early access to the Ad26COV2.S vaccine (commonly referred to as J&J or Johnson and Johnson) to health workers ahead of the third wave. In total 496 424 health workers received a dose of this vaccine as part of a Phase 3B study to evaluate its effectiveness in South Africa at a time when there were concerns as to whether vaccines work well against variants of concern.

This decision was made after the results of the ENSEMBLE study was published, demonstrating vaccine efficacy in a multi-country study conducted in three continents. This study provided evidence that the vaccine provided protection even against the Beta variant circulating in South Africa in early 2021. The Sisonke study confirmed these findings and showed that this single dose vaccine was safe, easy to administer and provided good protection against severe disease and death.

“By rolling out the Sisonke study, we bought valuable time for health care workers, and were able to protect them four months ahead of the national roll-out and ahead of the Delta driven third wave” says Professor Glenda Gray, one of the Co-National Principal Investigators of the Sisonke Study.

**J&J in the National Vaccination Programme:** The Ad26 vaccine was made available as Janssen® (J&J) vaccine in South Africa and became part of the National Vaccination Programme in the middle of 2021. The single-dose regimen has provided the backbone of campaigns for other essential workers like educators and members of the South African Police Service, and those who live in more rural locations. To date more than 5,2 million people in South Africa have received at least one dose of Janssen® (J&J) vaccine.

**Booster vaccinations:** Booster vaccinations are becoming available in many parts of the world. Scientific evidence on waning (progressive decrease of immunity) and the need for booster doses is evolving and some countries have decided to offer booster doses to certain high-risk populations like the elderly and health workers or other frontline workers. In South Africa, where only 30% of eligible adults have been fully vaccinated, increasing coverage of first doses to levels that would reduce hospital admissions and deaths during a fourth wave remains a top priority.

**Evidence of increased protection from a booster dose of Janssen® (J&J) vaccine:** A new trial, ENSEMBLE 2 evaluated a booster dose given at least two months after the first dose in 31 300 participants from more than nine countries. An Ad26.COVID.S dose administered two months after the primary Ad26.COVID.S dose substantially increases protection, especially against symptomatic and severe/critical disease COVID-19, including when caused by SARS-CoV-2 variants of concern. Vaccine efficacy against symptomatic disease was 94% in the US and 75% globally. At a global level vaccine efficacy was 100% against severe disease and critical disease. In this study, two doses were safe and usual vaccine safe effects ('reactogenicity') were reduced following the second dose. Based on this data, the American FDA has recommended a second dose of the Janssen® (J&J) vaccine in anyone over 18 years of age in the USA.

**Sisonke Boost Phase 3B study:** Based on this new information, and to bolster the immune response of our health workers ahead of a fourth wave, the SAMRC has worked with the National Department of Health, SAHPRA and J&J to provide early access to Janssen® (J&J) vaccine booster doses for all health workers

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who received a first dose of this vaccine as part of the Sisonke study. As before, access will be in the context of a Phase 3B study and results will be used to guide future decisions regarding boosters.

We are in the final stages of approvals from the regulators and ethics review committees, and vaccination will be open to all health workers, including pregnant and breastfeeding women, who received a first dose of the Janssen® (J&J) vaccine as part of the Sisonke study. Health workers who have received unauthorised booster doses of Cominarty® (Pfizer-BioNTech) vaccine after Janssen® vaccine are strongly encouraged not to accept an additional booster Janssen® vaccine as there are insufficient safety data for such a schedule. Co-National Investigator, Professor Linda-Gail Bekker says, “Sisonke was an important intervention to protect our frontline health care workers. Now it is important to ensure that protection is topped up with this boost ahead of potential new COVID-19 surges.”

**How the Sisonke Boost will work:** Health workers who participated in Sisonke will receive an invitation by SMS on the number they used to enrol for the first part of the study. As before, enrolment will be through the EVDS and will include an informed consent form which will need to be completed online. Sisonke booster vaccinations will be offered from the week of the 8<sup>th</sup> of November at selected sites to be announced in all nine provinces. Safety monitoring and evaluation of outcomes will be led by the SAMRC. Health workers who wish to take up this offer and have changed their cell phone numbers are advised to call the National Hotline on 0800 029 999 so that staff can update their contact details on EVDS. Please do not re-register on EVDS.

We welcome this unique partnership between government and researchers to provide booster doses to our health workers under the Sisonke study and to develop local evidence on ongoing effectiveness to inform the National rollout. The Acting Director General of Health, Dr Nicholas Crisp says: “Vaccines remain our most powerful weapon in the fight against the COVID-19 pandemic and our priority remains the most vulnerable groups, especially senior citizens or adults who live with compromised immunity in majority, ahead of a fourth wave”. He added that: “It is our collective responsibility as individuals, families and communities to protect ourselves and loved ones, including those who we spend most of our time with. Vaccines save lives and bring us one step closer to ending the pandemic”.

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