News Release

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Johnson & Johnson COVID-19 Vaccine Shows up to 85 Percent Effectiveness against Hospitalisation in South Africa While Omicron is Dominant[1]

Separate analysis showed the Johnson & Johnson COVID-19 vaccine as a heterologous booster generated 41-fold increase in neutralising antibodies and a 5.5-fold increase in CD8+ T-cells against Omicron[2]

NEW BRUNSWICK, N.J., 30 December 2021 – Johnson & Johnson (NYSE: JNJ) (the Company) today announced new preliminary results from the South African Phase 3b Sisonke study which showed that a homologous (same vaccine) booster shot of the Johnson & Johnson COVID-19 vaccine (Ad26.COV2.S) demonstrated up to 85 percent effectiveness against COVID-19-related hospitalisation.[1] The study, conducted by the South African Medical Research Council (SAMRC),[3] showed that the Johnson & Johnson booster reduced the risk of hospitalisation from COVID-19 among healthcare workers in South Africa after Omicron became the dominant variant.[1] During the months studied (mid-November to mid-December) the frequency of Omicron increased from 82 to 98 percent of COVID-19 cases in South Africa as reported by GISAID, an initiative that provides COVID-19 data.[4]

A second, separate analysis of the immune response to different vaccine regimens, conducted by Beth Israel Deaconess Medical Center (BIDMC), demonstrated that a heterologous booster (different vaccine) of the Johnson & Johnson COVID-19 vaccine in individuals who initially received the BNT162b2 mRNA vaccine generated a 41-fold increase in neutralising antibody responses by four weeks following the boost[2] and a 5.5-fold increase in CD8+ T-cells to Omicron by two weeks.[2] A homologous boost with BNT162b2 generated a 17-fold increase in neutralising antibodies by four weeks following the boost[2] and a 1.4-fold increase in CD8+ T-cells by two weeks.[2]

"Data from the Sisonke 2 study confirm that the Johnson & Johnson COVID-19 booster shot provides 85 percent effectiveness against hospitalisation in areas where Omicron is

dominant. This adds to our growing body of evidence which shows that the effectiveness of the Johnson & Johnson COVID-19 vaccine remains strong and stable over time, including against circulating variants such as Omicron and Delta," said Mathai Mammen, M.D., Ph.D., Global Head, Janssen Research & Development, LLC, Johnson & Johnson. "We believe that the protection could be due to the robust T-cell responses induced by the Johnson & Johnson COVID-19 vaccine. Furthermore, these data suggest that Omicron is not affecting the T-cell responses generated by our vaccine."

The data have been submitted to the pre-print server *medRxiv* by the studies' authors, with anticipation of publication in peer-reviewed journals.[1,2]

Phase 3b Sisonke 2 booster shot study in South African healthcare workers

Data from the Sisonke 2 trial (n=227,310), conducted among healthcare workers in South Africa who received the single-shot Johnson & Johnson COVID-19 vaccine as a primary dose, show that when a booster shot was administered six to nine months after a primary single dose, vaccine effectiveness (VE) increased over time from 63 percent (95% CI, 31-81%) at 0-13 days, up to 84 percent (95% CI, 67-92%) at 14-27 days and 85 percent (95% CI, 54-95%) at 1-2 months post-boost, after adjusting for confounders.[1]

Sisonke 2 was conducted in approximately 350 vaccination centres across all nine provinces of South Africa.[1] Utilising data from Discovery Health, a South African managed care organisation, trial investigators determined VE of the Johnson & Johnson COVID-19 booster shot (n=69,092) as compared to other unvaccinated individuals enrolled in the same managed care organisation, during the period from 15 November 2021, through 20 December 2021.[1]

Enrolment for the Sisonke 2 arm of the trial commenced just prior to the onset of the Omicron wave in South Africa, allowing researchers to evaluate the effectiveness of the Company's COVID-19 vaccine specifically as Omicron became the dominant variant in the country.[1]

"Even before you factor in the increased infectiousness of Omicron, we have to remember that healthcare workers on the frontlines are at a greatly increased risk of being affected by COVID-19 in the first place," said Glenda E. Gray*, MBBCH, FCPaed (SA), President and CEO of the SAMRC. "We are therefore encouraged to see that boosting with the Johnson & Johnson COVID-19 vaccine regimen provides strong protection in a challenging real-world setting where there is an elevated risk of exposure – not just to COVID-19, but to the highly transmissible Omicron variant."

Dr. Nicholas Crisp, the Deputy Director General of the South African National Department of Health said "The data showing the effectiveness of the Ad26.COV2 vaccine booster against Omicron in Sisonke is important, as this vaccine is part of our arsenal to combat COVID-19. This data should reassure healthcare workers who have not taken their booster to get vaccinated as soon as possible."

Antibody and T-Cell responses after heterologous boosting regimen greater than after homologous regimen against Omicron variant

An analysis of 65 individuals who received primary vaccination with two doses of an mRNA COVID-19 vaccine (BNT162b2), followed by a homologous booster shot of BNT162b2 (n=24) or a heterologous booster with the Johnson & Johnson COVID-19 vaccine (n=41) after at least six months, found both regimens increased humoral and cellular responses against Omicron.[2]

Antibody responses against Omicron were boosted by both the Johnson & Johnson COVID-19 vaccine and the BNT162b2 vaccine, with the Johnson & Johnson COVID-19 vaccine increasing neutralising antibody titres by 41-fold at four weeks post-boost.[2] The BNT162b2 vaccine was found to increase antibody titres to a higher level at week two post-boost, before declining to represent a 17-fold increase at week four post-boost.[2]

The Johnson & Johnson COVID-19 vaccine boosted median Omicron-reactive CD8+ T-cells by 5.5-fold, and Omicron-reactive CD4+ T-cells by 3.1-fold, while the homologous (BNT162b2) regimen boosted both Omicron-reactive CD4+ and CD8+ T-cells by 1.4-fold.[2]

T-cells can target and destroy cells infected by the virus that causes COVID-19 and are believed to contribute to protection against severe disease.[5] Specifically, CD8+ T-cells can directly destroy infected cells and are aided by CD4+ T-cells.[5]

"As the Omicron variant has mutated from the original SARS-CoV-2 strain, there is a need to understand how effective currently authorised COVID-19 vaccines remain at protecting against severe disease," said Dan Barouch*, M.D., Ph.D., Director of the Center for Virology and Vaccine Research at BIDMC. "Our analysis shows that a booster shot of the Johnson & Johnson COVID-19 vaccine generated a robust increase in both neutralising antibodies and T-cells to Omicron."

Additional information
The Johnson & Johnson COVID-19 vaccine has been authorised as booster by the European Commission and other healthcare bodies around the world.[6,7,8] Johnson & Johnson continues to submit relevant data to other regulators, the World Health Organization (WHO) and National Immunization Technical Advisory Groups (NITAGs) worldwide to inform decision-making on local vaccine administration strategies, as needed.

On 9 December 2021, the Strategic Advisory Group of Experts (SAGE) on Immunization for the World Health Organization (WHO) supported the use of the Johnson & Johnson COVID-19 vaccine as a second dose and heterologous booster in persons aged 18 years and above.[9]

For more information on the Company's multi-pronged approach to helping combat the pandemic, visit: https://www.janssen.com/emea/our-focus/infectious-diseases-vaccines/respiratory-infections/covid-19.

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**Dr. Dan Barouch and Dr. Glenda E. Gray are independent study investigators who have collaborated with Janssen Research & Development, LLC on clinical trials of the Johnson & Johnson COVID-19 vaccine.*

Authorised use
The Janssen COVID-19 vaccine has been granted Conditional Marketing Authorisation in the EU for active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.[6]

For more information, the EMA Summary of Product Characteristics is available at: www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-janssen-epar-product-information_en.pdf.

About Johnson & Johnson
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At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension. Learn more at www.janssen.com/emea. Follow us at @JanssenEMEA.

Cautions Concerning Forward-Looking Statements
This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding development, manufacture and distribution of the Johnson & Johnson COVID-19 vaccine. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of the Janssen Pharmaceutical Companies, and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behaviour and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 3, 2021, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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