News Release

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Real World Evidence Shows Johnson & Johnson COVID-19 Vaccine Resulted in Durable Protection Against Breakthrough Infection, Hospitalisation, and Intensive Care Unit Admission in the United States

NEW BRUNSWICK, N.J., 07 January 2022 – Johnson & Johnson (NYSE: JNJ) (the Company) today announced results from a large study on the durability of COVID-19 vaccines in the United States (U.S.), showing that a single dose of the Johnson & Johnson COVID-19 vaccine resulted in long-lasting protection for up to six months against COVID-19 breakthrough infections, hospitalisations, and intensive care unit (ICU) admissions.[1] The study was sponsored by the Janssen Pharmaceutical Companies of Johnson & Johnson and conducted in partnership with the Department of Science-Aetion, Inc, and the Division of Pharmacoepidemiology, Department of Medicine at Brigham and Women's Hospital and Harvard Medical School.[1]

"We continue to undertake extensive efforts to study the durability of protection offered by the Johnson & Johnson vaccine amidst the ever-changing COVID-19 pandemic," said Mathai Mammen, M.D., Ph.D., M.D., Ph.D., Executive Vice President, Pharmaceuticals, Janssen Research & Development LLC, Johnson & Johnson. "While these are rapidly evolving data, we are seeing vaccine effectiveness against COVID-19-related hospitalisation of approximately 80 percent from a single shot of the Johnson & Johnson vaccine, and this level of protection holds steady across the length of time studied thus far – up to six months. The sustained durability of our COVID-19 vaccine reflects its underlying immunology. We previously reported that our vaccine induces a strong antibody response as well as an increase in T-cells that is consistent across variants, including Omicron."

The new study posted on *medRxiv* looked at the durability profiles for all three vaccines authorised or approved in the U.S. using the same methodology across three outcomes of interest: COVID-19 breakthrough infections, hospitalisations, and ICU admissions.[1]

The study showed that the effectiveness of the Johnson & Johnson COVID-19 vaccine against breakthrough infections and hospitalisations remained durable up to six months.[1] The mRNA vaccines (two-doses) showed waning effectiveness for hospitalisations and breakthrough infections.[1] Although, vaccine effectiveness at baseline after a single dose of Johnson & Johnson COVID-19 is lower than that for the two-dose mRNA vaccine.[1] All three vaccines showed no evidence of waning protection against COVID-19-related ICU admissions at any point, showing strong sustained protection against critically-severe disease.[1] The study was not designed to compare the durability of vaccines.[1]

New Real World Evidence study details

Comprehensive studies to date on the durability of all vaccines authorised or approved for use in the U.S. have been limited, with many focusing on high-risk populations[2,3,4,5] or specific geographic regions or states.[6,7,8] This is a large COVID-19 real-world effectiveness durability study in the U.S., and the first to analyse the durability of baseline protection up to six months for all three U.S. authorised or approved vaccines, and for three COVID-19 outcomes of interest (breakthrough infections, hospitalisations, and ICU admissions). Researchers utilised national claims, laboratory, and hospital data covering 168 million individuals to conduct a matched case-control study between 1 January and 7 September 2021 for 17 million fully vaccinated individuals matched on calendar time, 3-digit zip code, age, sex, and comorbidity scores.[1]

The study assessed durability by measuring the Odds Ratio (OR), which represents the odds of a fully vaccinated individual having an outcome (breakthrough infection, hospitalisation, or ICU admission) in each month relative to the odds of having an outcome in the first month after full vaccination.[1] An OR greater than one indicates waning of the vaccine protection over time for that outcome.[1] The study authors acknowledged that direct comparisons of OR between vaccines should not be made as baseline differences may remain including initial effectiveness between the three vaccine cohorts.[1]

Johnson & Johnson COVID-19 vaccine (single-dose)

The Johnson & Johnson COVID-19 vaccine showed durability of effectiveness up to six months for hospitalisations and ICU admissions across the study period, with a modest increase in breakthrough infections starting in month 4.[1]

- The initial level of effectiveness at month 1 after full vaccination was found to be 81% (95% CI: 76%-82%) for hospitalisations and 74% (95% CI: 72%-75%) for breakthrough infections.[1]
- Durability:
    - There was no evidence of waning protection against COVID-19-related hospitalisation during the study period (OR = 1.25, 95% CI [0.86, 1.80] in month 5+).[1]
    - There was also no evidence of waning protection against breakthrough infection in the first three months of follow-up, with modest waning of protection against breakthrough infection observed in month 4 (OR = 1.16, 95% CI [1.04, 1.29]) and in month 5+ (OR = 1.31, 95% CI [1.18, 1.47]).[1]
    - There was no evidence of waning protection against COVID-19-related ICU admissions at any point (OR = 1.40, 95% CI [0.43, 4.55] in month 4).[1]
    - There was not sufficient follow-up to include a category for 6+ months for breakthrough infections and hospitalisations.[1]

BNT162b2 vaccine effectiveness (two doses 21-42 days apart)

BNT162b2 showed an increase in hospitalisations and breakthrough infections starting in month 2, with no waning of effectiveness for ICU admissions over the study period.[1]

- The initial level of effectiveness at month 1 after full vaccination was found to be 89% (95% CI: 88%-90%) for hospitalisations and 88% (95% CI: 87%-88%) for breakthrough infections.[1]
- Durability:
    - There was evidence that protection waned against COVID-19-related hospitalisation over time as compared to the first month of follow-up from vaccination (OR = 3.97, 95% CI [3.26, 4.83] in month 6+).[1]
    - There was evidence that protection waned against breakthrough infection where the waning was successively higher for each month of follow-up (OR = 2.93, 95% CI [2.72, 3.15] for BNT162b2 in month 6+).[1]
    - There was no evidence of waning protection against COVID-19-related ICU admissions at any point (OR = 1.36, 95% CI [0.80, 2.30] for BNT162b2 in month 4).[1]

mRNA-1273 vaccine effectiveness (two doses 28-42 days apart)
mRNA-1273 showed an increase in hospitalisations in month 3 and breakthrough infections in month 2, with no waning of effectiveness for ICU admissions over the study period.

- The initial level of effectiveness at month 1 after full vaccination was found to be 94% (95% CI: 93%-95%) for hospitalisations and 92% (95% CI: 91%-92%) for breakthrough infections.[1]
- Durability:
    - There was evidence of modest waning in protection against COVID-19-related hospitalisation over time as compared to the first month of follow-up from vaccination (OR = 1.66, 95% CI [1.26, 2.19] in month 6+).[1]
    - There was evidence that protection waned against breakthrough infection, where the waning was successively higher for each month of follow-up (OR = 2.76, 95% CI [2.51, 3.04] in month 6+).[1]
    - There was no evidence of waning protection against COVID-19-related ICU admissions at any point (OR = 1.17, 95% CI [0.64, 2.13] for mRNA-1273 in month 4).[1]

Other Recent Data for the Johnson & Johnson COVID-19 Vaccine
These results add to the body of evidence showing that the Johnson & Johnson COVID-19 vaccine elicits protection against variants of concern.[9,10]

Recently, preliminary data from the Phase 3b Sisonke booster study, conducted in November and December of 2021, demonstrated up to 85% effectiveness for the homologous (same vaccine) booster dose of the Johnson & Johnson vaccine, against COVID-19-related hospitalisation in South Africa when Omicron was dominant.[11]

The Company also recently announced that a heterologous booster (different vaccine) of the Johnson & Johnson 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 and a 5.5-fold increase in CD8+ T-cells to Omicron by two weeks.[12] A homologous boost with BNT162b2 generated a 17-fold increase in neutralising antibodies by four weeks following the boost and a 1.4-fold increase in CD8+ T-cells by two weeks.[12] Cellular immune responses, particularly CD8+ T cell responses, are likely critical for protection against severe SARS-CoV-2 disease.[13]

Additional information
The Johnson & Johnson COVID-19 vaccine has been authorised as a booster by multiple regulators and healthcare bodies around the world.[14,15,16,17] Johnson & Johnson continues to

submit relevant data to healthcare 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.

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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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.[14]

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
At Johnson & Johnson, we believe good health is the foundation of vibrant lives, thriving communities and forward progress. That's why for more than 130 years, we have aimed to keep people well at every age and every stage of life. Today, as the world's largest and most broadly-based healthcare company, we are committed to using our reach and size for good. We strive to improve access and affordability, create healthier communities, and put a healthy mind, body and environment within reach of everyone, everywhere. We are blending our heart, science and ingenuity to profoundly change the trajectory of health for humanity. Learn more at www.janssen.com/emea. Follow us at @JanssenEMEA.

About the Janssen Pharmaceutical Companies of Johnson & Johnson
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 behavior 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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