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News Release

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Johnson & Johnson COVID-19 Booster, Administered Six Months After Two-Dose Regimen of BNT162b2, Shows Substantial Increase in Antibody and T-cell Responses

Preliminary Phase 2 study[1] which includes data from a sub-set of participants, demonstrate value of mix-and-match approach; Johnson & Johnson booster increased neutralising and binding antibodies, similar to boosting with BNT162b2, and showed strong increase in T-cell responses[2]

NEW BRUNSWICK, N.J., 5 DECEMBER 2021 – Johnson & Johnson (NYSE: JNJ) (the Company) today announced preliminary results from a study, including a subset of participants from the Janssen-sponsored COV2008 study, conducted by Dan Barouch, M.D., Ph.D., et al. of Beth Israel Deaconess Medical Center (BIDMC), which showed that a booster shot of the Johnson & Johnson COVID-19 vaccine (Ad26.COV2.S), administered at six months after a two-dose primary regimen of BNT162b2, increased both antibody and T-cell responses.[2] These results demonstrate the potential benefits of heterologous boosting (mix-and-match). The article describing these results has been published on *medRxiv*.[2]

"There is early evidence to suggest that a mix-and-match boosting approach may provide individuals with different immune response against COVID-19 than a homologous boosting approach," said Dan Barouch, M.D., Ph.D., Director of the Center for Virology and Vaccine Research at BIDMC. "In this preliminary study, when a booster dose of Ad26.COV2.S was given to individuals six months after a primary regimen with the BNT162b2 vaccine, there was a comparable increase of antibody responses at week four following the boost and a greater increase of CD8+ T-cell responses with Ad26.COV2.S compared with BNT162b2."

"These results provide valuable scientific insights for our vaccine when used as a mix-and-match booster and can help inform boosting strategies with the goal to curb the pandemic," said Mathai Mammen, M.D., Ph.D., Global Head, Janssen Research & Development, Johnson & Johnson. "These data add to the growing body of evidence demonstrating that a mix-and-match booster dose of the Johnson & Johnson COVID-19 vaccine successfully increases humoral responses and cellular responses against the original strain of SARS-CoV-2, as well as the Beta and Delta variants."[3,4,5]

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These Phase 2 data[1,2] are reinforced by preliminary results from the UK COV-BOOST clinical study published in *The Lancet*,[6] which demonstrated that following primary vaccination with two doses of either BNT162b2 (n=106) or ChAdOx1 nCov-19 (n=108), a booster dose of the Johnson & Johnson COVID-19 vaccine increased both antibody and T-cell responses.[6]

Cellular (T-Cell) responses
In this preliminary study, boosting with the Johnson & Johnson COVID-19 vaccine after a primary vaccine regimen of BNT162b2 appears to lead to a greater increase in CD8+ T-cell responses than boosting with BNT162b2.[2] These T-cell response data suggest differences between immune responses following homologous boosting with mix-and-match boosting.[2]

The Johnson & Johnson COVID-19 vaccine leverages Janssen's AdVac® technology and cell-mediated immunity, including CD4+ and CD8+ responses.[7] T-cells can target and destroy cells infected by the virus that causes COVID-19.[8] Specifically, CD8+ T-cells can directly destroy infected cells and are aided by CD4+ T-cells.[8]

Humoral (antibody) responses
Both the Johnson & Johnson COVID-19 vaccine and BNT162b2 as boosters led to similar neutralising and binding antibody levels against the original SARS-CoV-2 strain, as well as the Delta and Beta variants, four weeks following the boost.[2] However, after a mix-and-match booster dose of the Johnson & Johnson COVID-19 vaccine, antibodies continued to increase for at least four weeks whereas in individuals who received a homologous boost with the BNT162b2 vaccine, antibodies declined from week two to week four post-boost.[2]

Neutralising antibodies are capable of binding to the virus' spike protein in a way that neutralises the virus.[9]

Study design[1,2]
For this study, a specimen biorepository at Beth Israel Deaconess Medical Center (BIDMC) obtained samples from individuals who received the BNT162b2 vaccine.[2] Participants either continued follow-up in the biorepository and were boosted with 30 ug BNT162b2 or were enrolled in the COV2008 study (NCT04999111) and were boosted with 5, 2.5, or $1x10^{10}$ vp of the Johnson & Johnson COVID-19 vaccine (n=41).[2] The COV2008 study is a Johnson & Johnson sponsored, ongoing blinded Phase 2 clinical trial (VAC31518COV2008) to evaluate its COVID-19 vaccine as a booster in adults 18 years of age and older.[2]

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.[10] For more information please visit: https://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.jnj.com. Follow us at @JNJNews.

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. Follow us at @JanssenGlobal.

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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