

**News Release**

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**Booster Dose for Johnson & Johnson COVID-19 Vaccine Granted Approval by South African Health Products Regulatory Authority (SAHPRA)**

*SAHPRA approval based on data showing a booster shot of the Johnson & Johnson COVID-19 vaccine increased protection to 75 percent against symptomatic COVID-19 infection globally<sup>1</sup>*

*Data also demonstrated 100 percent protection against severe/critical COVID-19, at least 14 days post-booster vaccination<sup>1</sup>*

*The Johnson & Johnson COVID-19 vaccine, when given as a booster or primary dose, was generally well-tolerated<sup>1,2</sup>*

**JOHANNESBURG, 23 December, 2021** – Johnson & Johnson (the Company) today announced that the South African Health Products Regulatory Authority (SAHPRA) has granted approval for use of the Company's COVID-19 vaccine as a booster (second dose) for adults aged 18 and older at least two months after primary vaccination with a single-dose of the Johnson & Johnson COVID-19 vaccine, and as a 'mix and match' booster following primary vaccination with an approved two-dose mRNA COVID-19 vaccine regimen (known as heterologous boosting).<sup>3</sup> The dosing interval for the heterologous booster dose is the same as that authorised for a booster dose of the vaccine used for primary vaccination.<sup>3</sup>

“Vaccines remain critical to tackling the COVID-19 pandemic and we are pleased with today’s approval from SAHPRA supporting the use of our COVID-19 vaccine as a booster for eligible individuals in South Africa, regardless of which vaccine they initially receive,” said Moustafa Kamel, M.D., Medical Affairs Director, Janssen South Africa.

The SAHPRA approval was based on a comprehensive data package that included results from the Phase 3 ENSEMBLE 2 study, which found a booster of the Johnson & Johnson COVID-19 vaccine given two months after the primary dose provided 75 percent protection against symptomatic (moderate to severe) COVID-19 globally (CI, 55%-87%) and 94 percent protection against symptomatic (moderate to severe) COVID-19 in the U.S. (CI, 59%-100%).<sup>1</sup> It also demonstrated 100 percent protection against severe COVID-19, at least 14 days post-booster vaccination (CI, 33%-100%).<sup>1</sup> The vaccine, when given as a booster or primary dose, was generally well-tolerated, with no new safety signals observed in the two-dose ENSEMBLE 2 trial compared with single-dose studies.<sup>1,4,5</sup>

Also included in the data package reviewed by SAHPRA were results from multiple real-world evidence (RWE) studies, including the Company’s previously announced RWE study that demonstrated similar estimates of single-dose vaccine effectiveness as observed in our randomised clinical trials.<sup>6</sup> The effectiveness estimates remained stable with no evidence of reduced effectiveness over time before the Delta variant emerged and after it became the dominant strain in the U.S. from March through August (sequencing data were not available for analysis).<sup>1,7</sup>

The SAHPRA approval is supported by the latest data for heterologous boosting with the Johnson & Johnson COVID-19 vaccine.<sup>8,10</sup> Interim data from the National Institute of Allergy and Infectious Disease (NIAID) “MixNMatch” study demonstrated that a booster of the Johnson & Johnson COVID-19 vaccine increases immune response regardless of a person’s primary vaccination.<sup>8</sup> A second study by the Beth Israel Deaconess Medical Center (BIDMC), including a subset of participants from the Janssen-sponsored COV2008 study,<sup>9</sup> demonstrated the potential benefits of heterologous boosting: a booster dose of the Johnson & Johnson vaccine administered at six months after a two-dose primary regimen of the Pfizer/BioNTech vaccine, increased both antibody and T-cell responses.<sup>10</sup> In these participants, 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, resulting in similar antibody levels in both groups.<sup>10</sup>

The Company’s single-dose COVID-19 vaccine, developed by its Janssen Pharmaceutical Companies of Johnson & Johnson, received Emergency Use Authorization in the United States on 27 February 2021<sup>11</sup>, Conditional Marketing Authorisation (CMA) by the European Commission on 11 March<sup>12</sup>, and Registration with Conditions by the South African Health Products Regulatory Authority (SAHPRA) on 31 March 2021.<sup>13</sup> On 21 October 2021, the U.S. Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) authorised for emergency use a booster dose of the Johnson & Johnson COVID-19 vaccine for adults aged 18 and older.<sup>14</sup> 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 heterologous booster dose in persons aged 18 years and above.<sup>15</sup>

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>.

### **Authorised use**

The Company's COVID-19 vaccine has been granted Registration with Conditions in South Africa 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.<sup>11</sup>

For more information, the SAHPRA Summary of Product Characteristics is available at: <https://aefi-reporting.sahpra.org.za/stdrefs-eu-smpc-closing-sequence-english-clean.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 <https://www.janssen.com/southafrica>.

### **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 <https://www.janssen.com/southafrica>.

### **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 our 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](http://www.sec.gov), [www.jnj.com](http://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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- <sup>1</sup> FDA. Vaccines and Related Biological Products Advisory Committee October 14-15, 2021 Meeting Presentation. Available at: <https://www.fda.gov/media/153129/download> Last accessed: December 2021.
  - <sup>2</sup> Sadoff J, Gray G, Vandebosch A et al. Safety and Efficacy of Single-Dose Ad26.COVS Vaccine against Covid-19. NEJM. 2021; 384:2187-201. DOI: 10.1056/NEJMoa2101544.
  - <sup>3</sup> SAHPRA Media release. SAHPRA approval of second/booster dose of the COVID-19 vaccine Janssen. Available at: <https://www.sahpra.org.za/news-and-updates/sahpra-approval-of-second-booster-dose-of-the-covid-19-vaccine-janssen/> Last accessed: December 2021.
  - <sup>4</sup> Janssen Data on File. ENSEMBLE Study. 2021.
  - <sup>5</sup> Janssen data on file. ENSEMBLE 2 data. December 2021.
  - <sup>6</sup> Polinski J. et al. Effectiveness of the Single-Dose Ad26.COVS COVID Vaccine. medRxiv 2021.09.10.21263385; doi: <https://doi.org/10.1101/2021.09.10.21263385>.
  - <sup>7</sup> FDA. Vaccines and Related Biological Products Advisory Committee October 14-15, 2021 Meeting Presentation. Available at: <https://www.fda.gov/media/153037/download> Last accessed: December 2021.
  - <sup>8</sup> Atmar, R.L et al. Heterologous SARS-CoV-2 Booster Vaccinations – Preliminary Report. medRxiv 2021.10.10.21264827
  - <sup>9</sup> ClinicalTrials.gov. A Study of Ad26.COVS Administered as Booster Vaccination in Adults Who Have Previously Received Primary Vaccination With Ad26.COVS or BNT162b2. Available at: <https://clinicaltrials.gov/ct2/show/NCT04999111?id=NCT04999111&draw=2&rank=1>. Accessed December 2021.
  - <sup>10</sup> Tan SC, Collier AY, Jingyou JL et al. Ad26.COVS or BNT162b2 Boosting of BNT162b2 Vaccinated Individuals. Available at: <https://doi.org/10.1101/2021.12.02.21267198>. Accessed December 2021.
  - <sup>11</sup> FDA. Janssen COVID-19 Vaccine. Available at: <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine>. Accessed December 2021.
  - <sup>12</sup> European Medicines Agency. EMA recommends COVID-19 Vaccine Janssen for authorisation in the EU. Available at: <https://www.ema.europa.eu/en/news/ema-recommends-covid-19-vaccine-janssen-authorisation-eu>. Accessed December 2021.
  - <sup>13</sup> Janssen. Johnson & Johnson Single-Dose COVID-19 Vaccine Granted Registration by South African Health Products Regulatory Authority. Available at: <https://www.janssen.com/southafrica/johnson-johnson-single-dose-covid-19-vaccine-granted-registration-south-african-health-products>. Last accessed: December 2021.
  - <sup>14</sup> FDA. Fact Sheet for Recipients and Caregivers. Emergency Use Authorization (EUA) of The Janssen COVID-19 Vaccine To Prevent Coronavirus Disease 2019 (COVID-19) In Individuals 18 Years Of Age And Older. Available at: <https://www.fda.gov/media/146305/download>. Accessed December 2021.
  - <sup>15</sup> WHO. Interim recommendations for the use of the Janssen Ad26.COVS (COVID-19) vaccine. Available at: <https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-Ad26.COVS-2021.1>. Accessed December 2021.