



## Media Statement

### **Johnson & Johnson Single-Shot COVID-19 Vaccine Janssen® Granted Provisional Approval by Medsafe in New Zealand**

*Data published in the New England Journal of Medicine demonstrated the vaccine protects against COVID-19 related hospitalisation in broad geographic regions, including those with emerging variants<sup>1</sup>*

**AUCKLAND, NEW ZEALAND, 7 July 2021** – Johnson & Johnson (NYSE: JNJ) (the Company) today announced that the New Zealand medicines regulator, Medsafe, has granted Provisional Approval for its single-dose COVID-19 vaccine Janssen®, developed by the Janssen Pharmaceutical Companies of Johnson & Johnson, to prevent COVID-19 in individuals 18 years of age and older.

This decision was based on scientific evidence, including data from the Phase 3 ENSEMBLE study which demonstrates the vaccine is 85 percent effective in preventing severe disease, and delivered protection against COVID-19 related hospitalisation and death, across countries with different variants, beginning 28 days after vaccination<sup>1</sup>.

“We are pleased that Medsafe’s review has shown the COVID-19 Vaccine Janssen® meets the high safety, efficacy, and quality standards required for provisional use in New Zealand,” said Dr Sophie Glover-Koudounas, Executive Director, Medical & Scientific Affairs, Janssen Australia and New Zealand.

“We welcome today’s Provisional Approval as it provides the opportunity to help many more communities in need, as we continue to do everything we can to bring an end to this pandemic,” Dr Glover-Koudounas said.

The Company is working closely with the New Zealand Government to confirm delivery timelines and is committed to supply 2 million doses on a not-for-profit basis.

The Johnson & Johnson single-dose COVID-19 Vaccine Janssen® is compatible with standard vaccine storage and distribution channels enabling delivery to remote areas. The vaccine is estimated to remain stable for two years at -20°C, and a maximum of three months of which can be at refrigeration at temperatures of 2°-8°C. The Company will distribute the vaccine using the same cold chain technologies it uses today to transport other medicines<sup>2</sup>.

#### **Johnson & Johnson’s COVID-19 Vaccine Janssen®**

The Johnson & Johnson COVID-19 Vaccine Janssen® uses a human Ad26–based vector and leverages the AdVac® vaccine platform, a unique and proprietary technology that was also used to develop and manufacture Janssen’s other vaccine regimen and construct investigational vaccine candidates for other infectious diseases<sup>3</sup>.

#### **Phase 3 ENSEMBLE Study Design**

The Phase 3 ENSEMBLE study is a randomised, double-blind, placebo-controlled clinical trial in individuals 18 years of age and older<sup>4</sup>. The study was designed to evaluate the safety and efficacy of the Company’s vaccine candidate in protecting against both moderate and severe COVID-19 disease, with assessment of efficacy as of day 14 and as of day 28 as co-primary endpoints<sup>5</sup>. The study enrolled a total of 43,783 participants.

The trial, conducted in eight countries across three continents (Argentina, Brazil, Chile, Colombia, Mexico, Peru, South Africa, United States)<sup>6</sup>, includes a diverse and broad population including 34 percent of participants over age 60.<sup>1</sup> Forty-one percent of participants in the study had comorbidities associated with an increased risk for progression to severe COVID-19.<sup>1</sup>

For more information on the Company's approach to helping combat the pandemic, visit: [www.janssen.com/newzealand/our-response-covid-19](http://www.janssen.com/newzealand/our-response-covid-19)

### **Commitment to Equitable Access**

Equitable access is at the centre of Johnson & Johnson's COVID-19 response. The Company is committed to ensuring global access to the Johnson & Johnson single-shot COVID-19 vaccine candidate on a not-for-profit basis for emergency pandemic use.

Johnson & Johnson has signed an agreement with Gavi, The Vaccine Alliance to supply up to 500 million doses of the single-shot Janssen COVID-19 vaccine to the COVAX Facility for low and middle-income nations.

### **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/newzealand](http://www.janssen.com/newzealand). Follow us at @JanssenANZ.

### **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/newzealand](http://www.janssen.com/newzealand). Follow us at @Janssenanz.

### **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 of a potential preventive vaccine for COVID-19. 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](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.

## REFERENCES

---

<sup>1</sup> Sadoff J et al. [Safety and Efficacy of Single-Dose Ad26.COV2.S Vaccine against Covid-19](#). *New Engl J Med*. DOI: 10.1056/NEJMoa2101544.

<sup>2</sup> New Zealand Data Sheet COVID-19 Vaccine Janssen, May 2021.

<sup>3</sup> Custers, J., Kim, D., et al. Vaccines based on replication incompetent Ad26 viral vectors: Standardized template with key considerations for a risk/benefit assessment. *Vaccine*. 2020.

<sup>4</sup> ClinicalTrials.gov. A study of Ad26.COV2.S for the Prevention of SARS-CoV-2-Mediated COVID-19 in Adult Participants (ENSEMBLE).

Available at: <https://clinicaltrials.gov/ct2/show/NCT04505722>. Last accessed: April 2021.

<sup>5</sup> Johnson & Johnson. COVID-19 Phase 3 study clinical protocol. Available at: <https://www.jnj.com/coronavirus/covid-19-phase-3-study-clinical-protocol>. Last accessed: April 2021.

### Media Contacts (New Zealand):

Maeve Eikli

+61 437-720-435

[meikli@its.jnj.com](mailto:meikli@its.jnj.com)

[media@its.jnj.com](mailto:media@its.jnj.com)