



News Release

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Johnson & Johnson Announces Landmark Agreement to Enable its COVID-19 Vaccine to be Manufactured and Made Available by an African Company for People Living in Africa

Aspen will manufacture and provide the Johnson & Johnson COVID-19 vaccine under its own brand name per the terms of agreement

Ensuring equitable, global access to COVID-19 vaccines has been a pillar of Johnson & Johnson's response since the earliest days of the pandemic

The production of COVID-19 vaccines on multiple continents is critical in supporting an equitable response, controlling the pandemic, and improving long-term health security^{1,2}

NEW BRUNSWICK, NJ (8 March 2022) – Johnson & Johnson (NYSE: JNJ) (the Company) today announced the completion of a landmark agreement between Janssen Pharmaceuticals, Inc., and manufacturer Aspen SA Operations (Pty) Ltd, based in South Africa, to enable the first COVID-19 vaccine to be manufactured and made available by an African company for people living in Africa, with the goal of increasing COVID-19 vaccination rates across the continent.

Expanding global vaccination coverage is critically important in controlling the COVID-19 pandemic and reducing the risk of emergence of new SARS-CoV-2 variants.^{1,2} Currently, only about 12 percent of people in Africa are fully vaccinated, which is well below the World Health Organization's target of 70 percent population coverage for all countries.^{3,4}

Our response to the COVID-19 pandemic has been guided by the conviction that unless everyone is safe, no one is safe, which is why we worked to develop and deliver a vaccine that can protect the health of everyone, everywhere.

"From the outset of this pandemic we aimed to develop a simple-to-use and accessible vaccine that could be transported around the world through standard vaccine distribution channels," said Martin Fitchet, M.D., Head of Global Public Health, Johnson & Johnson, Cilag GmbH International. "We initiated clinical trials in all regions of the world to generate evidence across multiple geographies and diverse at-risk populations and forged a strategic partnership with Aspen in Africa and others to manufacture our vaccine globally. We're proud to take our long-standing collaboration with Aspen to the next level, to continue to address the COVID-19 threat and lay the groundwork for a healthier, more secure future for people in Africa."

To date, Johnson & Johnson has shipped more than 200 million vaccine doses to Africa through a combination of our advance purchase agreements with the African Vaccine Acquisition Trust, South Africa and Gavi, the Vaccine Alliance, on behalf of the COVAX Facility, along with government donations.^{5,6} As one of our contract manufacturers since November 2020, Aspen has been a significant supplier within the Johnson & Johnson global network.⁷

The agreement enables Aspen, using COVID-19 vaccine drug substance supplied by Johnson & Johnson, to produce Aspen-branded finished vaccine and make doses available to the public sector in Africa, including all 55 Member States of the African Union and key multilateral entities supporting Africa's COVID-19 vaccination drive, inclusive of the African Vaccine Acquisition Trust (AVAT), and the COVAX Facility.

"With the conclusion of this agreement, our vision for Africa's own vaccine has become a reality," said Stephen Saad, Aspen Group Chief Executive. "This has been achieved through tremendous teamwork and collaboration between Johnson & Johnson and Aspen. Through this agreement and their earlier actions, Johnson & Johnson has demonstrated its commitment to our continent. Initially by choosing Aspen, located in Africa, as a core manufacturing partner, and then by showing resolve and dedication to a technical transfer process during the most stringent lockdown periods of the COVID outbreak."

Johnson & Johnson's Equitable Response to COVID-19

A commitment to global equity has guided the Company's response since the beginning of the pandemic, starting with the decision to pursue a vaccine that can provide protection with a single dose and be easily stored and distributed with standard refrigeration globally, including in resource-limited, rural or remote settings.

Johnson & Johnson supported the development of its vaccine with a truly global and inclusive clinical research program that studied the vaccine across the U.S., Europe, Africa, Asia and Latin America as we sought to generate evidence across multiple geographies and diverse, at-risk populations, including in resource-limited settings.⁸ We complemented this by supporting a large-scale implementation study for our vaccine in South Africa.⁹ The "Sisonke" study made the Johnson & Johnson COVID-19 vaccine available to 500,000 frontline healthcare workers across the country.¹⁰

In parallel, the Company forged a global supply network that included Aspen and partners in the U.S., Europe and India, and entered into advance purchase agreements with Gavi, on behalf of the COVAX Facility, and AVAT to supply 400 million vaccine doses to low- and middle-income countries (LMICs) through 2022.⁵

"The urgency and necessity of developing and delivering our COVID-19 vaccine required our R&D teams to find new and exciting ways to use our novel vaccine technology to rapidly progress our science and maximise our impact for humanity," said Penny Heaton, M.D., Global Therapeutic Area Head, Vaccines, Janssen Research & Development, LLC. "We have proudly contributed to protecting hundreds of millions of people from COVID-19. Our experiences will have major benefits for the future of vaccine development and Johnson & Johnson's ongoing research and development programs as we continue to bring cutting-edge science to bear on complex health challenges."

In 2021, Johnson & Johnson provided its vaccine globally at a not-for-profit price, and through its advance purchase agreements and country donations, shipped approximately 70% of its global vaccine supply to LMICs.¹¹ The Company remains committed to ensuring its vaccine is accessible to people around the world and continues to advocate that governments with available doses follow the example of the U.S., European Union and others and immediately ramp up dose sharing, particularly through the COVAX Facility.

Johnson & Johnson has also pledged its support to the COVAX Humanitarian Buffer through an agreement with the U.S. Government and Gavi.¹² This agreement enables access to our COVID-19 vaccine for the world's most vulnerable people, such as those living in conflict zones and other humanitarian settings who are at risk of exclusion from traditional vaccination campaigns.¹²

About the Johnson & Johnson COVID-19 Vaccine

The Johnson & Johnson COVID-19 vaccine has a robust profile in scientific, clinical, and real-world studies, generating strong, persistent activity against SARS-CoV-2 and variants such as Delta and Omicron.^{13,14,15} The vaccine's efficacy, both as a single dose and in boosted regimens, combined with its compatibility with standard refrigeration requirements, positions it for ease of deployment in any setting.¹⁶

The Johnson & Johnson COVID-19 vaccine has an Emergency Use Listing (EUL) from the World Health Organization (WHO) and has been authorised in many other countries worldwide, including 50 countries in Africa.^{17,18} The vaccine is authorised by the U.S. Food and Drug Administration (FDA) through an Emergency Use Authorisation (EUA)¹⁹, and has a Conditional Marketing Authorisation from the European Commission for use across the European Union (EU).²⁰

On February 28, the European Medicines Agency approved an extension of the shelf-life of the Johnson & Johnson COVID-19 vaccine to 11 months when refrigerated at temperatures of 2 to 8 degrees Celsius (36 to 46 degrees Fahrenheit).¹⁶ On March 7, Johnson & Johnson confirmed that the U.S. FDA has extended the shelf-life of the Company's vaccine from six months to nine months when stored at these same temperatures.²¹ These decisions are based on data from ongoing stability assessment studies.^{16,21} Johnson & Johnson has also submitted these data regarding the vaccine's shelf-life to the WHO, and a decision is expected shortly.²²

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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. Janssen Research & Development, LLC, Janssen Pharmaceuticals Inc., and Cilag GmbH International are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding an agreement with Aspen SA Operations (Pty) Ltd relating to the 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 Janssen Pharmaceuticals, Inc., the Janssen Pharmaceutical Companies, and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: the potential that the expected benefits and opportunities of the agreement may not be realized or may take longer to realize than expected; 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 2, 2022, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Report on Form 10-Q and other 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 Janssen Pharmaceuticals, Inc., 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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References

¹ Feinmann J. Covid-19: global vaccine production is a mess and shortages are down to more than just hoarding. BMJ 2021; 375 doi: <https://doi.org/10.1136/bmj.n2375>.

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- ² Gavi. We can stop the cycle of new variants continuing indefinitely with a pandemic vaccine pool. Available at: <https://www.gavi.org/vaccineswork/we-can-stop-cycle-new-variants-continuing-indefinitely-pandemic-vaccine-pool> Last accessed: March 2022.
- ³ WHO. Africa needs to ramp up COVID-19 vaccination six-fold. Available at: <https://www.afro.who.int/news/africa-needs-ramp-covid-19-vaccination-six-fold> Last accessed: March 2022.
- ⁴ Africa CDC. Africa CDC vaccine dashboard. Available at: <https://africacdc.org/covid-19-vaccination/> Last accessed: March 2022.
- ⁵ J&J. Johnson & Johnson Announces Advance Purchase Agreement with the African Vaccine Acquisition Trust for the Company's COVID-19 Vaccine Candidate. Available at: <https://www.jnj.com/johnson-johnson-announces-advance-purchase-agreement-with-the-african-vaccine-acquisition-trust-for-the-companys-covid-19-vaccine-candidate> Last accessed: March 2022.
- ⁶ GAVI. Gavi signs agreement with Johnson & Johnson for supply of its COVID-19 vaccine to COVAX. Available at: <https://www.gavi.org/news/media-room/gavi-signs-agreement-johnson-johnson-supply-its-covid-19-vaccine-covax> Last accessed: March 2022.
- ⁷ Aspen Holdings. Aspen announces agreement with Johnson & Johnson to manufacture investigational covid-19 vaccine candidate. Available at: <https://www.aspenpharma.com/2020/11/02/aspen-announces-agreement-with-johnson-johnson-to-manufacture-investigational-covid-19-vaccine-candidate/> Last accessed: March 2022.
- ⁸ 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: March 2022.
- ⁹ Sisonke Study. Available at: <http://sisonkestudy.samrc.ac.za/indexsisonke.html> Last accessed: March 2022.
- ¹⁰ ClinicalTrials.gov. Sisonke (Together): OPEN LABEL TRIAL COVID-19 (Sisonke). Available at: <https://clinicaltrials.gov/ct2/show/NCT04838795> Last accessed: March 2022.
- ¹¹ Janssen Data on file. Donations to LMICs. March 2022.
- ¹² J&J. Johnson & Johnson Enters into Agreement to Provide its Single-Shot COVID-19 Vaccine for the World's Most Vulnerable People through Novel Humanitarian Buffer. Available at: <https://www.jnj.com/johnson-johnson-enters-into-agreement-to-provide-its-single-shot-covid-19-vaccine-for-the-worlds-most-vulnerable-people-through-novel-humanitarian-buffer> Last accessed: March 2022.
- ¹³ Polinski J. et al. Effectiveness of the Single-Dose Ad26.COV2.S COVID Vaccine. medRxiv 2021.09.10.21263385; doi: <https://doi.org/10.1101/2021.09.10.21263385>.
- ¹⁴ Sisonke. Available at: <https://sacoronavirus.co.za/wp-content/uploads/2021/08/Sisonke-Provisional-Results-6-August-2021GG2.pdf> Last accessed: March 2022.
- ¹⁵ Gray GE, Collie S, Garrett N et al. Vaccine effectiveness against hospital admission in South African health care workers who received a homologous booster of Ad26.COV2 during an Omicron COVID19 wave: Preliminary Results of the Sisonke 2 Study. Available at: <https://www.medrxiv.org/content/10.1101/2021.12.28.21268436v1> Last accessed: March 2022.
- ¹⁶ EMA. COVID-19 Vaccine Janssen Summary of Product Characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-janssen-epar-product-information_en.pdf Last accessed: March 2022.
- ¹⁷ J&J. Johnson & Johnson Single-Shot COVID-19 Vaccine Granted Emergency Use Listing by the World Health Organization. Available at: <https://www.jnj.com/johnson-johnson-single-shot-covid-19-vaccine-granted-emergency-use-listing-by-the-world-health-organization> Last accessed: March 2022.
- ¹⁸ COVID-19 Vaccine Tracker. Janssen (Johnson & Johnson): Ad26.COV2.S. Available at: <https://covid19.trackvaccines.org/vaccines/1/> Last accessed: March 2022.
- ¹⁹ FDA. Janssen COVID-19 Vaccine. Available at: <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine>. Last accessed: March 2022.
- ²⁰ 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> Last accessed: March 2022.
- ²¹ Janssen Media statement. Available at: https://www.janssen.com/us/sites/www_janssen_com_usa/files/statement_on_u.s._fda_approval_of_shelf_life_extension_for_the_johnson_and_johnson_covid-19_vaccine.pdf Last accessed: March 2022.
- ²² Janssen data on file. Shelf-life extension application to WHO. March 2022.