Media Statement

February 28, 2021

Johnson & Johnson Confirms Advance Purchase Agreement with the Government of the Republic of South Africa for Janssen's COVID-19 Vaccine Candidate

Janssen Pharmaceutica NV, one of the Janssen Pharmaceutical Companies of Johnson & Johnson (NYSE: JNJ) ("the Company"), has entered into an agreement with the Government of the Republic of South Africa to supply 11 million doses of its COVID-19 vaccine candidate, Ad26.COV2.S. The availability of the vaccine candidate is subject to its successful development and regulatory approval. The vaccine will be provided at a global not-for-profit basis for emergency pandemic use.

Additionally, to ensure equitable distribution, in December 2020, the Company entered into an agreement in principle with Gavi, the Vaccine Alliance (Gavi) in support of the COVAX Facility. Johnson & Johnson and Gavi expect to enter into an Advance Purchase Agreement (APA) that would provide up to 500 million doses of the Janssen vaccine to COVAX through 2022. At this time, 190 countries have joined the COVAX Facility, including South Africa.[1]

The COVAX Facility is a global mechanism for pooled procurement and distribution of COVID-19 vaccines in 190 participating countries, including 92 lower-income countries. The Facility is an important mechanism for promoting equitable access in lower-income countries that can significantly increase their chances of securing successful vaccines.

These collaborations are part of Johnson & Johnson's commitment to ensuring widespread global access to its COVID-19 vaccine candidate upon authorization, on a not-for-profit basis for emergency pandemic use. Recognising the global demand for COVID-19 vaccines, Johnson & Johnson is working tirelessly to further expand the available doses, once authorized.

Regulatory Filings

On February 27, 2021, the Janssen COVID-19 vaccine candidate was authorized by the U.S. FDA for Emergency Use, as the first single-dose vaccine in the fight against the global pandemic, whilst a Conditional Marketing Authorisation Application (cMAA) was submitted in the European Union on February 15, 2021. In addition, on February 19, the Company submitted the single-dose Janssen COVID-19 vaccine candidate for Emergency Use Listing (EUL) with the World Health Organization. Rolling submissions for the COVID-19 vaccine candidate have been initiated in several countries worldwide.

Janssen's COVID-19 Vaccine Candidate

The Company's COVID-19 vaccine candidate leverages the AdVac® vaccine platform, a unique and proprietary technology that was also used to develop and manufacture Janssen's European Commission-approved Ebola vaccine regimen and construct its investigational Zika, RSV, and HIV vaccines.[3,4,5,6,7]

On January 29, the Company announced topline data from the Phase 3 ENSEMBLE study clinical trial, which found that the single-dose Janssen COVID-19 vaccine candidate met all primary and key secondary endpoints. In December 2020, the Company began to submit Phase 2 data to the South African Health Products Regulatory Authority, per rolling submission to the European Medicines Agency, and additional data will be submitted as it becomes available.

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Notice to Investors 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, 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:

[1] Johnson & Johnson Announces Agreement in Principle with Gavi to Supply Janssen's COVID-19 Vaccine Candidate to Lower-Income Countries in 2021. Available at: https://www.janssen.com/emea/sites/www_janssen_com_emea/files/johnson_johnson_announces_agreement_in_principle_with_gavi_to_supply_janssens_covid-19_vaccine_candidate_to_lower-income_countries_in_2021.pdf. Last accessed: January 2021.
[3] ClinicalTrials.gov. A study of Ad26.COV2.S for the Prevention of SARS-CoV-2-mediated COVID-19 in Adults (ENSEMBLE 2). Available at: https://clinicaltrials.gov/ct2/show/NCT04614948?term=ENSEMBLE+2&draw=2&rank=1. Last accessed: January 2021.
[4] Custers, J., Kim, D., et al., 2020. Vaccines based on replication incompetent Ad26 viral vectors: Standardized template with key considerations for a risk/benefit assessment. Vaccine.

[5] Johnson & Johnson Announces Its First Phase 3 COVID-19 Vaccine Trial ENSEMBLE is Fully Enrolled. Available at: https://www.janssen.com/emea/sites/www_janssen_com_emea/files/johnson_and_johnson_announces_its_first_phase_3_covid19_vaccine_trial_ensemble_is_fully_enroled_.pdf. Last accessed: January 2021.
[6] ClinicalTrials.gov. A study of Ad26.COV2.S in Adults (COVID-19). NCT04436276. Available at: https://clinicaltrials.gov/ct2/show/NCT04436276. Last accessed: January 2021.
[7] 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: January 2021.