

Johnson & Johnson Announces Agreement in Principle with Gavi to Supply Janssen's COVID-19 Vaccine Candidate to Lower-Income Countries in 2021

Janssen Pharmaceutica NV, one of the Janssen Pharmaceutical Companies of Johnson & Johnson (the Company), will provide up to 500 million doses of its investigational COVID-19 vaccine candidate as part of an agreement in principle with Gavi, The Vaccine Alliance (Gavi). Gavi is the leading multilateral organisation responsible for equitable access to vaccines and coordination of procurement and distribution of COVID-19 vaccines, including to lower-income countries, via the COVAX Facility.¹ These doses will be distributed through 2022, if the vaccine candidate is proven to be efficacious with a good safety profile.

The Company and Gavi expect to enter into an Advance Purchase Agreement (APA) that would provide the COVAX Facility with 100 million doses of Janssen's COVID-19 vaccine candidate in 2021, assuming the vaccine candidate receives regulatory approvals. Gavi also has the opportunity to order another 100 million doses in 2021, and up to 300 million doses in 2022, for a combined total of up to 500 million doses through 2022.

This collaboration is a part of the Company's commitment to ensuring widespread global access to its COVID-19 vaccine candidate on a not-for-profit basis for emergency pandemic use. In September 2020, Johnson & Johnson joined other life sciences companies and the Bill & Melinda Gates Foundation in signing an unprecedented communiqué which outlined an unwavering commitment to equitable access to the innovations being developed to fight the pandemic.²

The COVAX Facility is a global risk-sharing mechanism, co-led by Gavi, for pooled procurement and equitable distribution of COVID-19 vaccines to all participating countries.¹ The Facility is an important mechanism for ensuring equitable access in lower-income countries that can significantly increase their chances of securing successful vaccines. At this time, 190 countries have joined the COVAX Facility, including 92 low- and lower-middle-income countries.³

Janssen's investigational COVID-19 vaccine candidate

The investigational Janssen COVID-19 vaccine candidate leverages the Company's AdVac[®] vaccine platform, which was also used to develop and manufacture Janssen's European Commission-approved Ebola vaccine regimen and construct its Zika, RSV, and HIV investigational vaccine candidates.⁴ Janssen's AdVac[®] technology has been used to vaccinate more than 150,000 people to date across the Company's investigational and approved vaccines.^{4,5,6,7,8}

The Company anticipates interim data from the Phase 3 ENSEMBLE study⁸ for its single-dose Janssen COVID-19 vaccine candidate to be available by the end of January 2021; however, as this trial is dependent on disease events, the timing is approximate. If the data indicate the vaccine is efficacious with a good safety profile, the Company expects to submit a conditional Marketing Authorisation Application (cMAA) to the European Medicines Agency (EMA) as soon as able.

For more information on the Company's multi-pronged approach to helping combat the pandemic, please visit: www.janssen.com/EMEA/COVID19.

###

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 potential preventive and treatment regimens 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 December 29, 2019, 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 COVAX. Available at: <https://www.gavi.org/covax-facility>. Last accessed: December 2020.
- 2 Johnson & Johnson Joins Other Companies in Signing a Landmark Communiqué on Expanded Global Access for COVID-19. Available at: <https://www.jnj.com/latest-news/johnson-johnson-signs-communiqué-on-expanded-global-access-for-covid-19-vaccines>. Last accessed: December 2020.
- 3 UNICEF outlining plans to transport up to 850 tonnes of COVID-19 vaccines per month on behalf of COVAX, in 'mammoth and historic' logistics. Available at: <https://www.unicef.org/press-releases/unicef-outlining-plans-transport-850-tonnes-covid-19-vaccines-month-behalf-covax>. Last accessed: December 2020.
- 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 Enroled. 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: December 2020.
- 6 ClinicalTrials.gov. A study of Ad26.COVS.2 in Adults (COVID-19). NCT04436276. Available at: <https://clinicaltrials.gov/ct2/show/NCT04436276>. Last accessed: December 2020.
- 7 ClinicalTrials.gov. A study of Ad26.COVS.2 for the Prevention of SARS-CoV-2-Mediated COVID-19 in Adults Participants (ENSEMBLE 2). NCT04614948. Available at: <https://clinicaltrials.gov/ct2/show/NCT04614948>. Last accessed: December 2020.
- 8 ClinicalTrials.gov. A Study of Ad26.COVS.2 for the Prevention of SARS-CoV-2-Mediated COVID-19 in Adult Participants (ENSEMBLE). Available at: <https://clinicaltrials.gov/ct2/show/NCT04505722>. Last accessed: December 2020.