



Johnson & Johnson COVID-19 Vaccine Roll-out to Resume in Europe Following European Medicines Agency (EMA) Review

April 20, 2021

EMA Confirms Overall Benefit-Risk Profile Remains Positive

Company to update the COVID-19 Vaccine Janssen Summary of Product Characteristics and Package Leaflet to include important information on very rare adverse event

Johnson & Johnson remains committed to supplying 200 million doses of its COVID-19 vaccine to the European Union, Norway and Iceland

NEW BRUNSWICK, N.J., April 20, 2021 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) (the Company) today announced that the European Medicines Agency's (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) has provided updated guidance for use of the Company's COVID-19 vaccine and confirmed the overall benefit-risk profile remains positive. The guidance follows PRAC review of a small number of cases of a very rare adverse event involving blood clots in combination with low platelet counts that can occur within approximately one to three weeks following injection with the Company's COVID-19 vaccine.

As a result, Johnson & Johnson will update its COVID-19 vaccine Summary of Product Characteristics and Package Leaflet to include important information on the diagnosis and management of this very rare adverse event. Healthcare professionals will be alerted to the signs and symptoms of thromboembolism with thrombocytopenia, as well as the appropriate course of treatment.

Following the [PRAC recommendation](#), the Company will resume shipment of the Janssen COVID-19 vaccine in the European Union (EU), Norway and Iceland. The updated EMA and Healthcare Professionals guidance will be available to national healthcare authorities.

"The safety and well-being of the people who use our products is our number one priority. We appreciate the rigorous review of the PRAC and share the goal of raising awareness of the signs and symptoms of this very rare event to ensure the correct diagnosis and appropriate treatment," said Paul Stoffels, M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer at Johnson & Johnson. "We strongly believe in the positive benefits of our single-shot, easily transportable COVID-19 vaccine to help protect the health of people everywhere and reach communities in need globally. We are committed to equitable access and to bringing an affordable COVID-19 vaccine to the public on a not-for-profit basis for emergency pandemic use."

Data from the global ENSEMBLE Phase 3 trial demonstrated the Company's single-dose vaccine provided protection against COVID-19 related hospitalization and death across demographics and geographies, including areas with emerging variants.¹

The U.S. Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) currently are reviewing these same cases.² On April 14, 2021, the CDC convened a meeting of the Advisory Committee on Immunization Practices (ACIP) to review these cases and assess their potential significance.² The ACIP plans to reconvene on April 23, 2021, for further discussion.

Johnson & Johnson's COVID-19 Vaccine

The Johnson & Johnson COVID-19 vaccine, developed by the Janssen Pharmaceutical Companies of Johnson & Johnson, received Conditional Marketing Authorization from the European Commission on March 11, 2021, to prevent COVID-19 in individuals 18 years of age and older.²

This decision was based on the totality of scientific evidence, including data from the Phase 3 ENSEMBLE study that demonstrated the vaccine was 85 percent effective in preventing severe disease across all regions studied, and showed protection against COVID-19 related hospitalization and death, beginning 28 days after vaccination.^{3,4}

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>.

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/emea/>. Follow us at @JanssenEMEA.

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/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 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 Janssen. Johnson & Johnson Announces Single-Shot Janssen COVID-19 Vaccine Candidate Met Primary Endpoints in Interim Analysis of its Phase 3 ENSEMBLE Trial. Available at: https://www.janssen.com/emea/sites/www.janssen.com_emea/files/johnson_johnson_announces_single-shot_janssen_covid-19_vaccine_candidate_met_primary_endpoints_in_interim_analysis_of_its_phase_3_ensemble_trial.pdf. Last accessed April 2021.

² Johnson & Johnson Single-Shot COVID-19 Vaccine Granted Conditional Marketing Authorization by European Commission. Available at: <https://www.jnj.com/johnson-johnson-single-shot-covid-19-vaccine-granted-conditional-marketing-authorization-by-european-commission>. Last accessed: April 2021.

³ Johnson & Johnson. Johnson & Johnson COVID-19 Vaccine Authorized by U.S. FDA For Emergency Use - First Single-Shot Vaccine in Fight Against Global Pandemic. Available at: <https://www.jnj.com/johnson-johnson-covid-19-vaccine-authorized-by-u-s-fda-for-emergency-use-first-single-shot-vaccine-in-fight-against-global-pandemic>. Last accessed April 2021.

⁴ 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 April 2021.



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Media Contacts: Jake Sargent, +1 732-524-1090, JSargen3@its.jnj.com, or Seema Kumar, +1 908-405-1144, SKumar10@its.jnj.com, or Katie Buckley, +44 7900-655-261, KBuckley8@its.jnj.com, or Investor Relations: Chris DeOrefice, +1 732-524-2955, or Jennifer McIntyre, +1 732-524-3922