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

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 – Johnson & Johnson 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.

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.**Error! Bookmark not defined.Error! Bookmark not defined.** 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.

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-usefirst-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.