Media Statement

April 21, 2021

Johnson & Johnson Statement on FDA Observations at Emergent BioSolutions (Updated)

The quality and safety of our COVID-19 vaccine is paramount. On April 3, 2021, Johnson & Johnson announced it would increase its oversight of drug substance manufacturing at the Emergent BioSolutions Bayview facility, including additional controls and personnel, to ensure the quality standards of our company and the U. S. Food & Drug Administration (FDA) are met. Since then, the Company has worked closely with the U.S. government, including the FDA, and with the European Medicines Agency (EMA), concerning the FDA inspection at Emergent Bayview, which concluded on Tuesday, April 20, 2021.

Johnson & Johnson will exercise its oversight authority to ensure that all of FDA's observations with respect to the Emergent facility are addressed promptly and comprehensively. The Company will also continue to work toward securing Emergency Use Authorization in the United States for drug substance manufactured at Emergent Bayview as quickly as possible, so that the Company can help bring an end to this global pandemic.

To meet its commitments, the Company is establishing a global vaccine supply network, where, in addition to our internal manufacturing site in Leiden, the Netherlands, ten manufacturing sites will be involved in the production of the vaccine across different facilities, sometimes in different countries and continents, before the vaccine can be distributed globally. We are working around the clock to develop and broadly activate our manufacturing capabilities to supply our COVID-19 vaccine worldwide, and we appreciate the ongoing and extensive collaborations and partnerships we have with governments, health authorities and other companies to help end this pandemic.

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