Media Statement

October 12, 2020

Johnson & Johnson Temporarily Pauses All Dosing in Our Janssen COVID-19 Vaccine Candidate Clinical Trials

At Johnson & Johnson, there is no greater priority than the safety and well being of the people we serve every day around the world. We are committed to providing transparent updates throughout the clinical development process of our vaccine candidate, in compliance with regulatory standards and our own high ethical and scientific principles.

We have temporarily paused further dosing in all our COVID-19 vaccine candidate clinical trials, including the Phase 3 ENSEMBLE trial, due to an unexplained illness in a study participant. Following our guidelines, the participant's illness is being reviewed and evaluated by the ENSEMBLE independent Data Safety Monitoring Board (DSMB) as well as our internal clinical and safety physicians.

Adverse events – illnesses, accidents, etc. - even those that are serious, are an expected part of any clinical study, especially large studies. Based on our strong commitment to safety, all clinical studies conducted by the Janssen Pharmaceutical Companies of Johnson & Johnson have prespecified guidelines. These ensure our studies may be paused if an unexpected serious adverse event (SAE) that might be related to a vaccine or investigational medicine is reported, so there can be a careful review of all of the medical information before deciding whether to restart the study.

We must respect this participant's privacy. We're also learning more about this participant's illness, and it's important to have all the facts before we share additional information.

SAEs are not uncommon in clinical trials, and the number of SAEs can reasonably be expected to increase in trials involving large numbers of participants. Further, as many trials are placebo-controlled, it is not always immediately apparent whether a participant received a study treatment or a placebo. **"Study Pause" vs. "Regulatory Hold:" What's the Difference?**

While these terms are sometimes used interchangeably, there is a significant distinction between a **study pause** and a **regulatory hold** of a clinical trial.

- A **study pause**, in which recruitment or dosing is paused by the study sponsor, is a standard component of a clinical trial protocol. Johnson & Johnson has robust mechanisms in place to protect the safety of participants in its clinical trials. While the Company informs all study investigators, we typically do not communicate study pauses publicly.
- A **regulatory hold** of a clinical trial is a requirement by a regulatory health authority, such as the U.S. Food and Drug Administration (FDA). We proactively disclose any regulatory hold of a pivotal clinical trial.

Notice to Investors Concerning Forward-Looking Statements

This contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding development of potential preventive 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 materialise, actual results could vary materially from the expectations and projections of Janssen Pharmaceuticals Inc., 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 behaviour 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.