Johnson 4 Johnson

## Media Statement

November 11, 2020

## Johnson & Johnson Resumes all Clinical Trials of its Janssen COVID-19 Vaccine Candidate in Europe

Johnson & Johnson has resumed recruitment, enrolment and vaccination in all clinical trials of its investigational Janssen COVID-19 vaccine across Europe, after a <u>temporary pause</u>. Trials in the U.S, South Africa and some Latin American countries are already ongoing.

Following consultation with the concerned EU regulatory authorities, clinical trials of the Janssen COVID-19 vaccine candidate in Europe will resume this week. Clinical trials to be resumed are the Phase 2a studies in Germany, the Netherlands and Spain, as well as the Phase 1/2a study in Belgium.

Preparations are also ongoing for the initiation of a second Phase 3 clinical trial of Janssen's investigational COVID-19 vaccine candidate. The trial, which will study the safety and efficacy of a two-dose regimen, is anticipated to start later this month across several European countries. This follows positive interim results from the Company's <u>Phase 1/2a clinical study</u>, which showed that the safety profile and immunogenicity of the Janssen COVID-19 vaccine candidate were supportive of further development.

At Johnson & Johnson, there is no greater priority than the health and safety of the people we serve every day around the world. Our primary goal is to ensure the safety, well-being and privacy of the participants and all those involved in our trials.

Johnson & Johnson is developing and testing its Janssen COVID-19 vaccine candidate in accordance with high ethical standards and sound scientific principles, and we are also committed to accurate medical information and protecting participant privacy. We plan to disclose clinical trial data in our COVID-19 trials once those data are presented or published at pre-specified milestones and will proactively disclose regulatory trial holds requested by health authorities.

Johnson & Johnson is committed to bringing an affordable COVID-19 vaccine to the public on a not-for-profit basis for emergency pandemic use.

## 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 materialize, 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 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 <u>www.sec.gov</u>, <u>www.jnj.com</u> 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.