Media Statement

13 January 2021

Johnson & Johnson COVID-19 Vaccine Candidate Interim Phase 1/2a Data Published in *New England Journal of Medicine*

Interim Phase 1/2a data were published today in the *New England Journal of Medicine*[1] demonstrating that the Company's single-dose investigational COVID-19 vaccine candidate (JNJ-78436735) – being developed by the Janssen Pharmaceutical Companies of Johnson & Johnson – provided an immune response that lasted for at least 71 days, the duration of time measured in this study in participants aged 18-55 years. A preprint of a previous interim analysis was posted on *medRxiv* in September 2020.[2]

The Phase 1/2a interim analysis showed that the investigational Janssen COVID-19 vaccine candidate induced an immune response and was generally well-tolerated across all study participants.[1] Data showed that, after a single vaccination, neutralising antibodies against COVID-19 were detected in over 90 percent of study participants at Day 29 and 100 percent of participants aged 18-55 years at Day 57.[1] These neutralising antibodies remained stable through Day 71, currently the latest timepoint available in this ongoing study, in all participants aged 18-55 years. Data on durability of immune responses in trial participants aged over 65 years will be available in late January and longer-term follow-up to one year is planned.[1]

The Company anticipates announcing topline Phase 3 data for its single-dose Janssen COVID-19 vaccine candidate[3] in late January 2021; however, as this trial is dependent on disease events, the timing is approximate. If the single-dose vaccine is shown to be efficacious with a good safety profile, the Company expects to submit an application for Emergency Use Authorization with the U.S. Food and Drug Administration shortly afterwards, with other regulatory applications around the world to be made subsequently.

This Phase 1/2a study has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority,[1] under Contract No. HHSO100201700018C.

Phase 1/2a study design

This ongoing Phase 1/2a multi-centre, randomised, double-blind, placebo-controlled trial aims to evaluate the safety, reactogenicity, and immunogenicity of Janssen's COVID-19 vaccine candidate at two dose levels ($5x10^{10}$ or $1x10^{11}$ viral particles), administered intramuscularly as single-dose or two-dose schedules, eight weeks apart, in healthy adults (aged 18 to 55 years; n=405 or >65 years; n=405).[1,4] The study is ongoing at multiple clinical sites in Belgium and the United States.[1,4]

The full set of results for this Phase 1/2a study will be published once the complete trial data are available.

Phase 1/2a interim analysis safety data

The interim analysis also included unblinded safety data which showed that injection site (local) and systemic reactions to vaccinations either occurred on the day of immunisation or the next day, and generally resolved within 24 hours.[1] The most

frequent solicited, mild-to-moderate adverse events (side effects typically associated with vaccinations) in the vaccine study arms were fatigue, headache, myalgia and injection site pain. The most frequent systemic adverse event was fever. Reactogenicity was lower in the older age group.[1] The study also evaluated a two-dose regimen, in which reactogenicity was observed to be lower after the second vaccine dose.[1]

Five serious adverse events were reported; one participant visited the hospital for a fever that was associated with vaccination (the participant recovered within 12 hours); the remaining four were confirmed by study investigators as unrelated to the vaccine candidate.[1]

Phase 1/2a interim analysis immune response data
The interim data show that, following a single vaccination, neutralising antibodies (VNA) titres – a laboratory test measuring the presence of neutralising antibodies in blood – against COVID-19 were detected in over 90 percent of tested participants at Day 29. In participants aged 18-55 years, this increased to 100 percent at Day 57 – irrespective of vaccine dose or age group.[1] VNA titres then remained stable until at least Day 71 (currently the latest available time point in this ongoing study).[1] Data on durability of immune responses in trial participants aged over 65 years after Day 29 will be shared in late January. The interim analysis showed the safety profile and immunogenicity after a single dose of the COVID-19 vaccine candidate were supportive of further development.[1]

The study also evaluated a two-dose regimen, in which the data showed that a second dose of the vaccine candidate, administered 56 days apart, was less reactogenic while it triggered more than a two-fold increase in antibodies against COVID-19.[1]

Janssen's investigational COVID-19 vaccine candidate
The investigational Janssen COVID-19 vaccine candidate leverages the Company's AdVac® vaccine platform, which was also used to develop and manufacture Janssen's European Commission-approved Ebola vaccine regimen and construct its Zika, RSV, and HIV investigational vaccine candidates.[5] Janssen's AdVac® technology has been used to vaccinate more than 200,000 people to date.[5,6,7,8,9,10]

Janssen is investigating multiple doses and dosing regimens of its COVID-19 vaccine candidate to evaluate long-term efficacy.[7,8] The Company is studying a single-dose of its vaccine candidate in the Phase 3 ENSEMBLE trial,[3] which completed enrolment on December 17, 2020,[6] and a two-dose regimen in the Phase 3 ENSEMBLE 2 study which is ongoing.[8]

Johnson & Johnson continues to develop and test its COVID-19 vaccine candidate in accordance with ethical standards and sound scientific principles. The Company is committed to transparency and sharing information related to its ongoing clinical studies.[11]

ENSEMBLE was initiated in collaboration with the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services (HHS) under Other Transaction Agreement HHSO100201700018C, and the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH) at HHS.[12]

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.

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Notice to Investors 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 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.

References

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