Media Statement

September 25, 2020

(This statement was updated on October 4, 2020 to include additional information)

Johnson & Johnson Posts Interim Results from Phase 1/2a Clinical Trial of its Janssen COVID-19 Vaccine Candidate

Interim analysis from Phase 1/2a First-in-Human trial supports further clinical development of investigational vaccine candidate JNJ-7843735 (also known as Ad26.COV2.S)

Interim analysis from the ongoing Phase 1/2a clinical trial of the Janssen COVID-19 vaccine candidate (JNJ-78436735) was posted today on the pre-print server *medRxiv*.[1]

The data demonstrate that a single dose of JNJ-78436735 induced a strong neutralising antibody response in nearly all participants aged 18 years and older and was generally well-tolerated. Immune responses were similar across the age groups studied, including older adults.[1]

The ongoing Phase 1/2a clinical trial is designed to study the safety and immunogenicity of two dose levels of the Janssen COVID-19 vaccine, and as single and two-dose schedules.[2] The interim analysis showed that a single dose induced a robust immune response and was generally well-tolerated.[1] These data are consistent with preclinical studies, published in the scientific journal *Nature,* which showed that a single dose of the vaccine successfully prevented subsequent infection and provided complete protection in the lungs of nonhuman primates.[3]

Based on these findings, the single dose of the Janssen COVID-19 vaccine candidate of $5x10^{10}$ virus particles (vp) has been selected for further evaluation in the Phase 3 ENSEMBLE clinical trial.[1,4] The Company also plans on running a Phase 3 clinical trial of a two-dose regimen of JNJ-78436735 versus placebo later this year.

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

Immune Response Data

Seroconversion (the development of detectable antibodies) was observed in 99 percent of participants aged 18-55 years of age. 98 percent of participants were positive for neutralising antibodies against SARS-CoV-2 at day 29 post-vaccination.[1] The Janssen COVID-19 vaccine candidate elicited strong antibody responses, strong T cell responses, and a Th1 response believed likely to mitigate the risk of vaccine-associated enhanced respiratory disease.[1],[5]

Immunogenicity (the ability to trigger an immune response) data from participants aged 65 years of age and above were available for the first 15 participants at the time of this post, with strong humoral and cellular immune responses elicited in these participants who received a single dose of Janssen's COVID-19 vaccine candidate.[1]

Safety and Tolerability Data

Interim safety data from the Phase 1/2a trial indicated that the majority of adverse events reported were mild to moderate (grade 1 and grade 2) in severity.[1] Two serious adverse events were reported, the first for hypotension which the investigator determined to not be vaccine related, and the second was a participant with a fever who was hospitalised due to suspicion of having COVID-19 but recovered within 12 hours; the fever was subsequently judged by the investigator to be vaccine related. No grade 4 (life-threatening) adverse events, solicited or unsolicited, were reported in any cohort and no participant discontinued the study due to an adverse event. The analysis showed there was a trend toward higher reactogenicity with the higher vaccine dose and with younger age.[1]

In clinical studies investigating vaccines, it is well known that vaccines often induce local and systemic side-effects that are mild to moderate and transient without consequences. In vaccine clinical trials, these types of side effects are actively sought ("solicited").[6] The interim safety data in this Phase 1/2a study is blinded to ensure participants and trial investigators are not made aware which participants received a single dose of Janssen's COVID-19 vaccine candidate versus a placebo.[1]

Study Design

This 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, administered intramuscularly as single-dose or two-dose schedules, eight weeks apart, in healthy adults 18-55 and greater than 65 years of age. The study is ongoing at multiple clinical sites in Belgium and the United States.[1,2]

Additional Information

"We are very encouraged by the immunogenicity of our COVID-19 vaccine candidate based on the antibody and T-cell data that was seen after a single dose and reported in the interim analysis of our Phase 1/2a trial," said Mathai Mammen, M.D., Ph.D., Global Head of Janssen Research & Development, Johnson & Johnson. "Our scientific confidence of vaccine efficacy is based on mathematical modelling that relates the antibody levels we have seen in humans to the levels required for disease protection that we observed in non-human primates. We are now evaluating a single-dose of our COVID-19 vaccine candidate versus placebo in the ENSEMBLE Phase 3 study."

At day 29, 98 percent of participants in cohort 1a had detectable wild type SARS-CoV-2 virus neutralising antibodies, with a titer higher than 1:100 in >80% of participants. [1]

A single dose of a safe and effective vaccine would offer a significant benefit during a global pandemic emergency. However, a two-dose schedule may have potential to offer enhanced durability in some participants. Therefore, Janssen is studying a single-dose of its vaccine candidate in its pivotal ENSEMBLE trial[4] and plans to run a Phase 3 clinical trial with a two-dose regimen of JNJ-78436735 versus placebo later this year.

Substantial clinical experience exists for Janssen Ad26 vaccine platform (known as AdVac®).[7] Approved and investigational vaccines based on this platform have been administered to over 100,000 people across its global clinical programmes.[8,9]

For more information on Johnson & Johnson's multi-pronged approach to helping combat the pandemic, www.Janssen.com/EMEA/COVID19.

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 potential preventive and treatment 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 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 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.

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1 Sadoff J., Le Gras M., Shukarev G., et al. Safety and immunogenicity of the Ad26.COV2.S COVID-19 vaccine candidate: Interim results of a phase 1/2a, double blind, randomized, placebo-controlled trial. medRxiv. 2020. Available at: https://www.medrxiv.org/content/10.1101/2020.09.23.20199604v1.full.pdf. Last accessed: October 2020.

2 Clinicaltrials.gov. A Study of Ad26.COV2.S in Adults (COVID-19). NCT04436276. Available at: https://clinicaltrials.gov/ct2/show/NCT04436276. Last accessed: October 2020.

3 Mercado NB, Zahn R, Wegmann F, et al. Single-shot Ad26 vaccine protects against SARS-CoV-2 in rhesus macaques. Nature. 2020 Jul 30:1-6.

4 ClinicalTrials.gov. A study of Ad26.COV2.S for the Prevention of SARS-CoV-2-Mediated COVID-19 in Adult Participants (ENSEMBLE). Available at: https://clinicaltrials.gov/ct2/show/NCT04505722. Last accessed: October 2020.

5 Lambert PH, Ambrosino DM, Andersen SR, et al. Consensus summary report for CEPI/BC March 12-13, 2020 meeting: Assessment of risk of disease enhancement with COVID-19 vaccines. Vaccine. 2020;38(31):4783-4791.

6 Hervé C, Laupèze B, Del Giudice G, Didierlaurent AM, Da Silva FT. The how's and what's of vaccine reactogenicity. NPJ vaccines. 2019 Sep 24;4(1):1-1.

7 Clinicaltrials.gov. Search results: Ad26 and Janssen. Available at: https://clinicaltrials.gov/ct2/results?term=Ad26+and+Janssen&Search=Search. Last accessed October 2020.

8 Janssen data on file. Grand total of individuals who have been vaccinated with AdVac vaccines. October 2020.

9 Janssen. Janssen Vaccine Technologies. Available at: https://www.janssen.com/infectious-diseases-and-vaccines/vaccine-technologies. Last accessed: October 2020.