Media Statement

16 November 2020

Johnson & Johnson Initiates Second Global Phase 3 Clinical Trial of its Janssen COVID-19 Vaccine Candidate

The Phase 3 ENSEMBLE study (NCT04505722) of the single-dose regimen of JNJ-78436735, the investigational vaccine candidate for the prevention of COVID-19 being developed by the Janssen Pharmaceutical Companies of Johnson & Johnson, continues to enrol and vaccinate study participants. ENSEMBLE is proceeding to enrol up to 60,000 participants worldwide.[1]

In addition to the single-dose regimen ENSEMBLE study, Janssen has now initiated the two-dose regimen ENSEMBLE 2 trial (NCT04614948). ENSEMBLE 2 is a complementary, planned, pivotal, large-scale, multi-country Phase 3 trial that will study the safety and efficacy of a two-dose regimen of the investigational Janssen vaccine candidate for the prevention of COVID-19 in up to 30,000 participants worldwide.[2] The ENSEMBLE and ENSEMBLE 2 trials will run in parallel.

While a potentially effective single-dose preventive COVID-19 vaccine with a good safety profile would have significant benefits, particularly in a pandemic setting, Janssen's COVID-19 vaccine programme has been designed to be extremely thorough and driven by science. As such, we are investigating multiple doses and dosing regimens to evaluate their long-term efficacy.[1,2]

The Phase 3 ENSEMBLE and ENSEMBLE 2 trials follow positive interim results from the Company's ongoing Phase 1/2a clinical study, which is studying the safety profile and immunogenicity of both a single-dose and two-dose vaccination. The interim analysis showed that a single dose of the COVID-19 vaccine candidate induced a robust immune response and was generally well-tolerated.[3,4]

PHASE 3 ENSEMBLE 2 STUDY

The Phase 3 ENSEMBLE 2 study (NCT04614948) is a randomised, double-blind, placebo-controlled clinical trial designed to evaluate the safety and efficacy of a two-dose vaccine regimen versus placebo in adults 18 years old and older with or without stable comorbidities associated with an increased risk for severe COVID-19. The study will assess efficacy of the investigational vaccine after both the first and second dose to evaluate protection against the virus and potential incremental benefits for duration of protection with a second dose.[2]

Janssen will enrol participants in Belgium, Colombia, France, Germany, the Philippines, South Africa, Spain, the United Kingdom and the United States.[2] In order to evaluate the efficacy of Janssen's COVID-19 vaccine candidate, clinical trial sites in countries and areas with high incidence of COVID-19 and the ability to achieve a rapid initiation were selected.

In the UK, ENSEMBLE 2 is being conducted in collaboration with the UK National Institute for Health Research (NIHR).[5]

The Company is committed to transparency and sharing information related to the Phase 3 ENSEMBLE 2 study.

JANSSEN'S INVESTIGATIONAL COVID-19 VACCINE CANDIDATE

The Janssen COVID-19 vaccine candidate leverages the Company's AdVac® technology platform, which was also used to develop and manufacture Janssen's European Commission-approved Ebola vaccine and construct its Zika, RSV, and HIV investigational vaccine candidates.[6] Janssen's AdVac® technology platform has been used to vaccinate more than 110,000 people to date across Janssen's investigational vaccine programmes.[7]

For more information on Johnson & Johnson's multi-pronged approach to helping combat the pandemic, visit: www.janssen.com/emea/covid19.

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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 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 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

1 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: November 2020.
2 ClinicalTrials.gov. A Study of Ad26.COV2.S for the Prevention of SARS-CoV-2-mediated COVID-19 in Adults (ENSEMBLE 2). Available at: https://clinicaltrials.gov/ct2/show/NCT04614948. Last accessed: November 2020.

3 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: November 2020.
4 Clinicaltrials.gov. A Study of Ad26.COV2.S in Adults (COVID-19). NCT04436276. Available at: https://clinicaltrials.gov/ct2/show/NCT04436276. Last accessed: November 2020.
5 National Institute for Health Research. A Phase 3 COVID-19 Vaccine Study. Available at: https://www.nihr.ac.uk/covid-studies/study-detail.htm?entryId=288552. Last accessed: November 2020.
6 ClinicalTrials.gov. Search results: Ad26 and Janssen. Available at: https://clinicaltrials.gov/ct2/results?term=Ad26+and+Janssen&Search=Search. Last accessed: November 2020.
7 Janssen data on file. Grand total of individuals who have been vaccinated with AdVac vaccines. November 2020.