Lehdistötiedote

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Johnson & Johnson ilmoitti tänään kolmannen vaiheen ENSEMBLE-tutkimuksen välianalyysissään, että yrityksen tytäryhtiön Janssenin yhden annoksen COVID-19 -rokotekandidaatti saavutti sen kliiniselle tutkimukselle asetetut päätetapahtumat

Rokotekandidaatin teho kohtalaiseen tai vakavaan COVID-19 tautiin oli 72 % Yhdysvalloissa ja 66 % tutkimusmaissa kaiken kaikkiaan 28 päivää rokotuksen jälkeen.

Vakavaa COVID-19 tautia vastaan rokotteen teho oli 85%. Rokote osoittautui estävän täysin sairaalahoidon tarpeen ja kuolemantapaukset päivän 28 kohdalla.

Suoja vakavaa tautia vastaan havaittiin kaikissa maissa ja ikärymissä. Suoja kattoi useat virusmuunnokset, mukaan lukien virusmuunnos, joka on havaittu Etelä-Afrikassa (SARS-CoV-2 muunnos B.1.351[ii]).

Yhden pistoksen rokote, joka sopii tavanomaisiin rokotteiden jakelukanaviin, tarjoaa tärkeän avun pandemiaolosuhteissa.

”Koronarokotteen kehittäminen ei ole yritysten välistä kilpailua vaan taistelua yhteistä vihollista vastaan. Me Janssenilla olemme työskennelleet yhdessä muiden yritysten, hallitusten ja terveysviranomaisten kanssa rokotteen kehitystyössä. Olen ylpeä tänään julkaistuista tuloksista, jotka vievät meitä kaikkia jälleen eteenpäin taistelussa koronaa vastaan”, sanoo Suomen Janssenin maajohtaja Tim Schenk.

LISÄTIEDOT: Janssen Finland yhteiskuntasuhde- ja viestintäpäällikkö Pirjo Mäenpää, pmaenpaa@its.jnj.com, puh. 050-3466366

LEHDISTÖTIEDOTE KOKONAISUUDESSAAN:

NEW BRUNSWICK, N.J., January 29, 2021 – Johnson & Johnson (NYSE: JNJ) (the Company) today announced topline efficacy and safety data from the Phase 3 ENSEMBLE clinical trial, demonstrating that the investigational single-dose COVID-19 vaccine in development at its Janssen Pharmaceutical Companies met all primary and

key secondary endpoints. The topline safety and efficacy data are based on 43,783 participants accruing 468 symptomatic cases of COVID-19.

The Phase 3 ENSEMBLE study is designed to evaluate the efficacy and safety of the Janssen COVID-19 vaccine candidate in protecting moderate to severe COVID-19, with co-primary endpoints of 14 days and 28 days following vaccination. Among all participants from different geographies and including those infected with an emerging viral variant, Janssen's COVID-19 vaccine candidate was 66% effective overall in preventing moderate to severe COVID-19, 28 days after vaccination. The onset of protection was observed as early as day 14. The level of protection against moderate to severe COVID-19 infection was 72% in the United States, 66% in Latin America and 57% in South Africa, 28 days post-vaccination.

Prevention of severe disease; protection against COVID-related hospitalization and death

The vaccine candidate was 85 percent effective in preventing severe disease across all regions studied,[i] 28 days after vaccination in all adults 18 years and older. Efficacy against severe disease increased over time with no cases in vaccinated participants reported after day 49.

The Janssen COVID-19 vaccine candidate demonstrated complete protection against COVID-related hospitalization and death, 28 days post-vaccination. There was a clear effect of the vaccine on COVID-19 cases requiring medical intervention (hospitalization, ICU admission, mechanical ventilation, extracorporeal membrane oxygenation (ECMO)), with no reported cases among participants who had received the Janssen COVID-19 vaccine, 28 days post-vaccination.

In the study, the definition of severe COVID-19 disease included laboratory-confirmed SARS-CoV-2 and one or more of the following: signs consistent with severe systemic illness, admission to an intensive care unit, respiratory failure, shock, organ failure or death, among other factors. Moderate COVID-19 disease was defined as laboratory-confirmed SARS-CoV-2 and one or more of the following: evidence of pneumonia, deep vein thrombosis, shortness of breath or abnormal blood oxygen saturation above 93%, abnormal respiratory rate (≥20); or two or more systemic symptoms suggestive of COVID-19.

Protection was generally consistent across race, age groups, including adults over 60 years of age (N= 13,610), and across all variants and regions studied, including South Africa where nearly all cases of COVID-19 (95%) were due to infection with a SARS-CoV-2 variant from the B.1.351 lineage[ii].

Multi-continent Study Provides Clinical Data on Multiple Emerging Viral Mutations

The ENSEMBLE study results include efficacy against newly emerging strains of coronavirus, including some highly infectious variants present in the US, Latin America and South Africa. The Phase 3 ENSEMBLE trial is being conducted at the height of the COVID-19 pandemic in eight countries and three regions, at a time when disease spread has accelerated throughout the world resulting in people having increased exposure to the virus.

Trial participants of the phase 3 ENSEMBLE study continue to be followed for up to two years for assessments of safety and efficacy. Therefore, these data may be updated based on ongoing analysis. The comprehensive available data set will be submitted to a peer-reviewed journal in the coming weeks.

Phase 3 ENSEMBLE Study Safety Data

The analysis included a concurrent review of the available Phase 3 ENSEMBLE study safety data by the Data and Safety Monitoring Board (DSMB), an independent group of experts, that did not report any significant safety concerns relating to the vaccine. A review of adverse events indicated that a single-dose of Janssen's COVID-19 vaccine candidate was generally well-tolerated.

The safety profile was consistent with other vaccine candidates using Janssen's AdVac® technology among more than 200,000 people to date. Overall fever rates were 9% and Grade 3 fever 0.2%. Overall serious adverse events (SAEs) reported were higher in participants who received placebo as compared to the active vaccine candidate. No anaphylaxis was observed.

Phase 3 ENSEMBLE Study Design
The Phase 3 ENSEMBLE study is a randomized, double-blind, placebo-controlled clinical trial designed to evaluate the safety and efficacy of a single-dose vaccine versus placebo in adults 18 years old and older.

The ENSEMBLE study was designed to evaluate the safety and efficacy of the Janssen vaccine candidate in protecting against both moderate and severe COVID-19 disease, with assessment of efficacy as of day 14 and as of day 28 as co-primary endpoints.

Phase 3 ENSEMBLE Study Demographics

The trial, conducted in eight countries across three continents, includes a diverse and broad population including 34% (N= 14,672) of participants over age 60.

The study enrolled 44% (N=19,302) of participants in the United States, 41% (N=17,905) in Central and South America (Argentina, Brazil, Chile, Colombia, Mexico, Peru), 15% (N=6,576) in South Africa.

Forty-five percent of participants are female, 55% male.

Among participants globally, 59% are White/Caucasian; 45% are Hispanic and/or Latinx; 19% are Black/African American; 9% are Native American and 3% are Asian. In the United States, 74% are White/Caucasian; (15% are Hispanic) and/or Latinx; 13% are Black/African American; 6% are Asian and 1% are Native American.

Forty-one percent of participants in the study had comorbidities associated with an increased risk for progression to severe COVID-19 (overall 41%, obesity (28.5%), type 2 diabetes (7.3%), hypertension (10.3%), HIV (2.8%); also other immunocompromised participants were in the study.

About the Janssen Pharmaceutical Companies of Johnson & Johnson
At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension. Learn more at www.janssen.com. Follow us at @JanssenGlobal.

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[i] https://www.jnj.com/coronavirus/covid-19-phase-3-study-clinical-protocol

[ii] The B.1.351 lineage also known as 501Y.V2 variant and 20H/501Y.V2 (formerly 20C/501Y.V2) is a variant of SARS-CoV-2, the virus that causes COVID-19