Johnson & Johnsonin yhden annoksen koronarokote sai ehdollisen myyntiluvan Euroopan komissiolta

-Tutkimustiedot osoittivat, että rokote suojaa koronaviruksesta johtuvalta sairaalahoitoon joutumiselta eri puolilla maailmaa - mukaan lukien ne maat, joissa esiintyy virusmuunnoksia.[1]

- Komission päätös tehtiin sen jälkeen, kun Euroopan lääkevirasto oli suositellut Johnson & Johnsonin koronarokotetta[2]

- Yrityksen tavoitteena on aloittaa rokotetoimitukset EU-maihin huhtikuun loppupuolella ja tämän vuoden aikana toimitetaan yhteensä 200 miljoonaa rokoteannosta.[3]

Johnson & Johnson Single-Shot COVID-19 Vaccine Granted Conditional Marketing Authorisation by European Commission

- Data have demonstrated vaccine protects against COVID-19 related hospitalization in broad geographic regions, including those with emerging variants 1 [1]

-Decision follows the European Medicines Agency recommendation of the J&J COVID-19 vaccine[2]

- The Company aims to begin delivering its vaccine in the second half of April to EU Member States and is committed to supply 200 million doses in 2021 [3]

NEW BRUNSWICK, N.J., March 11, 2021 – Johnson & Johnson today announced that the European Commission (EC) has granted a Conditional Marketing Authorisation (CMA) for its single-dose COVID-19 vaccine, developed by the Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen), to prevent COVID-19 in individuals 18 years of age and older.

The CMA follows a Positive Opinion from the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP).2 The CMA is valid in all 27 member states of the European Union (EU), plus Norway, Iceland and Liechtenstein.[4]

Data from the Phase 3 ENSEMBLE study demonstrated the vaccine was well-tolerated, was 85 percent effective in preventing severe disease across all regions studied and showed protection against COVID-19 related hospitalization and death beginning 28 days after vaccination.[2]

Johnson & Johnson is committed to making its COVID-19 vaccine available on a not-for-profit basis for emergency pandemic use. Pursuant to an agreement with the EC, Johnson & Johnson is reaffirming its commitment to deliver 200 million doses of its Janssen single dose COVID-19 vaccine candidate to the EU in 2021 starting in the second quarter. The Company plans to supply 200 million doses to EU Member

In December 2020, the Company announced that Janssen initiated a rolling submission with the EMA for its single-dose COVID-19 vaccine candidate, enabling an expedited CHMP review process.[5] The COVID-19 vaccine candidate has also been filed for an Emergency Use Listing (EUL) with the World Health Organization.[6] Rolling submissions for our vaccine candidate have also been initiated in several countries worldwide.

The Company received Emergency Use Authorization (EUA) in the United States on February 27,[7] following a unanimous vote by the U.S. Food and Drug Administration's Vaccines and Related Biological Products Advisory Committee on February 26, 2021.[8] The Johnson & Johnson single-dose COVID-19 vaccine has also been granted Interim Order authorization in Canada.[9]

Manufacturing and Supply Chain Information

The Johnson & Johnson COVID-19 single-dose vaccine is compatible with standard vaccine storage and distribution channels enabling delivery to remote areas.[7] The vaccine is estimated to remain stable for two years at -20°C, and a maximum of three months of which can be at routine refrigeration at temperatures of 2°-8°C.[7,10] The Company will ship the vaccine using the same cold chain technologies it uses today to transport treatments for cancer, immunological disorders and other medicines.[7,10] The COVID-19 vaccine should not be re-frozen if distributed at temperatures of 2°-8°C.[7]

The Johnson & Johnson COVID-19 vaccine leverages the AdVac® vaccine platform, a unique and proprietary technology that was also used to develop and manufacture Janssen's European Commission-approved Ebola vaccine regimen and construct its investigational Zika, RSV, and HIV vaccines.[10]

Phase 3 ENSEMBLE Study Design The Phase 3 ENSEMBLE study is a randomized, double-blind, placebo-controlled clinical trial in individuals 18 years of age and older.[11] The study was designed to evaluate the safety and efficacy of the Company's 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.[12] The study enrolled a total of 43,783 participants.[7]

The trial, conducted in eight countries across three continents, includes a diverse and broad population including 34 percent of participants over age 60.[2,11] Forty-one percent of participants in the study had comorbidities associated with an increased risk for progression to severe COVID-19.[2]

About Johnson & Johnson

At Johnson & Johnson, we believe good health is the foundation of vibrant lives, thriving communities and forward progress. That's why for more than 130 years, we have aimed to keep people well at every age and every stage of life. Today, as the world's largest and most broadly-based healthcare company, we are committed to using our reach and size for good. We strive to improve access and affordability, create healthier communities, and put a healthy mind, body and environment within reach of everyone, everywhere. We are blending our heart, science and ingenuity to profoundly change the trajectory of health for humanity.

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.

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