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News Release

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Janssen Announces Respiratory Syncytial Virus (RSV) Adult Vaccine Candidate Maintains Significant Efficacy Regardless of Lower Respiratory Tract Disease Severity

First RSV vaccine candidate to show significant efficacy – up to 80 percent[1]

NEW BRUNSWICK, N.J., 7 December 2021 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced vaccine efficacy and safety data from its Phase 2b CYPRESS study of its respiratory syncytial virus (RSV) adult vaccine candidate.[1,2] Results show that the vaccine candidate was effective in protecting against three clinical definitions of lower respiratory tract disease (LRTD) caused by RSV, demonstrating vaccine efficacy of 69.8 (CI, 43.7-84.7%) to 80 (CI, 52.2-92.9%) percent in adults aged 65 and older.[1] These data were presented at the Eighth European Scientific Working Group on Influenza (ESWI) meeting, held virtually from 4–7 December 2021.

"Data from our Phase 2b CYPRESS study bring us another step closer to delivering a potentially first-in-class vaccine to help protect older adults from RSV," said Penny Heaton, M.D., Global Therapeutic Area Head, Vaccines, Janssen Research & Development, LLC. "With no approved vaccine or broadly indicated antiviral available, older adults are at high risk of developing serious, potentially life-threatening illness from RSV. We have now shown significant efficacy and believe our vaccine has the potential to prevent the significant morbidity and mortality caused by RSV every year."

"RSV activity was unusually high this past summer, indicating that the seasonal respiratory viruses will definitely be back as the COVID-19 pandemic slows," said Ann R Falsey, M.D., Professor of Medicine, University of Rochester School of Medicine and presenting author. "Increasingly, RSV is becoming a major global public health concern. These latest data from the Phase 2b CYPRESS study give us all further hope that this RSV vaccine candidate has the potential play a pivotal role in protecting vulnerable populations worldwide."

Following an initial proof-of-concept study with Janssen's RSV adult vaccine candidate (Ad26.RSV.preF component only) in a human challenge study,[3] Janssen combined Ad26.RSV.preF with a prefusion F (preF) protein for induction of a more optimal immune response.[4,5] This combination single-dose regimen[4] was evaluated in the Phase 2b CYPRESS

study, which enrolled 5,782 participants across 40 sites in the United States.[1,2] Participants were randomised to receive Ad26.RSV.preF or placebo (n=2891 in each group) and were followed through one RSV season.[1,2]

The Phase 2b CYPRESS study met all endpoints

The CYPRESS study primary endpoint was the first occurrence of LRTD (lower respiratory tract disease) caused by RSV, during the first RSV season following vaccination, according to any of three case definitions: (1) ≥3 symptoms of lower respiratory tract infection (LRTI), (2) ≥2 symptoms of LRTI, or (3) ≥2 symptoms of LRTI or ≥1 symptom of LRTI with ≥1 systemic symptom.[1] Vaccine efficacy for LRTD case definitions 1, 2, and 3 were 80 percent (CI, 52.2-92.9%), 75 percent (CI, 50.1-88.5%), and 69.8 percent (CI, 43.7-84.7%), respectively.[1] Efficacy was 69.8 percent (CI, 42.7-85.1%) for the first occurrence of any symptomatic RSV-associated acute respiratory infection (ARI).[1]

Similarly, RSV-specific patient-reported outcomes data from the CYPRESS trial found less severe RSV symptoms in participants with RSV-associated ARI in the vaccine group than in the placebo group. Vaccinated participants who experienced RSV-associated ARI had milder symptoms and a faster return to usual health than the participants in the placebo group.[1]

Janssen's RSV adult vaccine candidate was shown to be generally well-tolerated

Solicited adverse events (AEs; fatigue, headache, nausea, myalgia, fever, injection site reactions) and unsolicited AEs were assessed from time of vaccination (Day 1) to Day 8 and Day 29, respectively, in a safety subset of 695 participants (vaccine, n=348; placebo, n=347).[6] Serious AEs (SAEs) were collected in all participants until the end of the RSV season (primary endpoint) or six months post-vaccination, whichever occurred later.[6] In the vaccine group, the most frequent solicited systemic AEs were fatigue, myalgia and headache, and the most frequent solicited local AE was pain/tenderness.[6] The rates of unsolicited AEs were similar in both groups (vaccine, 16.7%; placebo, 14.4%); in the overall study population, the rate of SAEs was similar between groups (vaccine, 4.6%; placebo, 4.7%), and none were found to be related to the vaccine.[6]

Phase 3 EVERGREEN study of Janssen's RSV adult vaccine candidate is already underway

Based on positive results from the Phase 2b CYPRESS study, which evaluated the efficacy and safety of Janssen's investigational RSV vaccine against RSV-associated LRTD in vaccinated adults aged 65 and older in the United States,[1,2] Janssen initiated the global Phase 3 EVERGREEN study.[7] The Phase 3 study will evaluate the efficacy, safety and immunogenicity of Janssen's adult vaccine candidate against LRTD caused by RSV, when compared with placebo in approximately 23,000 adults aged 60 years and older throughout North America and a selection of countries across Europe, Asia and the Southern Hemisphere.[7]

In September 2019, the U.S. Food and Drug Administration granted Breakthrough Therapy Designation for Janssen's RSV adult vaccine candidate for the prevention of LRTD caused by RSV in adults aged 60 years or older.[8] This was based on clinical data indicating the potential for substantial improvement compared to available standard of care on a clinically significant endpoint(s).[8] In November 2020, the European Medicines Agency's Committee for Medicinal Products for Human Use designated Janssen's RSV adult vaccine candidate as eligible for the priority medicines (PRIME) scheme.[9]

For more information on Janssen's commitment to battling infectious diseases, visit: https://www.janssen.com/emea/our-focus/infectious-diseases-vaccines.

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About Respiratory Syncytial Virus (RSV)
Respiratory syncytial virus (RSV) is a prevalent, highly contagious respiratory virus[10] and a leading cause of bronchiolitis and pneumonia,[11] affecting more than 64 million people worldwide in a typical year.[12] Because the symptoms of RSV can be difficult to distinguish from influenza or other respiratory infections, such as COVID-19,[13] many who are infected with RSV remain undiagnosed.[14] There are currently no vaccines or broadly-available antivirals to prevent or treat RSV in older adults.[14,15]

Older adults, young children and those with underlying health conditions are most at risk.[13] RSV impacts adults over 60 years and high-risk adults over 18 years who are more likely to develop a lower respiratory tract disease (LRTD).[13] Between 3-7 percent of older adults (age 60 and older) and 4-10 percent of high-risk adults (age 18 and older) experience RSV in a typical year.[16]

About CYPRESS (NCT03982199)[2]
CYPRESS is a randomised, double-blind, placebo-controlled Phase 2b trial investigating the safety and efficacy of Janssen's Respiratory Syncytial Virus (RSV) adult vaccine candidate.[2] The trial enrolled 5,782 participants (2,891 in each study arm) aged 65 years and older.[1,2] The participants were randomised 1:1 prior to the RSV season to receive Janssen's RSV adult vaccine candidate or placebo.[1] For further information, please see: https://clinicaltrials.gov/ct2/show/NCT03982199.

About EVERGREEN (NCT04908683)[7]
The EVERGREEN study is a randomised, double-blind, placebo-controlled Phase 3 efficacy study, which aims to confirm the efficacy of the vaccine candidate in the prevention of reverse transcription polymerase chain reaction (RT-PCR) confirmed lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) when compared to placebo in adults aged 60 years and older.[7] The clinical trial is being conducted in countries in North America, Europe, Africa, Latin America and Asia Pacific.[7] Trial participants will be randomised to receive either one dose of active vaccine candidate or placebo.[7] Prior to the following RSV season, participants who received the active vaccine will be re-randomised to receive either the active vaccine again, or placebo.[17] Participants will be followed for at least two RSV seasons.[7] For further information, please see: https://clinicaltrials.gov/ct2/show/NCT04908683.

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. Learn more at www.janssen.com/emea/. Follow us at @JanssenEMEA.

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/emea/. Follow us at @JanssenEMEA.

Cautions 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 RSV. 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 January 3, 2021, 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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