**News Release**

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# Janssen Announces Start of Phase 3 Trial for Investigational Respiratory Syncytial Virus (RSV) Vaccine in Older Adults

Positive Phase 2b data supporting further evaluation will be presented at IDWeek 2021

**RARITAN, N.J., September 29, 2021** – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced the initiation of its Phase 3 EVERGREEN study. The study will evaluate the efficacy, safety and immunogenicity of Janssen's investigational adult vaccine against lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (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.

The EVERGREEN study was initiated based on positive results from the Phase 2b CYPRESS study, the first large study evaluating 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.

Efficacy and immunogenicity data from the Phase 2b CYPRESS study will be presented at the virtual IDWeek 2021 taking place from September 29 – October 3 (Abstract #1106286).

"Positive data from our first RSV vaccine efficacy study and the initiation of the Phase 3 EVERGREEN study are crucial milestones in the clinical development of our investigational RSV adult vaccine, which has the potential to safely and effectively prevent lower respiratory tract disease caused by RSV in older adults," says Penny Heaton, M.D., Global Therapeutic Area Head, Vaccines, Janssen Research & Development, LLC. "With no vaccine or broadly-indicated antiviral treatment available, preventive solutions to address the significant morbidity and mortality in older adults caused by RSV have long been an unmet need."

Older adults are at high risk of developing a serious infection from RSV, a highly contagious, potentially life-threatening respiratory virus affecting more than 64 million people worldwide in a typical year, across all age groups.[1]

In September 2019, the U.S. Food and Drug Administration granted Breakthrough Therapy Designation for Janssen's investigational RSV adult vaccine for the prevention of LRTD caused by RSV in adults aged 60 years or older. This was based on clinical data indicating the potential for substantial improvement compared to available standard of care on a clinically

significant endpoint(s). In November 2020, the European Medicines Agency's Committee for Medicinal Products for Human Use designated Janssen's investigational RSV adult vaccine as eligible for the priority medicines (PRIME) scheme based on promising clinical data and an unmet need for a prophylactic option to prevent RSV in older adults.

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**About Respiratory Syncytial Virus (RSV)**
Respiratory syncytial virus (RSV) is a prevalent, highly contagious respiratory virus and a leading cause of bronchitis, bronchiolitis and pneumonia, affecting more than 64 million people worldwide in a typical year. Because the symptoms of RSV can be difficult to distinguish from influenza or other respiratory infections, such as COVID-19, many who are infected with RSV remain undiagnosed.

Older adults, young children and those with underlying health conditions are most at risk. RSV disproportionately impacts adults over 60 years and high-risk adults over 18 years who are more likely to develop a lower respiratory tract infection (LRTI). 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.

With no preventive vaccine or effective antiviral treatment available, RSV remains a major global public health concern and is a substantial health and economic burden globally.

**About CYPRESS (NCT03982199)**
CYPRESS (NCT03982199) is a randomized, double-blind, placebo-controlled Phase 2b trial. The trial enrolled 5,782 participants (2,891 in each study arm) aged 65 years and older. The participants were randomized 1:1 prior to the RSV season to receive Janssen's investigational RSV adult vaccine or placebo. Immunogenicity and safety assessments were performed in a subset of approximately 200 and 695 participants, respectively. Disease symptoms were collected through a questionnaire and/or by a clinician's assessment. For further information, please see: https://clinicaltrials.gov/ct2/show/NCT03982199

**About EVERGREEN (NCT04908683)**
The EVERGREEN study (NCT04908683) is a randomized, 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. The clinical trial is being conducted in countries in North America, Europe, Africa, Latin America and Asia Pacific. Trial participants will be randomized to receive either one dose of active investigational vaccine or placebo. After a year, participants who received the active vaccine will be re-randomized to receive either the active vaccine again, or placebo. Participants will be followed for at least two RSV seasons. For further information, please see: https://clinicaltrials.gov/ct2/show/NCT04908683.

**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.

***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 Janssen Research & Development, LLC, any of the other 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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[1] National Institute of Allergy and Infectious Diseases. Respiratory syncytial virus (RSV). Available at: https://www.niaid.nih.gov/diseases-conditions/respiratory-syncytial-virus-rsv. Last accessed: September 2021.