This statement has been adapted for audiences in the EMEA region.

News Release

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Janssen Announces Phase 2b Data Demonstrating its Investigational RSV Adult Vaccine Provided 80% Protection Against Lower Respiratory Infections in Older Adults

Phase 2b CYPRESS study met all primary and secondary endpoints[1]

RARITAN, N.J., 2 October 2021 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced that its investigational respiratory syncytial virus (RSV) vaccine candidate was highly efficacious in protecting against lower respiratory tract disease (LRTD) caused by RSV, demonstrating vaccine efficacy of 80 percent (CI, 52.2-92.9%) in adults aged 65 and older.[1] The study results were presented as a late-breaking abstract at the virtual IDWeek 2021 conference on 2 October.

"The findings from our CYPRESS study are very encouraging as we seek to deliver a long-awaited preventive vaccine to stave off the severe complications associated with RSV in adults," said Penny Heaton, M.D., Global Therapeutic Area Head, Vaccines, Janssen Research & Development, LLC. "Respiratory syncytial virus is a leading cause of bronchitis and pneumonia and one of the most common infections in the world. As older adults are at high risk of developing serious, potentially life-threatening illness from RSV, there is an urgent need for a vaccine to prevent the significant morbidity and mortality caused by the virus."

The CYPRESS study met its primary and secondary endpoints, with the investigational RSV adult vaccine demonstrating efficacy of 80 percent (CI, 52.2-92.9%) against confirmed RSV-associated LRTD.[1] The investigational RSV adult vaccine also demonstrated efficacy of 70 percent (CI, 42.7-85.1%) against any symptomatic RSV-associated acute respiratory infection (ARI).[1]

The investigational RSV adult vaccine candidate elicited robust humoral and cellular immune responses in adults aged 65 and older, with participants in the immunogenicity subset showing a substantial increase in RSV neutralising antibodies 14 days after vaccination.[1] The investigational RSV vaccine candidate was generally well-tolerated in all vaccinated participants.[1]

"RSV remains a major global public health concern and a cause of serious respiratory illness in all age groups," said Ann R. Falsey, M.D., Professor of Medicine, University of Rochester

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School of Medicine and presenting author. "The positive efficacy results from the CYPRESS study reinforce the potential of this investigational RSV vaccine in preventing serious disease resulting from RSV in older adults."

Following an initial proof-of-concept study with Janssen's investigational RSV adult vaccine (Ad26.RSV.preF component only) in a human challenge study,[2] Janssen combined Ad26.RSV.preF with a prefusion F (preF) protein for induction of a more optimal immune response. [3] This combination single-dose regimen was evaluated in the Phase 2b CYPRESS study, which enrolled more than 5,500 participants across 40 sites in the United States followed through a single RSV season.[4]

Based on the positive results from the Phase 2b CYPRESS study, which is 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,[1] Janssen initiated the global Phase 3 EVERGREEN study.[5] The Phase 3 study will evaluate the efficacy, safety and immunogenicity of Janssen's investigational adult vaccine 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.[5]

Currently there is no preventive vaccine or broadly available antiviral treatment for RSV,[6] a highly contagious, potentially life-threatening respiratory virus affecting more than 64 million people worldwide in a typical year, across all age groups.[7,8] With the most severe complications seen in older adults and young children, RSV remains a major global public health and economic concern.[7,9,10]

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.[11] This was based on clinical data indicating the potential for substantial improvement compared to available standard of care on a clinically significant endpoint(s).[11] 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.[12]

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About Respiratory Syncytial Virus (RSV)

Respiratory syncytial virus (RSV) is a prevalent, highly contagious respiratory virus[7] and a leading cause of bronchiolitis and pneumonia in children younger than one year,[13] affecting more than 64 million people worldwide in a typical year.[8] Because the symptoms of RSV can be difficult to distinguish from influenza or other respiratory infections, such as COVID-19,[6] many who are infected with RSV remain undiagnosed.[14]

Older adults, young children and those with underlying health conditions are most at risk.[6] RSV disproportionately impacts adults over 65 years and high-risk adults over 18 years who are more likely to develop a lower respiratory tract disease (LRTD).[6] 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.[10]

With no preventive vaccine or effective antiviral treatment available,[6] RSV remains a major global public health concern and is a substantial health and economic burden globally.[7,9,10]

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About CYPRESS (NCT03982199)[4]
CYPRESS (NCT03982199) is a randomised, double-blind, placebo-controlled Phase 2b trial.[4] The trial enrolled 5,782 participants (2,891 in each study arm) aged 65 years and older.[1] The participants were randomised 1:1 prior to the RSV season to receive Janssen's investigational RSV adult vaccine or placebo.[3] Immunogenicity and safety assessments were performed in a subset of approximately 200 and 700 participants, respectively.[1,3] Disease symptoms were collected through a questionnaire and/or by a clinician's assessment.[3]

The primary endpoint was the first occurrence of reverse transcription polymerase chain reaction (RT-PCR) confirmed lower respiratory tract disease (LRTD) caused by RSV[4] according to any of 3 case definitions: (1) three or more symptoms of lower respiratory tract infection (LRTI), (2) two or more symptoms of LRTI, or (3) two or more symptoms of LRTI or one or more symptom of LRTI with one or more systemic symptom.[3] The secondary efficacy endpoint was the first occurrence of any RT-PCR-confirmed RSV-associated acute respiratory infection (ARI).[4] The study will be conducted over three years.[4]

For further information, please see: https://clinicaltrials.gov/ct2/show/NCT03982199.

About EVERGREEN (NCT04908683)[5]
The EVERGREEN study (NCT04908683) 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.[5] The clinical trial is being conducted in countries in North America, Europe, Africa, Latin America and Asia Pacific.[5] Trial participants will be randomised to receive either one dose of active investigational vaccine or placebo.[15] After a year, participants who received the active vaccine will be re-randomised to receive either the active vaccine again, or placebo.[15] Participants will be followed for at least two RSV seasons.[15] 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/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 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

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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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