



News Release

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Janssen Announces U.S. FDA Breakthrough Therapy Designation for Investigational Prophylactic Vaccine for the Prevention of Respiratory Syncytial Virus in Older Adults

Leiden, The Netherlands, September 3, 2019 – The Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen) announced today that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation for the Company's investigational prophylactic vaccine for the prevention of respiratory syncytial virus (RSV)-mediated lower respiratory tract disease in adults aged 60 years or older. Older adults are among the populations at highest risk of developing RSV, a highly-contagious, potentially life-threatening respiratory infection that affects more than 64 million people each year worldwide.¹

The FDA Breakthrough Therapy Designation was based on clinical data with Janssen's prophylactic RSV senior vaccine that may demonstrate substantial improvement compared to available standard of care on a clinically significant endpoint(s).²

"With no preventive vaccines or effective antiviral treatments currently available, RSV remains a significant cause of illness in at-risk populations, particularly older adults," said Johan Van Hoof, M.D., Global Therapeutic Area Head, Vaccines, and Managing Director, Janssen Vaccines & Prevention B.V., Janssen Pharmaceutica N.V. "This Breakthrough Therapy Designation represents clear recognition of the transformative potential of this investigational RSV preventive solution. We look forward to working closely with the FDA throughout the course of the prophylactic RSV senior vaccine development program."

As a result of being granted Breakthrough Therapy Designation, Janssen's prophylactic RSV senior vaccine candidate is now eligible for all associated FDA features.² The investigational prophylactic vaccine is currently in a Phase 2b proof of concept study to investigate the safety and efficacy of the vaccine against RSV in adults aged 65 years and older.

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About Respiratory Syncytial Virus (RSV)

Respiratory syncytial virus (RSV) is a highly prevalent, very contagious respiratory infection and a leading cause of bronchitis and pneumonia, affecting more than 64

million people each year worldwide.¹ Because the symptoms of RSV can be difficult to distinguish from influenza or other respiratory infections, many who are infected with RSV may not be properly diagnosed. Young children, older adults, and those with underlying health conditions are most at risk. Each year, RSV leads to more than 3 million hospitalizations and nearly 60,000 deaths in children under 5, nearly half of which occur in infants under 6 months old.³ Among older adults, RSV causes 177,000 hospitalizations and 14,000 deaths annually in the U.S. alone.⁴ With no preventive vaccine or effective antiviral treatment available, RSV is a substantial health and economic burden globally. Estimated hospitalization costs attributed to RSV in people aged 65 years or older exceed \$1 billion in the U.S. annually.⁵ Janssen's prophylactic RSV senior vaccine is part of a portfolio of vaccines that Janssen is developing for society's highest areas of unmet need.

About Janssen's Investigational Prophylactic Respiratory Syncytial Virus (RSV) Senior Vaccine

At Janssen, we are pursuing multiple avenues including preventive and therapeutic options to combat the serious harm caused by RSV infections. Our investigational prophylactic respiratory syncytial virus (RSV) senior vaccine is being investigated for the prevention of RSV-mediated lower respiratory tract disease in adults aged 60 years or older. The prophylactic RSV senior vaccine candidate leverages unique features of Janssen's adenovector platform (AdVac[®]). The investigational vaccine contains the gene encoding for the fusion protein of the RSV virus as an antigen.

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 and follow us at www.twitter.com/JanssenGlobal. Janssen Vaccines & Prevention B.V. is a member of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Notice to Investors 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 Vaccines & Prevention B.V., 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 December 30, 2018 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. Neither 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.

References:

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