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Newly Published Expert Opinion Article Details Evidence for Classifying Aging Immune System as a High-Risk Condition for Pneumococcal Vaccine Policy

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- *Review of scientific literature highlights increased risk of vaccine-preventable infectious diseases caused by the normal aging process that weakens immune responses*
- *Increased risk associated found to be independent of other underlying medical conditions*
- *Expert authors note there is enough evidence to support reevaluating adult vaccine policies to recognize the deleterious effects of immunosenesence*

NEW YORK, July 8, 2021 — Pfizer Inc. (NYSE: PFE) today announced the publication of an expert opinion piece highlighting the epidemiologic and biologic rationale for classifying immunosenescence as a high-risk condition and independent risk factor for infectious diseases, particularly pneumonia including its leading bacterial cause, Streptococcus pneumoniae. Immunosenescence is the age-related weakening of various protective immune responses.[1]

In the article, published in Expert Review of Vaccines, the authors reviewed the current scientific literature, which shows that this immunosenescence is associated with an increased risk of diseases associated with the bacterium Streptococcus pneumoniae, also known as pneumococcus, in otherwise healthy aging adults who do not have a compromised immune system because of an underlying medical condition.[1] Streptococcus pneumoniae, is the most common bacterial cause of meningitis and pneumonia globally.[2,3,4]

“While many adult vaccination policies are often limited to people with specific medical conditions, our findings confirm that age alone, should be classified as a high-risk factor for pneumococcal disease,” said James C. Appleby, BSPharm, MPH, ScD (Hon), Chief Executive Officer of The Gerontological Society of America (GSA) and a co-author on the study. “The evidence that we reviewed shows that the risk of pneumococcal pneumonia in older adults, even healthy ones, is comparable to that experienced by younger adults who are immune compromised. Considering immunocompromising conditions are already indicated for vaccination against pneumococcal disease, we believe there is a need for a comprehensive public health strategy that also includes immunosenescence.”

A normal part of healthy aging, immunosenescence is a multi-faceted process that occurs over a long time period.[1] Two hallmark characteristics of immunosenescence are cellular senescence, a state in which cells no longer divide and clear from the body, and inflammaging, a chronic low-grade inflammation in advancing age.[1] These can impact both innate (natural) immunity as well as adaptive (acquired) immunity. Cellular senescence in the respiratory tract, for example, impairs the body’s natural clearance of foreign materials, including pathogens.[1] Advancing age also is associated with a decline in the level of stem cells in bone marrow that produce T cells and other immune cells in response to an infectious pathogen.[1]

“Unquestionably, we must advance our vaccination policies to take a life-course approach with specific attention to protecting our aging populations,” said Jane M Barratt, Ph.D. is the Secretary General, International Federation on Ageing (IFA) and a co-author of the article. “Despite the increased risk of disease it causes, immunosenescence has not been included as a high-risk category in any vaccine policy in the world. As a group, we believe that needs to change and older people should be vaccinated before reaching ages at which their risk is highest, consistent with the approach for other immunocompromising conditions.”

The article was developed by Pfizer, the International Federation on Ageing, and The Gerontological Society of America, along with experts in microbiology from the School of Medicine of Griffith University, Queensland, Australia and the University Medical Centre Utrecht, The Netherlands. For this article, the authors reviewed epidemiologic, biologic, and clinical evidence supportive of immunosenescence as an immunocompromising condition, providing a rationale and framework for including immunosenescence as an independent risk factor in current vaccine policy, specifically for pneumococcal disease.

“Vaccines are one of the greatest public health advancements for improving health.,and for decades have helped prevent serious infectious diseases, which can sometimes be life threatening,” said Lindsay Grant, PhD, MPH, Senior Director, Global Epidemiology and Scientific Affairs for Pneumococcal Vaccines, Pfizer Inc. “While this review specifically focused on pneumococcal disease and vaccination, we believe similar epidemiological and biological assessments of other infectious diseases might illustrate that defining immunosenescence as an immunocompromising condition has a broader application.”

About Streptococcus pneumoniae

S. pneumoniae can infect people of all ages and result in non-invasive pneumococcal disease (PD) such as acute otitis media (AOM) and pneumonia, and invasive pneumococcal disease (IPD) such as meningitis.[4,5,6]

Non-invasive PD occurs outside of any normally sterile site, such as the blood, and includes AOM (middle ear infection) and pneumococcal pneumonia (acute respiratory infection that affects the lungs).[4,6,7,8] Pneumococcal pneumonia is a potentially serious respiratory infection that can result in hospitalization, including admission to the intensive care unit, and in severe cases, could be life-threatening.[4]

IPD occurs when bacteria invade parts of the body that are normally free from germs, such as blood or spinal fluid, and includes bacteremic pneumonia (pneumonia with bacteria present in the blood), bacteremia (bacteria in the blood) and meningitis (infection of the tissues surrounding the brain and spinal cord).[4,9] While less common than non-invasive PD, IPD is usually more severe.[8]

Community-acquired pneumonia (CAP) – pneumonia that is contracted outside of a healthcare setting – accounts for the vast majority of pneumonia cases, and is a leading cause of death due to infection in the United States and Europe, with the death rate in older adults often exceeding 10%.[10,11,12] S. pneumoniae has been recognized as one of the most frequent causes of CAP worldwide.[13,14] Historically, S. pneumoniae may account for as much as 40 to 50 percent of CAP cases in the elderly.[14,15]

About the International Federation on Ageing

The International Federation on Ageing (IFA) is an international non-governmental organization with a membership base comprising government, NGOs, academics, industry, and individuals in 80 countries. The IFA began operations in 1973, at a time when the social and economic impact of population ageing was only beginning to be understood by governments around the world. The IFA has general consultative status at the

United Nations and its agencies, and is engaged as a non-state actor with the World Health Organization. The IFA has been involved in informing key initiatives such as the UN Immunization Agenda 2030, and the UN Decade on Healthy Ageing, actively advocating for older people to be recognized in the Sustainable Development Goals, and maintaining a strong voice in the dialogue on how to best protect the rights of older people globally.

Gerontological Society of America

The Gerontological Society of America (GSA) is the nation's oldest and largest interdisciplinary organization devoted to research, education, and practice in the field of aging. The principal mission of the Society — and its 5,500+ members — is to advance the study of aging and disseminate information among scientists, decision makers, and the general public. GSA's structure also includes a policy institute, the National Academy on an Aging Society.

About Pfizer: Breakthroughs That Change Patients' Lives

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

Pfizer Disclosure Notice: The information contained in this release is as of July 8, 2021. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments. This release contains forward-looking information about pneumococcal disease and vaccination and potential epidemiological and biological assessments of other infectious diseases that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, and business and financial planning, including, without limitation, risks related to Pfizer's business and prospects, adverse developments in Pfizer's markets, or adverse developments in the U.S. or global capital markets, credit markets, regulatory environment or economies generally; the impact of COVID-19 on our business, operations and financial results; and competitive developments. A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2020 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com. 1 Lindsay R. Grant, Mary P. E. Slack, Qi Yan, Krzysztof Trzci?ski, Jane Barratt, Elizabeth Sobczyk, James Appleby, Alejandro Cané, Luis Jodar, Raul E. Isturiz & Bradford D. Gessner (2021) The epidemiologic and biologic basis for classifying older age as a high-risk, immunocompromising condition for pneumococcal vaccine policy, Expert Review of Vaccines, DOI: 10.1080/14760584.2021.1921579 2 Jain S, Self WH, Wunderink RG, et al. Community-acquired pneumonia requiring hospitalization among US adults. N Engl J Med. 2015;373(5):415-427. 3 Welte T, Torres A, Nathwani D. Clinical and economic burden of community-acquired pneumonia among adults in Europe. Thorax. 2012;67(1):71-79. 4 Centers for Disease Control and Prevention (CDC). In: Hamborsky J, Kroger A, Wolfe C,

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