SANOFI

Media Update

New research presented at *IDWeek 2021* reinforces Sanofi's robust vaccines pipeline and commitment to advancing public health protection

* Presentations focused on respiratory syncytial virus, meningococcal disease, and influenza

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New research from Sanofi Pasteur on respiratory syncytial virus (RSV), meningococcal disease, and influenza will be featured at *IDWeek 2021*, from September 29 to October 3, 2021, underscoring the company's pledge to develop meaningful solutions for patients.

> *"As one of the leading global vaccines companies, we continue to bring options which help protect people's health around the world,"* said Michael Greenberg, MD, MPH, Medical Head, Sanofi Pasteur North America. "*We look forward to sharing developments from our leading vaccines pipeline which underscore our ongoing commitment to uncovering insights that will help prevent severe infectious diseases at every stage of life, especially in diseases with an unmet need such as respiratory syncytial virus."*

Underscoring the need for all infant protection in RSV

RSV is a highly contagious virus that causes respiratory illness in infants, including lung infections such as bronchiolitis and pneumonia.[1] Illness coded as RSV specific bronchiolitis was found to be the leading cause of hospitalization in infants under 12 months, according to a study of pediatric hospitalizations between 1997 and 2000.[2] A study conducted from 2014 to 2015 showed 72% of infants hospitalized for RSV were previously healthy with no underlying conditions.[3]

Nirsevimab is being developed by Sanofi and AstraZeneca and is being evaluated as the first investigational long-acting antibody designed to help prevent lower respiratory tract infection (LRTI) caused by RSV in all infants from birth up to 12 months of age during their first RSV season.

The following data reinforce the need for a preventative option that could help to protect all infants with one dose for the entire RSV season:

- Medically Attended Illness Due to Respiratory Syncytial Virus Infection Among Infants in the United States During the 2016-17, 2017-18, 2018-19, and 2019-20 Seasons: The Need for all Infants Protection. Poster presentation number 1137.

- The Efficacy and Impact in Heathy Infants of Nirsevimab on Medically Attended RSV Lower Respiratory Tract Infection. Oral presentation number 1106281.*

** AstraZeneca leads all development activity through initial approvals.*

Evaluating the impact of vaccination for meningococcal disease

Meningococcal disease, which includes meningococcal meningitis, is a rare but potentially deadly bacterial infection.[4,5] Anyone can get meningococcal disease, but teens and young adults are among those who are at the highest risk for the infection.[6,7] Although rare, meningococcal disease develops rapidly and can claim the life of an otherwise healthy individual in as little as one day after the first symptoms appear.[4,5] The CDC recommends a first dose of the MenACWY vaccine at 11-12 years old and a second dose at 16 years old. Despite these recommendations, approximately half of U.S. teens have missed the crucial second dose.[8]

In the U.S., MenQuadfi® [Meningococcal (Groups A, C, Y, W) Conjugate Vaccine] is given to people 2 years of age and older to help prevent invasive meningococcal disease (including meningitis) caused by serogroups A, C, W, and Y of meningococcal bacteria.[7] MenQuadfi does not prevent serogroup B disease.[9] The following new research evaluates the long-term impact of MenQuadfi across various age groups:

- Immunogenicity and Safety of a Quadrivalent Meningococcal Conjugate Vaccine (MenACYW-TT) Administered as a Booster to Adults > 59 Years of Age (PNM-43489). Poster presentation number 1046.

- Immunogenicity and Safety of a Quadrivalent Meningococcal Conjugate Vaccine (MenACYW-TT) Administered as a Booster Dose in Adults and Adolescents Vaccinated Against Meningococcal Disease 3-6 Years Earlier (PNM-51872). Poster presentation number 3.

- Immunogenicity and Safety of a Quadrivalent Meningococcal Conjugate Vaccine (MenACYW-TT) Administered in Meningococcal Vaccine Naïve Participants Across a Broad Age Range (2-55 years) in Japan (PNM-51878). Poster presentation number 4.

Examining the relationship between influenza and antibiotic resistance patterns

New analyses will examine the link between antibiotic resistance patterns and seasonal influenza, which may help inform targeted antimicrobial stewardship initiatives during influenza season.

- Antibiotic Resistance Patterns, Seasonality, and Correlation with the Influenza Season in the United States: A Multicenter Evaluation. Oral presentation number 35.

- A Multicenter Analysis of Inpatient Antibiotic Use During the 2015-2019 Influenza Season in the US: Untapped Opportunities for Antimicrobial Stewardship. Poster presentation number 171.

These abstracts are currently available for meeting attendees viewing, and the full presentations (including audio and/or poster PDFs) will become available at the beginning of the data presentation session.

Editor's note:

About MenQuadfi
In the U.S., MenQuadfi vaccine is given to people 2 years of age and older to help prevent invasive meningococcal disease (including meningitis) caused by serogroups A, C, W, and Y of meningococcal bacteria. MenQuadfi does not prevent serogroup B disease.

MenQuadfi® is approved by The European Commission (EC) for the prevention of Invasive Meningococcal Disease in individuals 12 months of age and older and is currently under review by several health authorities across the world to help meet local immunization efforts.

About Nirsevimab
Nirsevimab is an investigational long-acting antibody designed to help protect all infants for the RSV season. Due to its extended half-life technology, nirsevimab is being investigated as a single dose for all infants experiencing their first RSV season and infants with congenital heart disease or chronic lung disease entering their first and second RSV season.

Nirsevimab is an immunization designed to provide prophylactic RSV protection to all infants via an antibody given directly to an infant to help prevent LRTI caused by RSV. Monoclonal antibodies do not require the activation of the immune system to help offer rapid and direct protection against disease.

In March 2017, Sanofi and AstraZeneca announced an agreement to develop and commercialize nirsevimab. Under the terms of the agreement, AstraZeneca leads all development and manufacturing activities, and Sanofi will lead commercialization activities and record revenues. Under the terms of the global agreement, Sanofi made an upfront payment of €120m, has paid a development milestone of €30m and will pay up to a further €465m upon achievement of certain development and sales-related milestones. The two companies share all costs and profits. Revenue from the agreement is reported as Collaboration Revenue in the Company's financial statements.

Nirsevimab has been granted breakthrough designation by four major regulatory agencies around the world. These include Breakthrough Therapy Designation by The China Center for Drug Evaluation under the National Medical Products Administration; Breakthrough Therapy Designation from the US Food and Drug Administration; access granted to the European Medicines Agency PRIority Medicines scheme; and Promising

Innovation Medicine designation by the Medicines and Healthcare Products Regulatory Agency. Nirsevimab is currently under clinical investigation and its safety and efficacy have not been reviewed by any regulatory authority.

About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

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Sanofi Forward-Looking Statements
This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the fact that product candidates if approved may not be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi's ability to benefit from external growth opportunities, to complete related transactions and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic and market conditions, cost containment initiatives and subsequent changes thereto, and the impact that COVID-19 will have on us, our customers, suppliers, vendors, and other business partners, and the financial condition of any one of them, as well as on our employees and on the global economy as a whole. Any material effect of COVID-19 on any of the foregoing could also adversely impact us. This situation is changing rapidly and additional impacts may arise of which we are not currently aware and may exacerbate other previously identified risks. The risks and uncertainties also include the uncertainties discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on

Form 20-F for the year ended December 31, 2020. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

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2. *Leader S, Kohlhase K. Recent trends in severe respiratory syncytial virus (RSV) among US infants, 1997 to 2000. J Pediatr. 2003; Nov; 143(5 Suppl):S127-S132. doi:10.1067/s0022-3476(03)00510-9. PMID: 14615711.*
3. *Arriola CS, Kim L, Langley G, Anderson EJ, Openo K, Martin AM, et al. Estimated Burden of Community-Onset Respiratory Syncytial Virus-Associated Hospitalizations Among Children Aged <2 Years in the United States, 2014-15. Journal of the Pediatric Infectious Diseases Society. 2020;9(5):587-95.*
4. *"Disease and Prevention Information." National Meningitis Association, https://www.nmaus.org/disease-prevention-information/.*
5. *"Meningococcal Disease." World Health Organization, World Health Organization, 24 June 2016, www.who.int/csr/disease/meningococcal/test/en/.*
6. *"Meningococcal Vaccination for Preteens and Teens: Information for Parents." Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, 26 July 2019, www.cdc.gov/vaccines/vpd/mening/public/adolescent-vaccine.html.*
7. *"Meningococcal – Clinical Information." Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, 31 May 2019, www.cdc.gov/meningococcal/clinical-info.html.*
8. *"National, Regional, State, and Selected Local Area Vaccination Coverage Among Adolescents Aged 13–17 Years — United States, 2019." Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, 22 Aug. 2019, https://www.cdc.gov/mmwr/volumes/69/wr/mm6933a1.htm.*
9. *MenQuadfi Prescribing Information. Swiftwater, PA: Sanofi Pasteur Inc.*