Press Release

sanofi

New Beyfortus data featured at IDWeek reinforce realworld effectiveness against RSV disease and hospitalization in infants

Paris, October 9, 2024. Sanofi advances its ambition to protect all infants from respiratory syncytial virus (RSV) disease with new Beyfortus (nirsevimab) data to be presented at the Infectious Disease Society of America's IDWeek 2024 annual meeting in Los Angeles, California, from October 16-19, 2024.

Thomas Triomphe

Executive Vice President, Vaccines, Sanofi

"The data featured at IDWeek from several national immunization programs will reinforce the proven efficacy and favorable safety profile of Beyfortus against RSV disease and hospitalization in infants. In just the first year of implementation, Beyfortus has demonstrated high real-world effectiveness consistently exceeding 80%. In addition, Beyfortus delivers this protection in the right dose for the right baby. We're proud to set a new standard with Beyfortus as the only approved and proven RSV protection for infants regardless of whether they are born before or during the RSV season, at term or preterm, healthy or with underlying conditions."

Beyfortus doses continue to be shipped to meet global commitments ahead of the 2024-2025 RSV season. A second manufacturing filling line has been approved by regulatory authorities in the US, Canada, and Europe and represents the majority of our supply for the 2024-2025 season. A third filling line, expected to provide additional doses for the 2024-2025 season, is approved by the European Medicines Agency and under review by the US Food and Drug Administration.

Beyfortus and RSV data at IDWeek 2024

- **Thursday, October 17, 12:15-1:30 pm PT:** RSV Prophylaxis with Nirsevimab in Infants: Systematic Review of Early Real-World Evidence on Effectiveness and Impact (Sanofi, presented by Oliver Martyn, MPH, Poster# P-631)
- **Thursday, October 17, 12:15-1:30 pm PT:** Implementation and Uptake of Nirsevimab within Nemours Children's Health Delaware Healthcare System (independent study by Nemours Children's Health Delaware, presented by Sara Mann, Poster# P-633)
- **Thursday, October 17, 1:15-2:00 pm PT** Preventing RSV Lower Respiratory Tract Disease in Infants: The First Year in Review (Sanofi, Learning Lounge event)
- **Thursday, October 17, 1:45-3:00 pm PT:** Universal Immunization Strategy Against Respiratory Syncytial Virus (RSV) Prevention in Chile with Nirsevimab during the 2024 Winter Season: First Southern Hemisphere Nationwide Effectiveness Data (independent study by University of Chile, presented by Juan Pablo Torres-Torretti, MD, PhD, during the Late Breaker Abstract Session: Respiratory Viruses Across All Ages, #169).
- **Friday, October 18, 12:15-1:30 pm PT:** Significant Reduction in Disease Burden and a Shift in Clinical Diagnoses in Children Hospitalized with Respiratory Syncytial Virus (RSV) after Nirsevimab Implementation in Catalonia (Spain) (independent study presented by Anna Creus-Costa, MD, Poster# P-1186)
- Friday, October 18, 12:15-1:30 pm PT: The burden of respiratory syncytial virus among Brazilian infants (BONSAI study): preliminary results (Sanofi, presented by Manoel Ribeiro, MD, PhD, Poster# P-1199)
- Saturday, October 19, 12:15-1:30 pm PT: Nirsevimab in Patient Samples Does Not Interfere with Respiratory Syncytial Virus (RSV) Detection by Commercially Available Rapid Antigen Tests (AstraZeneca, presented by Sarah R. Sincero, BSc, Poster# P-2179)

sanofi

About RSV

RSV is a highly contagious virus that can lead to serious respiratory illness for infants.¹ Two out of three infants are infected with RSV during their first year of life and almost all children are infected by their second birthday.^{1,2} RSV is the most common cause of lower respiratory tract disease, including bronchiolitis and pneumonia, in infants.³ It is also a leading cause of hospitalization in infants worldwide, with most hospitalizations for RSV occurring in healthy infants born at term.⁴⁻⁷ Globally, in 2019, there were approximately 33 million cases of acute lower respiratory infections leading to more than 3 million hospitalizations in children younger than 5 years.⁸ RSV-related direct medical costs, globally — including hospital, outpatient and follow-up care — were estimated at \in 4.82 billion in 2017.⁹

About Beyfortus

Beyfortus (nirsevimab) is the first immunization designed for all infants for protection against RSV disease through their first RSV season, including for those born healthy at term or preterm, or with specific health conditions. Beyfortus is also designed to protect children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.

As a long-acting antibody provided directly to newborns and infants as a single dose, Beyfortus offers rapid protection to help prevent lower respiratory tract disease caused by RSV without requiring activation of the immune system. Beyfortus administration can be timed to coincide with the RSV season.

Beyfortus has been approved for use in the European Union, the US, China, Japan, and many other countries around the world. Special designations to facilitate expedited development of Beyfortus were granted by several regulatory agencies, including Breakthrough Therapy Designation and Priority Review designation by The China Center for Drug Evaluation under the National Medical Products Administration; Breakthrough Therapy Designation and Fast Track Designation from the US Food and Drug Administration; access granted to the European Medicines Agency (EMA) PRIority MEdicines (PRIME) scheme and EMA accelerated assessment; Promising Innovative Medicine designation by the UK Medicines and Healthcare products Regulatory Agency; and Beyfortus has been named "a medicine for prioritized development" under the Project for Drug Selection to Promote New Drug Development in Pediatrics by the Japan Agency for Medical Research and Development.

About Sanofi

We are an innovative global healthcare company, driven by one purpose: we chase the miracles of science to improve people's lives. Our team, across the world, is dedicated to transforming the practice of medicine by working to turn the impossible into the possible. We provide potentially life-changing treatment options and life-saving vaccine protection to millions of people globally, while putting sustainability and social responsibility at the center of our ambitions.

Sanofi is listed on EURONEXT: SAN and NASDAQ: SNY

Media Relations

 Sandrine Guendoul | + 33 6 25 09 14 25 | sandrine.guendoul@sanofi.com

 Evan Berland | +1 215 432 0234 | evan.berland@sanofi.com

 Nicolas Obrist | + 33 6 77 21 27 55 | nicolas.obrist@sanofi.com

 Victor Rouault | + 33 6 70 93 71 40 | victor.rouault@sanofi.com

 Timothy Gilbert | + 1 516 521 2929 | timothy.gilbert@sanofi.com

Investor Relations

 Thomas Kudsk Larsen |+ 44 7545 513 693 | thomas.larsen@sanofi.com

 Alizé Kaisserian |+ 33 6 47 04 12 11 | alize.kaisserian@sanofi.com

 Arnaud Delépine |+ 33 6 73 69 36 93 | arnaud.delepine@sanofi.com

 Felix Lauscher |+ 1 908 612 7239 | felix.lauscher@sanofi.com

 Keita Browne |+ 1 781 249 1766 | keita.browne@sanofi.com

 Nathalie Pham |+ 33 7 85 93 30 17 | nathalie.pham@sanofi.com

 Tarik Elgoutni |+ 1 617 710 3587 | tarik.elgoutni@sanofi.com

sanofi

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 regarding the marketing and other potential of the product, or regarding potential future revenues from the product. 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, unexpected regulatory actions or delays, or government regulation generally, that could affect the availability or commercial potential of the product, the fact that product may not be commercially successful, the uncertainties inherent in research and development, including future clinical data and analysis of existing clinical data relating to the product, including post marketing, unexpected safety, quality or manufacturing issues, competition in general, risks associated with intellectual property and any related future litigation and the ultimate outcome of such litigation, and volatile economic and market conditions, and the impact that pandemics or other global crises may 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. 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, 2023. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

All trademarks mentioned in this press release are the property of the Sanofi group.

References:

- 1. U.S. Centers for Disease Control and Prevention. RSV in Infants and Young Children. https://www.cdc.gov/rsv/high-risk/infants-young-children.html. Accessed August 2023.
- Walsh EE. Respiratory Syncytial Virus Infection: An Illness for All Ages. Clinics in Chest Medicine. 2017;38(1):29-36. <u>https://doi.org/10.1016/j.ccm.2016.11.010</u>.
- 3. R K. Respiratory Syncytial Virus Vaccines. Plotkin SA, Orenstein WA, Offitt PA, Edwards KM, eds Plotkin's Vaccines 7th ed Philadelphia. 2018;7th ed. Philadelphia:943-9.
- 4. Leader S, Kohlhase K. Respiratory syncytial virus-coded pediatric hospitalizations, 1997 to 1999. *The Pediatric infectious disease journal.* 2002;21(7):629-32.
- 5. McLaurin KK, Farr AM, Wade SW, Diakun DR, Stewart DL. Respiratory syncytial virus hospitalization outcomes and costs of full-term and preterm infants. Journal of Perinatology: official journal of the California Perinatal Association. 2016;36(11):990-6.
- 6. Rha B, et al. Respiratory Syncytial Virus-Associated Hospitalizations Among Young Children: 2015-2016. *Pediatrics*. 2020;146:e20193611.
- 7. Arriola CS, et al. Estimated Burden of Community-Onset Respiratory Syncytial Virus-Associated Hospitalizations Among Children Aged <2 Years in the United States, 2014-15. *J Pediatric Infect Dis Soc.* 2020;9:587-595.
- 8. Li Y, et al. Global, regional, and national disease burden estimates of acute lower respiratory infections due to respiratory syncytial virus in children younger than 5 years in 2019: a systematic analysis. *Lancet.* 2022;399:92047–64.
- 9. Zhang S, et al. Cost of Respiratory Syncytial Virus-Associated Acute Lower Respiratory Infection Management in Young Children at the Regional and Global Level: A Systematic Review and Meta-Analysis. *J Infect Dis.* 2020;222(Suppl 7):S680-687.