

U.S. CDC Advisory Committee unanimously recommends routine use of Beyfortus™ (nirsevimab-alip) to protect infants against RSV disease

- * Recommendation for use in all infants below 8 months of age follows earlier than anticipated FDA approval and unanimous FDA Advisory Committee vote
- * Committee also voted unanimously to include *Beyfortus* in the Vaccines for Children program, supporting equitable access for all eligible infants
- * *Beyfortus*™ is the first RSV prevention approved to protect all infants in the U.S. through their first RSV season and will be available ahead of the 2023-2024 RSV season

Paris, August 3, 2023. The U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) voted unanimously 10 to 0 to recommend routine use of Sanofi and AstraZeneca's *Beyfortus*™ (nirsevimab-alip) for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease for newborns and infants below 8 months of age born during or entering their first RSV season.

The Committee also voted unanimously 10 to 0 to recommend routine use of *Beyfortus* for children aged 8 to 19 months who are at increased risk of severe RSV disease and entering their second RSV season.

Additionally, the ACIP voted unanimously 11 to 0 to include *Beyfortus* in the Vaccines for Children (VFC) program. *Beyfortus* will be available in the U.S. ahead of the upcoming 2023-2024 RSV season.

Thomas Triomphe

Executive Vice President, Vaccines, Sanofi

"Today, we have turned the corner on the threat of RSV to our youngest, most vulnerable population. The ACIP's unanimous recommendations for routine use of Beyfortus and inclusion in the Vaccines for Children program are critical steps toward providing millions of parents in the U.S. with the ability to protect their babies through their first RSV season, when they are most susceptible to severe RSV disease. We appreciate the FDA and CDC leadership, as well as the ACIP public health experts, for recognizing and quickly acting on the threat RSV poses to all infants."

Dr Regena Spratling, PhD, RN, APRN, CPNP-PC, FAANP, FAAN

President, National Association of Pediatric Nurse Practitioners

"As front-line providers managing the physical and emotional toll of RSV on our patients and their families, especially during the surges of the last two years, our community of pediatric-focused nurse practitioners welcomes the recent approval of nirsevimab. Today's ACIP vote to include nirsevimab in routine immunization schedules, along with continued efforts to educate the public about the impact of RSV prevention, will help ensure equitable access to this immunization and help alleviate the strain RSV disease places on babies, families, and health care systems."

The provisional ACIP recommendations will be forwarded to the director of the CDC and the U.S. Department of Health and Human Services for review and approval. The official recommendations will be published in the CDC's *Morbidity and Mortality Weekly Report (MMWR)*. Once approved, routine use of *Beyfortus* would be included in the CDC's Child and Adolescent Immunization Schedule.

About the U.S. ACIP and CDC recommendations

The ACIP is a body of independent health experts that advises the CDC and the nation on the types of populations and circumstances for which immunizations should be used. The CDC

reviews advice from the ACIP and publishes final recommendations in the *MMWR*. The Affordable Care Act (ACA) generally requires coverage for all immunizations administered in accordance with final CDC recommendations. This requirement applies to all non-grandfathered commercial plans and Medicaid expansion beneficiaries. Individuals, or their healthcare providers, should contact their health insurance plan to determine coverage and reimbursement requirements as well as adoption timeframes. The Vaccines for Children (VFC) program helps provide immunizations to children whose parents or guardians may not be able to afford them. This helps ensure that all children have a better chance of getting their recommended immunizations on schedule.

About RSV

RSV is a very contagious virus that can lead to serious respiratory illness for infants, according to the Centers for Disease Control and Prevention (CDC). RSV symptoms can include runny nose, coughing, sneezing, fever, decrease in appetite, and wheezing.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} In the U.S., RSV is the leading cause of hospitalization in infants under 12 months, averaging 16 times higher than the annual rate for influenza.^{3,4} Approximately 75% of infants hospitalized for RSV are born healthy and at term with no underlying conditions.⁵ Each year in the U.S., an estimated 590,000 RSV disease cases in infants under one require medical care, including physician office, urgent care, emergency room visits and hospitalizations.⁶

About Beyfortus

In the U.S., *Beyfortus* is the first RSV prevention approved to protect all infants through their first RSV season, including for those born healthy at term or preterm, or with specific health conditions that make them vulnerable to RSV disease. *Beyfortus* is also approved for 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.⁷ *Beyfortus* administration can be timed to the start of the RSV season.

Beyfortus was granted Breakthrough Therapy and Fast-Track designations and was [approved](#) by the FDA on July 17, 2023 following the [positive recommendation](#) of the FDA Antimicrobial Drugs Advisory Committee. The approval was based on the extensive *Beyfortus* clinical development program spanning three pivotal late-stage clinical trials. Across all clinical endpoints, a single dose of *Beyfortus* delivered high, consistent and sustained efficacy against RSV lower respiratory tract disease extending through five months, a typical RSV season.

In [March 2017](#), Sanofi and AstraZeneca announced an agreement to develop and commercialize *Beyfortus*. Under the terms of the agreement, AstraZeneca leads development and manufacturing activities and Sanofi leads commercialization activities and records revenues. Under the terms of the global agreement, Sanofi made an upfront payment of €120m, has paid development and regulatory milestones of €120m and will pay up to a further €375m upon achievement of certain regulatory and sales-related milestones. The two companies share costs and profits in all territories except in the U.S. where Sanofi consolidates 100% of the economic benefits in its Business Operating Income.

Beyfortus has been granted special designations to facilitate expedited development by several regulatory agencies around the world. These include 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 U.S. 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 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.

Beyfortus has been granted marketing authorization in the European Union, Great Britain and Canada for the prevention of RSV lower respiratory tract disease in newborns and infants from birth through their first RSV season and is currently undergoing regulatory review in China, Japan and several other countries. In Canada, nirsevimab is also approved for children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season and such indication is under review at the EMA level.

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 some 100 countries, 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

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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 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, 2022. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

References

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