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Press Release

New nirsevimab data analyses reinforce efficacy against RSV

- A prespecified pooled analysis of Phase 3 and Phase 2b data demonstrated an efficacy of 79.5% against medically attended lower respiratory tract infections (LRTI), including hospitalizations, caused by respiratory syncytial virus (RSV)[1]
- Nirsevimab is the first investigational immunization designed to protect all infants across the RSV season with a single dose
- Two analyses are being presented at the European Society for Paediatric Infectious Diseases meeting[1,2]

Paris, May 11, 2022. Results from a prespecified pooled analysis of the pivotal Phase 3 MELODY and Phase 2b nirsevimab trials demonstrated an efficacy (relative risk reduction versus placebo) of 79.5% (95% CI 65.9 to 87.7; P<0.0001) against medically attended LRTI, such as bronchiolitis or pneumonia, caused by RSV in infants born at term or preterm entering their first RSV season.[1]

In a separate pooled post-hoc analysis of the trials, blood samples taken from infants dosed with nirsevimab exhibited RSV neutralizing antibodies that were approximately 50-fold higher than baseline at Day 151 post-dose. RSV neutralizing antibody levels remained greater than 19-fold higher than placebo recipients with no known RSV infection through Day 361, suggesting protection may extend beyond Day 151.[2]

The safety profile across the nirsevimab and placebo groups, as reported in previous trials, remains similar.[3-6] These findings contribute to the growing body of evidence suggesting that nirsevimab can protect all infants through their first RSV season with a single dose.[1-7]

Eric Simões, MD
Clinical Professor, Pediatrics-Infectious Diseases, UC Denver School of Medicine
"RSV remains the most common cause of LRTI in infants and results in seasonal epidemics globally each year. These new analyses strengthen nirsevimab's potential to protect all infants across the RSV season with a single dose, which may lead to a paradigm shift in RSV prevention."

Jean-François Toussaint
Global Head of Research and Development Vaccines, Sanofi
"These new analyses are very consistent with and confirm the strong results observed in all Phase 2 and Phase 3 studies that evaluated nirsevimab in diverse pediatric populations. We take pride in the progress made to develop a potential solution to address this long unmet need for all infants."

Mene Pangalos
Executive Vice President, BioPharmaceuticals R&D, AstraZeneca
"Each year, RSV causes seasonal epidemics of LRTIs in infants. These analyses add to nirsevimab's compelling body of evidence as the first potential single-dose preventative immunization for all infants against RSV, addressing a clear unmet need in the RSV preventative landscape."

The data are being presented at the 40th Annual Meeting of the European Society for Paediatric Infectious Diseases (ESPID) from May 9-13 in Athens, Greece.

Nirsevimab is being developed by Sanofi and AstraZeneca.

About nirsevimab

Nirsevimab is an investigational long-acting antibody designed to protect all infants from birth entering their first RSV season with a single dose. Due to its extended half-life technology, nirsevimab is being developed as a single dose for protection of all infants through their first RSV season.[5,6,8]

Nirsevimab is an immunization designed to provide direct RSV protection to all infants via an antibody 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.[9]

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 regulatory designations to facilitate expedited development by several 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 (EMA) PRIority MEdicines scheme; Promising Innovative Medicine designation by the UK Medicines and Healthcare products Regulatory Agency; and 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 (AMED). The safety and efficacy of nirsevimab is currently being evaluated under an accelerated assessment procedure by the EMA. Nirsevimab has not been approved by any regulatory authority.

About the pivotal nirsevimab clinical trials

The Phase 2b trial was a randomized, placebo-controlled trial designed to measure the efficacy of nirsevimab against medically attended LRTI through 150 days post-dose. Healthy preterm infants of 29–35 weeks' gestation were randomized (2:1) to receive a single 50mg intramuscular injection of nirsevimab or placebo. Between November 2016 and December 2017, 1,453 infants were randomized (nirsevimab, n=969; placebo, n=484) at the RSV season start. Research was conducted in both hemispheres, at 164 sites in 23 countries.[6] Data was published in the *New England Journal of Medicine* (*NEJM)* in July 2020. The dosing regimen was optimized based on further exploration of this data. The subsquent Phase 3 study MELODY applied the optimized dosing regimen.[1,5]

The Phase 3 MELODY trial was a randomized, placebo-controlled trial conducted across 21 countries designed to determine efficacy of nirsevimab against medically attended LRTI due to RSV confirmed by reverse transcriptase polymerase chain reaction testing through 150 days after dosing, versus placebo, in healthy late preterm and term infants (35 weeks gestational age or greater) entering their first RSV season.[5] Infants were randomized (2:1) to receive a single 50mg (in infants weighing <5kg) or 100mg (in infants weighing ≥5kg) intramuscular injection of nirsevimab or placebo. Between July 2019 and March 2020, 1,490 infants were randomized to either nirsevimab or placebo at the RSV season start.[3] Data was published on the primary analysis in *NEJM* in March 2022.

The prespecified pooled analyses of the Phase 3 and the Phase 2b trials looked at infants receiving the optimized dosing regimen (infants <5 kg at dosing and receiving the 50 mg dose from Phase 2b and the infants from Phase 3), and demonstrated an efficacy of 79.5% (95% CI

65.9 to 87.7, P<0.0001) against medically attended LRTI and 77.3% (95% CI 50.3, 89.7, P<0.001) against RSV LRTI hospitalizations. The analysis was based on 2,350 infants of which 1,564 infants were randomized to receive nirsevimab and 786 infants were randomized to receive placebo.[1]

The results of MELODY, Phase 2/3 MEDLEY and the Phase 2b trials demonstrate that nirsevimab provides protection against RSV in all infants entering their first RSV season with a single dose.[1-5] This all-infant population includes preterm, healthy late preterm and term infants, as well as infants with specific conditions.

These trials form the basis of regulatory submissions that began in 2022.

About RSV

RSV is the most common cause of lower respiratory tract infections (LRTI), including bronchiolitis and pneumonia in infants.[10] It is also a leading cause of hospitalization in all infants, with most hospitalizations for RSV occurring in healthy infants born at term.[11-14] Globally, in 2015, there were approximately 30 million cases of acute lower respiratory infections leading to more than three million hospitalizations, and it was estimated that there were 60,000 in-hospital deaths of children younger than five years.[15,16] In recent months, there has been a resurgence of RSV following the easing of COVID-19 public health measures.[17,18] Globally, in 2017, RSV-related direct medical costs—including hospital, outpatient and follow-up care—were estimated at €4.82 billion.[19]

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

Media Relations

Sandrine Guendoul | + 33 6 25 09 14 25 | sandrine.guendoul@sanofi.com
Sally Bain | + 1 617 834 6026 | sally.bain@sanofi.com
Nicolas Obrist | + 33 6 77 21 27 55 | nicolas.obrist@sanofi.com
Kate Conway | + 1 508 364 4931 | kate.conway@sanofi.com

Investor Relations

Eva Schaefer-Jansen | + 33 7 86 80 56 39 | eva.schaefer-jansen@sanofi.com
Arnaud Delépine | + 33 6 73 69 36 93 | arnaud.delepine@sanofi.com
Corentine Driancourt | + 33 6 40 56 92 21 | corentine.driancourt@sanofi.com
Felix Lauscher | + 1 908 612 7239 | felix.lauscher@sanofi.com
Priya Nanduri | +1 908 981 5560 | priya.nanduri@sanofi.com
Nathalie Pham | + 33 7 85 93 30 17 | nathalie.pham@sanofi.com

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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, 2021. 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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