

Nirsevimab reduced respiratory syncytial virus infections requiring medical care in healthy premature infants in Phase 2b trial

- * Nirsevimab reduced respiratory syncytial virus (RSV) lower respiratory tract infections by 70 percent and related hospitalizations by 78 percent¹
- * Results published in *New England Journal of Medicine*
- * The investigative immunization demonstrated sustained protection across a typical five-month RSV season with a single dose¹
- * Sanofi will host a nirsevimab R&D investor event today at 5 p.m. CET/11 a.m. ET

PARIS – July 30, 2020 – Detailed results from the positive Phase 2b trial for nirsevimab showed a significant reduction in medically attended lower respiratory tract infections (LRTI), mainly bronchiolitis and pneumonia, and hospitalizations caused by respiratory syncytial virus (RSV) in healthy preterm infants.

Published in the *New England Journal of Medicine*, results from this trial demonstrate for the first time that a single dose monoclonal antibody can significantly reduce medically attended RSV LRTI in infants through the full RSV season.¹

“The data for nirsevimab are exciting, as they highlight the potential for this innovative approach to protect infants from RSV with just one injection for the entire season,” said Dr. Joseph Domachowske, study author, Professor of Pediatrics, Professor of Microbiology and Immunology, and Director of the Global Maternal-Child and Pediatric Health Program at the SUNY Upstate Medical University. *“Nirsevimab offers the important potential to reduce hospitalizations and emergency department and in-office visits, which are a significant burden for healthcare systems.”*

Nirsevimab is an extended half-life RSV monoclonal antibody (mAb), being developed in partnership with AstraZeneca as a passive immunization, meaning a protective antibody is administered directly to an infant to help prevent RSV. Nirsevimab could set a new standard of care by offering an innovative immunization for immediate and sustained protection for all infants during their first RSV season, when they are most at risk for infection or complication. Ninety percent of all babies will be infected with RSV before the age of two.²

Phase 2b trial met primary and secondary endpoints

On the primary endpoint, nirsevimab achieved a statistically significant 70.1% (95% CI: 52.3%-81.2%) reduction of medically attended RSV LRTI compared to placebo through

150 days post-dose. On the secondary endpoint, nirsevimab achieved a 78.4% (95% CI: 51.9%-90.3%) relative reduction in the incidence of hospitalizations due to RSV LRTI compared to placebo through 150 days post-dose. The safety profile for nirsevimab was similar to placebo, with no significant hypersensitivity reactions observed.¹

“It’s encouraging to see from these data that serious complications from RSV can be reduced in healthy preterm infants,” said John Shiver, Senior Vice President, Global Research and Development, Sanofi Pasteur. *“Up to 80 percent of babies who are hospitalized from RSV are otherwise healthy with no prior complications, but currently these infants have no approved preventative option to protect them.”*

A nirsevimab R&D investor event will be held today at 5 p.m. CET/11 a.m. ET. Sanofi speakers include:

- Thomas Triomphe, Global Head of Sanofi Pasteur
- Su-Peung Ng, Global Head of Medical, Sanofi Pasteur
- Jon Heinrichs, Global Project Head, nirsevimab, Sanofi Pasteur
- John Shiver, Global Head of Research & Development, Sanofi Pasteur

Joining for the the Q&A session:

- Paul Hudson, Chief Executive Officer
- John Reed, Global Head of Research & Development
- Jean-Baptiste de Chatillon, Chief Financial Officer

Additional information about today’s session can be found at:

<https://www.sanofi.com/en/investors/financial-results-and-events/investor-presentations/nirsevimab-presentation>

About RSV

RSV, a common, contagious virus that infects the respiratory tract,³ is the most common cause of bronchiolitis and pneumonia and results in millions of hospitalizations globally⁴ in children younger than one year in the United States.⁵ Globally, in 2015, there were approximately 33 million cases of acute lower respiratory infections causing more than three million hospitalizations, and it was estimated that there were 60,000 in-hospital deaths of children younger than five years.⁴ Up to 80 percent of babies who are hospitalized due to RSV are otherwise healthy.^{6,7} Moreover, medically-attended LRTIs are associated with increased costs to the healthcare system.⁸

Nirsevimab Clinical Trials

The Phase 2b study was conducted by AstraZeneca at 164 sites in 23 countries. Healthy preterm infants of 29–35 weeks’ gestation were randomized (2:1) to receive a single intramuscular injection of nirsevimab or placebo. Between November 2016 and December 2017, 1447 infants were dosed (nirsevimab, n=966; placebo, n=481) at the RSV season start.¹

In July 2019, Sanofi and AstraZeneca initiated pivotal Phase 3 and Phase 2/3 trials to measure the safety and efficacy of nirsevimab to prevent LRTI caused by RSV in full-term,

healthy late preterm and high-risk babies.^{9,10} The trials will be conducted in more than 350 sites across Northern and Southern Hemispheres.

The full results of the Phase 3 and Phase 2/3 trials are anticipated in 2023.

About Nirsevimab

Nirsevimab is an extended half-life RSV mAb being developed for the prevention of LRTI caused by RSV for use in all infants experiencing their first RSV season and for children with congenital heart disease or chronic lung disease entering their first and second RSV season.^{9,3}

Nirsevimab is a passive immunization, whereby an antibody is given directly to an infant to help prevent RSV, unlike active immunization, in which a person's immune system is activated to prevent or fight infection.¹¹ Passive immunization could offer immediate protection.

In March 2017, AstraZeneca and Sanofi Pasteur announced an [agreement](#) to develop and commercialize nirsevimab jointly. Under the terms of the agreement, AstraZeneca leads all development activity through initial approvals and retains manufacturing activities and Sanofi Pasteur will lead commercialization activities. In February 2019, AstraZeneca and Sanofi Pasteur's nirsevimab [received Breakthrough Therapy Designation](#) from the US Food and Drug Administration and were [granted access to the PRiority MEDicines \(PRIME\) scheme](#) by the European Medicines Agency

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.

Sanofi, Empowering Life

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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, 2019. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

¹ Clinicaltrials.gov. A Study to Evaluate the Safety and Efficacy of MEDI8897 for the Prevention of Medically Attended RSV LRTI in Healthy Preterm Infants. (MEDI8897 Ph2b). <https://clinicaltrials.gov/ct2/show/results/NCT02878330>. Accessed July 2020.

² Adamko DJ, Friesen M. Why does respiratory syncytial virus appear to cause asthma? *Journal of Allergy and Clinical Immunology*. 2012;130(1):101-102. doi:10.1016/j.jaci.2012.05.024.

³ Centers for Disease Control and Prevention. RSV in Infants and Young Children. <https://www.cdc.gov/rsv/high-risk/infants-young-children.html>. Accessed July 2020.

⁴ Shi T, et al. Global, regional, and national disease burden estimates of acute lower respiratory infections due to respiratory syncytial virus in young children in 2015: a systematic review and modelling study. *Lancet* 2017; 390: 946–58.

⁵ Plotkin's Vaccines (Seventh Edition), Elsevier, 2018, Pages 943-949; IASR Vol. 39 p207-209: December, 2018 (<https://www.niid.go.jp/niid/en/865-iasr/8491-466te.html>)

⁶ Hall CB, et al. "The Burden of Respiratory Syncytial Virus Infection in Young Children," *New England Journal of Medicine*. 2009; 360(6):588-98.

⁷ Arriola, C, 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*. 2019.

⁸ Leistner R, et al. "Attributable Costs of Ventilator-Associated Lower Respiratory Tract Infection (LRTI) Acquired on Intensive Care Units: a Retrospectively Matched Cohort Study." *Antimicrobial Resistance and Infection Control*, vol. 2, no. 1, 4 Apr. 2013, p. 13., doi:10.1186/2047-2994-2-13

⁹ Clinicaltrials.gov. A Study to Evaluate the Safety and Efficacy of MEDI8897 for the Prevention of Medically Attended RSV LRTI in Healthy Late Preterm and Term Infants (MELODY). <https://clinicaltrials.gov/ct2/show/NCT03979313>. Accessed July 2020.

¹⁰ Clinicaltrials.gov. A Study to Evaluate the Safety of MEDI8897 for the Prevention of Medically Attended Respiratory Syncytial Virus (RSV) Lower Respiratory Track Infection (LRTI) in High-risk Children. <https://clinicaltrials.gov/ct2/show/NCT03959488>. Accessed July 2020.

¹¹ Vaccines & Immunizations." Centers for Disease Control and Prevention. August 18, 2017. Accessed July 2020. <https://www.cdc.gov/vaccines/vac-gen/immunity-types.htm>.