

### *Nirsevimab EMA regulatory submission accepted under accelerated assessment for RSV protection in all infants*

- \* Nirsevimab is the first investigational long-acting antibody designed to protect all infants for the respiratory syncytial virus (RSV) season with a single dose
- \* European regulatory decision could come as early as second half of 2022
- \* If approved, nirsevimab will be the first immunization of its kind aiming to provide RSV protection in all infants

**Paris, February 17, 2022.** The European Medicines Agency (EMA) has accepted the Marketing Authorization Application (MAA) for nirsevimab under an accelerated assessment procedure. Nirsevimab, the first investigational long-acting antibody designed to protect all infants against medically attended lower respiratory tract infections (LRTI) for the respiratory syncytial virus (RSV) season, is being developed by Sanofi and AstraZeneca.

Nirsevimab is being investigated as a single dose for all infants experiencing their first RSV season. The EMA's Committee for Medicinal Products for Human Use (CHMP) granted nirsevimab accelerated assessment as it was deemed of major interest for public health and therapeutic innovation. [Accelerated assessment](#) aims to reduce the timeframe for the CHMP to review a MAA compared to the standard procedure and follows the EMA granting access to the [PRiority Medicines \(PRIME\) scheme](#) in 2019.

#### ***Jean-François Toussaint***

Global Head of Research and Development Vaccines, Sanofi

*“RSV is a leading cause of hospitalization in all infants, and recent spikes in bronchiolitis and hospitalizations caused by RSV infection around the globe further demonstrate the need for a preventative option that can help protect all infants. We are pleased to receive this regulatory filing acceptance and remain confident in nirsevimab’s potential to change the current RSV prevention paradigm as a possible single dose option that may offer sustained protection to all infants for the season.”*

The MAA is based on positive results from the [Phase 3 MELODY trial](#), [Phase 2/3 MEDLEY trial](#), and [Phase 2b trial](#) which demonstrated nirsevimab’s efficacy against LRTI due to RSV with a single dose for the RSV season and was well tolerated.

Data from the MELODY and MEDLEY trials will be published in an upcoming peer-reviewed journal.

#### ***Mene Pangalos***

Executive Vice President, BioPharmaceuticals R&D, AstraZeneca

*“Each year, respiratory syncytial virus causes seasonal epidemics of lower respiratory tract infections in infants and preventative options are currently limited to infants at higher risk. We are excited that the EMA has accepted this regulatory submission under an accelerated assessment procedure, as nirsevimab has the potential to be the first immunization to offer protection for all infants against respiratory syncytial viruses as shown by the extensive clinical trial program.”*

Additional global regulatory submissions are planned in 2022.

## **About RSV**

RSV is a common, contagious virus that causes seasonal epidemics of lower respiratory tract infections (LRTI), and is the leading cause of lower respiratory tract infection, such as bronchiolitis and pneumonia, in infants.<sup>1-4</sup> It is also a leading cause of hospitalizations in all infants.<sup>5,6</sup> 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.<sup>3,7</sup> In recent months, there has been a resurgence of RSV following the easing of COVID-19 public health measures.<sup>8,9</sup> Most hospitalizations for RSV occur in otherwise healthy infants born at term.<sup>10,11</sup> Medically attended LRTIs are associated with increased costs to the healthcare system.<sup>12</sup>

## **About nirsevimab**

Nirsevimab is an investigational long-acting antibody designed to protect all infants for the RSV season with a single dose. Due to its extended half-life technology, nirsevimab is being developed as a single dose for all infants experiencing their first RSV season and infants with specific conditions, such as congenital heart disease or chronic lung disease, entering their first and second RSV season.<sup>13-15</sup>

Nirsevimab is an immunization designed to provide direct prophylactic 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.<sup>16</sup>

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 [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). Nirsevimab is currently under clinical investigation and its safety and efficacy have not been reviewed by any regulatory authority.

## *[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](mailto:sandrine.guendoul@sanofi.com)

**Sally Bain** | + 1 617 834 6026 | [sally.bain@sanofi.com](mailto:sally.bain@sanofi.com)

**Chrystel Baude** | + 33 6 70 98 70 59 | [chrystel.baude@sanofi.com](mailto:chrystel.baude@sanofi.com)

**Nicolas Obrist** | + 33 6 77 21 27 55 | [nicolas.obrist@sanofi.com](mailto:nicolas.obrist@sanofi.com)

**Victor Rouault** | + 33 6 70 93 71 40 | [victor.rouault@sanofi.com](mailto:victor.rouault@sanofi.com)

**Lisa Zobel** | + 1 908 967 4605 | [lisa.zobel@sanofi.com](mailto:lisa.zobel@sanofi.com)

### Investor Relations

**Eva Schaefer-Jansen** | + 33 7 86 80 56 39 | [eva.schaefer-jansen@sanofi.com](mailto:eva.schaefer-jansen@sanofi.com)

**Arnaud Delépine** | + 33 6 73 69 36 93 | [arnaud.delepine@sanofi.com](mailto:arnaud.delepine@sanofi.com)

**Corentine Driancourt** | + 33 6 40 56 92 21 | [corentine.driancourt@sanofi.com](mailto:corentine.driancourt@sanofi.com)

**Felix Lauscher** | + 1 908 612 7239 | [felix.lauscher@sanofi.com](mailto:felix.lauscher@sanofi.com)

**Priya Nanduri** | [priya.nanduri@sanofi.com](mailto:priya.nanduri@sanofi.com)

**Nathalie Pham** | + 33 7 85 93 30 17 | [nathalie.pham@sanofi.com](mailto:nathalie.pham@sanofi.com)

---

### 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.

1. Piedimonte G, Perez MK. Respiratory syncytial virus infection and bronchiolitis. *Pediatr Rev.* 2014;35:519-53.
2. Oymar K, et al. Acute bronchiolitis in infants, a review. *Scand J Trauma Resusc Emerg Med.* 2014;22:23.
3. 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.
4. 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.
5. Leader S, Kohlhase K. Respiratory syncytial virus-coded pediatric hospitalizations, 1997 to 1999. *The Pediatric infectious disease journal.* 2002;21(7):629-32.
6. 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
7. Oxford Vaccines Group. What is RSV? <https://vk.ovg.ox.ac.uk/vk/rsv>. Accessed January 2022.
8. Ujiie M, Tsuzuki S, Nakamoto T, et al. Resurgence of Respiratory Syncytial Virus Infections during COVID-19 Pandemic, Tokyo, Japan. *Emerging Infectious Diseases.* 2021;27(11):2969-2970. doi:10.3201/eid2711.211565.
9. CDC Health Alert Network. Increased Interseasonal Respiratory Syncytial Virus (RSV) Activity in Parts of the Southern United States. Centers for Disease Control and Prevention. June 10 2021. <https://emergency.cdc.gov/han/2021/han00443.asp> Accessed: February 2022

10. Rha B et al. Respiratory Syncytial Virus–Associated Hospitalizations Among Young Children: 2015–2016. *Pediatrics*. 2020;146(1):e20193611.
11. 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.
12. 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
13. *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 February 2022.
14. *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 February 2022.
15. Zhu Q, et al. A highly potent extended half-life antibody as a potential RSV vaccine surrogate for all infants. *Sci Transl Med*. 2017;9:pil: eaaj1928
16. Centers for Disease Control and Prevention. Vaccines & Immunizations. August 18, 2017. <https://www.cdc.gov/vaccines/vac-gen/immunity-types.htm>. Accessed February 2022.