# Nirsevimab delivers 83% reduction in RSV infant hospitalizations in a real-world clinical trial setting

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- HARMONIE Phase 3b data reinforce nirsevimab's consistent and high efficacy against infant hospitalizations due to RSV

- Data presented at ESPID add to the body of evidence demonstrating nirsevimab's protection against RSV-related lower respiratory tract disease (LRTD) and confirm its favorable safety profile in multi-country, real-world conditions

Paris, May 12, 2023. New data from the HARMONIE Phase 3b clinical trial show an 83.21% (95% CI 67.77 to 92.04; P<0.001) reduction in hospitalizations due to RSV-related LRTD in infants under 12 months of age who received a single dose of nirsevimab, compared to infants who received no RSV intervention.1

The Hospitalized RSV Monoclonal Antibody Prevention (HARMONIE) study is a large, multi-country European interventional clinical trial aiming to determine the efficacy and safety of a single intramuscular dose of nirsevimab, with data collected in a real-world setting during the 2022-2023 RSV season.1 The trial recruited more than 8,000 infants and took place at nearly 250 sites across France, Germany and the United Kingdom. The data from HARMONIE were presented at the 41st Annual Meeting of the European Society for Paediatric Infectious Diseases (ESPID).

Executive Vice President, Vaccines, Sanofi

> This winter saw higher rates of RSV-related infant hospitalizations than during pandemic or pre-pandemic years. The HARMONIE data demonstrate the real-world impact nirsevimab has on pediatric hospitalizations, and illustrate its importance for infants, their families and public health.

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> RSV-related chest infections lead to high numbers of infants under 12 months old being hospitalized every year. These data reinforce the potential public health benefit of nirsevimab in terms of helping to reduce the strain on hospitals caused each year by RSV.

The data from HARMONIE also show that nirsevimab reduced the incidence of hospitalizations due to severe RSV-related LRTD (patients whose oxygen level is under 90% and require oxygen supplementation) by 75.71% (95% CI 32.75 to 92.91; P<0.001).1

Additionally, nirsevimab demonstrated a reduction of 58.04% (95% CI 39.69 to 71.19; P<0.001) in the incidence of all-cause LRTD hospitalization compared to infants who received no RSV intervention.1 This means the overall burden on healthcare systems could be reduced significantly if all infants receive nirsevimab. RSV-related direct medical costs, globally — including hospital, outpatient and follow-up care — were estimated at €4.82 billion in 2017.2

Throughout HARMONIE, nirsevimab maintained a favorable safety profile, consistent with the pivotal trial results.

RSV is the most common cause of LRTD, including bronchiolitis and pneumonia, in infants.5-8 It is also a leading cause of hospitalization in all infants, with most hospitalizations for RSV occurring in healthy infants born at term.9-12 Globally, in 2019, there were approximately 33 million cases of acute lower respiratory infections leading to more than three million hospitalizations, and it was estimated that there were 26,300 in-hospital deaths of children younger than five years.12

The Hospitalized RSV Monoclonal Antibody Prevention (HARMONIE) study is a large European interventional clinical trial aiming to determine the efficacy and safety of a single intramuscular (IM) dose of nirsevimab (<5 kg 50 mg; ≥5 kg 100 mg), compared to no intervention (standard of care), for the prevention of hospitalizations due to RSV-related LRTD in infants under 12 months of age who are not eligible to receive palivizumab.

Sanofi and academic investigators worked together to design and deliver HARMONIE with digital solutions to minimize the burden on families, site staff and health systems. The trial opened at nearly 250 sites, supported by National Institute of Health Research infrastructure (UK), the PEDSTART network (France) and NETSTAP e.V. (Germany) and has recruited over 8000 infants.13 The primary efficacy data for HARMONIE were collected during the 2022-2023 RSV season.1 Participant follow-up will conclude at 12 months.

Nirsevimab, a long-acting antibody designed for all infants for protection against RSV disease from birth through their first RSV season with a single dose, is being developed jointly by Sanofi and AstraZeneca. Nirsevimab has been developed to offer newborns and infants direct RSV protection via an antibody to help prevent medically attended lower respiratory tract infections caused by RSV. Monoclonal antibodies do not require the activation of the immune system to help offer timely, rapid and direct protection against the disease.14

Nirsevimab has been granted special 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 U.S. Food and Drug Administration; access granted to the European Medicines Agency (EMA) PRIority MEdicines (PRIME) scheme; Promising Innovative Medicine designation by the UK Medicines and Healthcare products Regulatory Agency;15 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 (AMED). The safety and efficacy of nirsevimab was evaluated under an accelerated assessment procedure by the EMA.

Nirsevimab has been granted marketing authorization in the European Union, the United Kingdom 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 the U.S. In Canada, Beyfortus is also approved for children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.

In March 2017, Sanofi and AstraZeneca announced an agreement to develop and commercialize nirsevimab. Under the terms of the agreement, AstraZeneca leads development and manufacturing activities, and Sanofi leads commercialization activities and record revenues. Under the terms of the global agreement, Sanofi made an upfront payment of €120m, has paid development and regulatory milestones of €55m and will pay up to a further €440m upon achievement of certain regulatory and sales-related milestones. The two companies share costs and profits in all territories except in the US where Sanofi consolidate 100% of the economic benefits in its Business Operating Income.

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