Nirsevimab real-world evidence: effectiveness, public health impact and safety from 2 years of post-marketing experience

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Poster #P300

INTRODUCTION / BACKGROUND

- Nirsevimab is a long-acting monoclonal antibody (mAb) developed to provide **rapid and durable protection** through direct passive immunization against respiratory syncytial virus (RSV) lower respiratory tract disease (LRTD) for all infants.[1,2]
- **Extensive post-marketing experience accumulated** globally since nirsevimab's first approval in late 2022 and first launch in 2023 provides **robust evidence on nirsevimab's effectiveness, impact, and safety in real-world settings**.
- **Patient safety is of utmost importance** and is closely monitored across the entire product lifecycle, from clinical development through post-marketing.
- The **benefits of nirsevimab have been confirmed through real-world evidence**, showing significant reduction in RSV LRTD in infants.
- The safety of nirsevimab **continues to be closely monitored** with increasing use. Real-world experience can help to identify any potential new or rare unexpected risks. Spontaneous cases evaluation is one of the tools to assess safety and detect any emerging safety issues for proactive mitigation. Despite limitations, passive surveillance is likely to identify events and safety concerns at the population level.[3–5]

OBJECTIVE

To provide a comprehensive overview of the real-world experience with nirsevimab over two complete RSV seasons.

METHODS

- This analysis incorporated multiple sources of data, including literature review of published real-world data on nirsevimab and post-marketing safety data from Sanofi's global safety database from October 30, 2022 through August 31, 2025.
- MedDRA (Medical Dictionary for Regulatory Activities) version 28.0 was used for coding of adverse events (AEs).
- Predefined safety outcomes were determined and closely monitored based on experience with other mAbs (e.g., palivizumab; hypersensitivity, seizures, thrombocytopenia), known risks in this vulnerable population (e.g., apnea), and potential risks in pediatric populations following active immunization (e.g., hypotonic-hyporesponsive episodes [HHE], seizures).

RESULTS

More than 9 million doses of nirsevimab had been distributed globally up to August 31, 2025 (proxy for doses administered in infants) representing two complete RSV seasons of nirsevimab exposure since its first routine use in some countries in September 2023.

Clinical effectiveness evidence

- **More than 50 real-world studies** conducted across 12 countries have shown that nirsevimab has effectiveness against RSV-associated outcomes with real-world use **(figure)**.[6–8]
- A systematic literature review (SLR) and meta-analysis of real-world effectiveness in infants reported **70–87% effectiveness for medically-attended RSV lower respiratory tract infection** (LRTI) and **67–83% for hospitalizations associated with RSV**,[9] consistent with pre-licensure clinical trial results.[10–13]

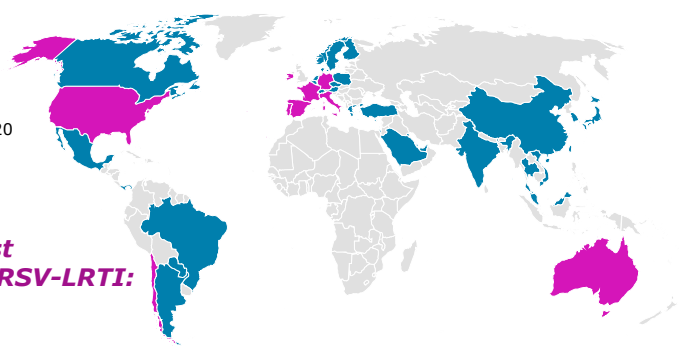
Public health impact

- Implementation of RSV prevention with nirsevimab reduced RSV hospitalization among infants by 47–92% and RSV-bronchiolitis hospitalization by up to 85%, according to a recent SLR and meta-analysis.[9] Nirsevimab has shown a **high impact on RSV disease burden** in countries with high uptake.[6,7,14]
- Nirse-GAL study data in Spain suggest that preventing RSV infection early in life with nirsevimab helps preserve healthy lung development, translating into reduced morbidity beyond infancy.[7]
- In Chile, incorporating nirsevimab into the national immunization program for infants in 2024 reduced RSV hospitalizations by 78% relative to previous seasons (2019, 2022, and 2023).[6]

Nirsevimab real-world effectiveness & impact data

Effectiveness against RSV-LRTI hospitalization:
Chile: 76.4%[6]
France: 65-83%[15, 16]
Italy: 65.5%[17]
Spain: 75.8–88.7%[18-20]
USA: 80.5–98.0%[21,22]

Effectiveness against medically-attended RSV-LRTI:
USA: 68.4–71.7%[21,22]



Countries where nirsevimab has been launched

Countries where nirsevimab has been launched, with effectiveness and/or impact data available

Post-marketing safety surveillance data

Favorable safety profile maintained in real-world use

- **Spontaneous cases reported were mostly non-serious and self-limiting, consistent with clinical development observations, with no unanticipated safety concerns detected.[1]**

Standard precautions for hypersensitivity apply, as with any biological

- As with other biological products, hypersensitivity reactions were reported following nirsevimab administration.
- In January 2024, Sanofi adjudicated that hypersensitivity reactions should be added to the "Undesirable Effects" section of the Product Information.[1] In addition, the US FDA required an update of the "Warnings and Precautions" section.[1]
- Reported signs and symptoms were consistent in severity, seriousness, and frequency with those expected for hypersensitivity reactions. Available evidence did not establish a reasonable causal relationship between nirsevimab and severe hypersensitivity reactions such as anaphylaxis.

No emerging/unanticipated risks requiring clinical practice changes

- While HHE and apnea have been reported following active immunization (vaccines) in the pediatric population,[23–29] no specific published data are available regarding passive immunization. After further evaluation of the reported cases, neither HHE nor apnea has been confirmed as an identified risk associated with nirsevimab, with reported rates of these AEs remaining within expected baseline rates for the infant population.
- Evaluation of additional predefined safety outcomes, including thrombocytopenia and seizures, showed no evidence suggesting a causal association with nirsevimab.
- As with any immunization, mAbs do not protect 100% of individuals. Confirmed cases of clinical immunization failure were reported following nirsevimab administration. However, these cases were consistent with expectations based on observed effectiveness in real-world settings.

Proper administration technique, patient screening remain essential

- Medication errors have been monitored as part of routine pharmacovigilance activities. No relevant safety findings or patterns were identified which would require specific measures. Of note, several regulatory authorities issued national communications providing guidance on correct administration of RSV immunization products in the context of the evolving RSV prevention landscape (including RSV maternal immunization).

Potential limitations

- Effectiveness estimates may vary across countries due to residual bias or population differences, in addition to true country-specific differences.
- Under-reporting, differential reporting, and maturity of pharmacovigilance systems are known limitations of passive surveillance.[3–5]

CONCLUSIONS

- The robust evidence foundation from **two complete RSV seasons across multiple countries** supports **continued confidence in nirsevimab's role as an important strategy for RSV prevention in all infants**.
- **Real-world effectiveness and impact data reinforce clinical trial evidence**, demonstrating that nirsevimab effectively prevents RSV LRTD in infants and has a **meaningful public health impact** through reduced RSV disease burden.
- Comprehensive **post-marketing safety data of over 9 million doses** distributed confirms **nirsevimab's favorable safety profile,** with no emerging or unanticipated safety concerns identified in the infant population.
- Real-world data confirm **nirsevimab's favorable benefit-risk**, supporting its integration into worldwide national immunization programs **to protect all infants against RSV disease**.

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CONFLICTS OF INTEREST
All authors are employees of Sanofi and may hold shares and/or stock options in the company.

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