Duration of effect: Based on clinical and PK data, a single dose of Beyfortus* offers a minimum duration of protection of at least 5 months.†*

sanofi

Available this Fall!

When RSV season is here, Beyfortus® is at hand.[1–3]

An antibody indicated for the prevention of RSV lower respiratory tract disease in infants during their first season[1]

Beyfortus® (nirsevimab)

NACI Statement Update

National Advisory Committee on Immunization (NACI) recommends RSV immunization programs use nirsevimab to prevent severe RSV disease. Programs can build and expand over time depending on access to supply, cost-effectiveness, and affordability of available options (STRONG RECOMMENDATION‡).[4,5]

‡ Strong recommendation applies to most populations/individuals and should be followed unless a clear and compelling rationale for an alternative approach is present.

Scan to review the full statement

Beyfortus* (nirsevimab injection) is indicated for the prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract disease in:

- Neonates and infants during their first RSV season.
- Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season, which may include but is not limited to children with: chronic lung disease of prematurity (CLD), hemodynamically significant congenital heart disease (CHD), immunocompromised states, Down syndrome, cystic fibrosis, neuromuscular disease, and congenital airway anomalies.

RSV=respiratory syncytial virus.
Sanofi & AstraZeneca are collaborating on the development and commercialization of Beyfortus*.
* Clinical significance is unknown.[1]
† Beyfortus* is a human monoclonal antibody.[1]

About Beyfortus®

Offers **protection** against RSV lower respiratory tract disease (LRTD) for infants during their first RSV season[1]

Assessed in **three clinical studies,** in **>3,800 infants** across **31 countries**[1,*,†]

Designed to evaluate the following infant patient populations:

- Safety and efficacy in healthy infants born preterm (Study 3) (n=1,453)
- Safety and efficacy in healthy infants born late preterm and term (MELODY) (n=1,490 primary cohort)
- Safety and descriptive efficacy in individuals at high risk of severe RSV disease (MEDLEY) (n=925)

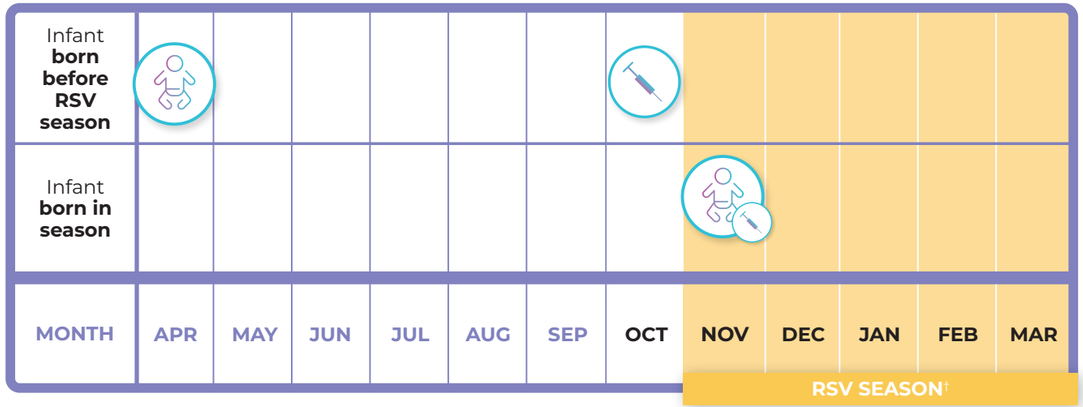
GA=gestational age; LRTD=lower respiratory tract disease; RSV=respiratory syncytial virus.

* Beyfortus® was assessed in three clinical studies: phase IIb and phase III randomized, double-blind, placebo-controlled studies to evaluate safety and efficacy against RSV in healthy preterm infants and against RSV in term and late preterm infants (Study 3 and MELODY, respectively), and in one Phase II/III, randomized, double-blind, palivizumab-controlled study to evaluate safety and descriptive efficacy against RSV in individuals at higher risk for severe RSV disease including preterm infants, infants with CLD or prematurity or hemodynamically significant CHD entering their first RSV season, and children at higher risk including those with CLD or CHD in their second RSV season (MEDLEY).[1]

† Clinical significance has not been established.

Beyfortus® should be administered prior to commencement of the RSV season, or from birth for infants born during the RSV season[1]

Illustrative example only*



Please see the product monograph for complete dosing and administration recommendations

* Chart represents examples only and not mandatory/recommended specific timings.

† Shaded area indicates a typical RSV season in a temperate northern hemisphere climate. The RSV season varies by region.[2]

In very and moderately preterm infants (GA ≥29 to <35 weeks) entering their first RSV season:

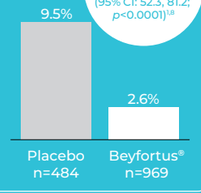
Beyfortus® demonstrated statistically significant efficacy in reducing the relative risk of medically attended RSV-associated lower respiratory tract infection (MA RSV LRTI), including hospitalizations, by 70.1% vs. placebo (95% CI: 52.3, 81.2; *p*<0.0001)[1*†‡]

Study 3

Primary endpoint

Incidence of MA RSV LRTI, including hospitalizations, caused by RT-PCR-confirmed RSV, characterized predominantly as bronchiolitis or pneumonia, through 150 days post dose[1]

70.1% RRR (95% CI: 52.3, 81.2; *p*<0.0001)[1,8]

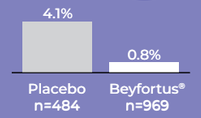


Adapted from the Beyfortus® Product Monograph, 2024.

Secondary endpoint

Incidence of MA RSV LRTI requiring hospitalization through 150 days post dose[1]

78.4% RRR (95% CI: 51.9, 90.3; *p*<0.001)[1,10]



Adapted from the Beyfortus® Product Monograph, 2024.

CI=confidence interval; GA=gestational age; MA=medically attended; LRTI=lower respiratory tract infection; RRR=relative risk reduction.

* **Study design:** Randomized, double-blind, placebo-controlled phase 2b multicentre trial. Study population included 1,453 very and moderately preterm infants (GA ≥29 to <35 weeks) entering their first RSV season. Infants were randomized 2:1 to receive a fixed single intramuscular 50 mg dose of Beyfortus® (n=969) or placebo (n=484). Please note, 50 mg is not a recommended dose for infants with body weight ≥5 kg. The recommended dose for infants with body weight ≥5 kg is a single IM dose of 100 mg.[1]

† Signs of LRTI were defined by having one of the following findings at physical examination indicating lower respiratory tract involvement (e.g., rhonchi, rales, crackles, or wheeze); and at least one sign of clinical severity (increased respiratory rate, hypoxemia, acute hypoxic or ventilatory failure, new onset apnea, nasal flaring, retractions, grunting, or dehydration due to respiratory distress). RSV hospitalization was defined as hospitalization for LRTI with a positive RSV test, or worsening of respiratory status and positive RSV test in an already hospitalized patient.

‡ The relative risk reduction and 95% CI were calculated using modified Poisson regression with robust variance including stratification factors (hemisphere and age at randomization).[1]

In term and late preterm infants (GA ≥35 weeks) entering their first RSV season:

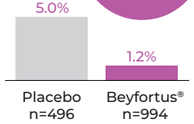
Beyfortus® demonstrated statistically significant efficacy in reducing the relative risk of MA RSV LRTI, including hospitalizations, by 74.5% vs. placebo (95% CI: 49.6–87.1; *p*<0.0001)[1*†‡]

MELODY

Primary endpoint (primary cohort)

Incidence of MA RSV LRTI, including hospitalizations, caused by RT-PCR-confirmed RSV, characterized predominantly as bronchiolitis or pneumonia through 150 days post dose[1]

74.5% RRR (95% CI: 49.6–87.1; *p*<0.0001)[1]



Adapted from the Beyfortus® Product Monograph, 2024.

Secondary endpoint (all subjects)

Incidence of MA RSV LRTI requiring hospitalization through 150 days post injection[1]

MELODY continued to enroll infants following the primary analysis, and overall, 3,012 infants (all subjects) were randomized to receive Beyfortus® (n=2,009) or placebo (n=1,003)[1]

- **76.8% RRR** in incidence of MA RSV LRTI requiring **hospitalization** through to Day 150 vs. placebo (95% CI: 49.4, 89.4). Incidence was 0.4% with Beyfortus® vs. 2.0% with placebo[1]

CI=confidence interval; GA=gestational age; LRTI=lower respiratory tract infection; MA=medically attended; RRR=relative risk reduction; RSV=respiratory syncytial virus; RT-PCR=reverse transcription polymerase chain reaction.

* **Study design:** Randomized, double-blind, placebo-controlled phase 3 multicentre trial. Study population included 1,490 term and late preterm infants (GA ≥35 weeks) entering their first RSV season for the primary cohort, with 3,012 term and late preterm infants (GA ≥35 weeks) entering their first RSV season for all subjects. Infants were randomized 2:1 to receive a single intramuscular dose of 50 mg Beyfortus® if <5 kg weight or 100 mg Beyfortus® if ≥5 kg weight at the time of administration (n=994), or placebo (n=496) for the primary cohort, Beyfortus® (n=2,009), or placebo (n=1,003) for all subjects.[1]

† Signs of LRTI were defined by having one of the following findings at physical examination indicating lower respiratory tract involvement (e.g., rhonchi, rales, crackles, or wheeze); and at least one sign of clinical severity (increased respiratory rate, hypoxemia, acute hypoxic or ventilatory failure, new onset apnea, nasal flaring, retractions, grunting, or dehydration due to respiratory distress). RSV hospitalization was defined as hospitalization for LRTI with a positive RSV test, or worsening of respiratory status and positive RSV test in an already hospitalized patient.[1]

‡ The relative risk reduction and 95% CI were calculated using modified Poisson regression with robust variance including stratification factors (hemisphere and age at randomization).[1]

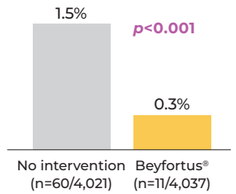
The data presented on this page is from an open-label, pragmatic, two-group, randomized trial. The study was conducted outside of Canada, specifically across HARMONIE trial sites in France, Germany, and the United Kingdom. Data relating to subjective endpoints should be interpreted cautiously due to the risk of bias.

Incidence of RSV LRTI hospitalization of Beyfortus® vs. standard of care (no intervention)[1]

Phase 3b (HARMONIE)*

Primary endpoint

Incidence of RSV LRTI hospitalization through the RSV season†‡



Adapted from Drysdale SB, et al. 2023.

Study limitations include a short 3-month follow-up period and an open-label design, where parents knew their infant's treatment, potentially influencing behaviour. Some infants without lower respiratory tract infections may have been hospitalized for RSV-related reasons like dehydration, and some hospitalized for lower respiratory tract infections did not undergo RSV testing.

* **Study design:** open-label, non-blinded, randomized multi-center parallel two-arm study. Study population included 8,058 healthy infants aged ≤12 months ineligible for palivizumab, born at a gestational age of ≥29 weeks, and entering their first RSV season. Infants were randomized 1:1 to receive a single intramuscular dose of 50 mg Beyfortus® if weight <5 kg or 100 mg if weight ≥5 kg at the time of administration (n=4,037), or no intervention group (standard of care) (n=4,021).

† Defined as admission to the hospital on the basis of the treating physician's decision and confirmation of RSV by means of a positive result of a test performed in accordance with routine practice, during the RSV season in France, Germany, and the United Kingdom.

‡ The RSV season began on September 11, 2022 (week 37), in France; on October 9, 2022 (week 41), in Germany; and on September 4, 2022 (week 36), in the United Kingdom. The RSV season ended on February 29, 2023 in each country.

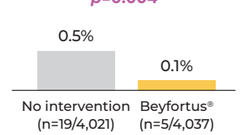
The data presented on this page is from an open-label, pragmatic, two-group, randomized trial. The study was conducted outside of Canada, specifically across HARMONIE trial sites in France, Germany, and the United Kingdom. Data relating to subjective endpoints should be interpreted cautiously due to the risk of bias.

Incidence of very severe RSV LRTI[1]

Phase 3b (HARMONIE)*

Secondary endpoint

Incidence of very severe RSV LRTI through the RSV season†‡



Adapted from Drysdale SB, et al. 2023.

Treatment related adverse events occurred in 2.1% (n=86) of infants in the Beyfortus® group and most adverse events in the standard of care group were grade 1 or 2 in severity in this trial.

Study limitations include a short 3-month follow-up period and an open-label design, where parents knew their infant's treatment, potentially influencing behaviour. Some infants without lower respiratory tract infections may have been hospitalized for RSV-related reasons like dehydration, and some hospitalized for lower respiratory tract infections did not undergo RSV testing.

* **Study design:** open-label, non-blinded, randomized multi-center parallel two-arm study. Study population included 8,058 healthy infants aged ≤12 months ineligible for palivizumab, born at a gestational age of ≥29 weeks, and entering their first RSV season. Infants were randomized 1:1 to receive a single intramuscular dose of 50 mg Beyfortus® if weight <5 kg or 100 mg if weight ≥5 kg at the time of administration (n=4,037), or no intervention group (standard of care) (n=4,021).

† The RSV season began on September 11, 2022 (week 37), in France; on October 9, 2022 (week 41), in Germany; and on September 4, 2022 (week 36), in the United Kingdom. The RSV season ended on February 29, 2023 in each country.

‡ Defined as hospitalization for RSV-associated lower respiratory tract infection with an oxygen saturation <90% (in accordance with the World Health Organization case definition) at any time during hospitalization and the need for supplemental oxygen.

Beyfortus® was generally well tolerated in clinical trials[1]

The most frequent adverse reaction was a rash (0.7% in Beyfortus* and 0.3% in placebo, occurring within 14 days post dose), as well as pyrexia (0.5% vs. 0.6% in placebo) and injection site reactions (0.3% vs. 0% in placebo) within 7 days post dose.[1]

The safety profile for Beyfortus* was generally comparable to placebo in term and preterm infants (GA ≥29 weeks) (data pooled from Study 3 and MELODY).[1]

The overall rates of adverse events (AEs) irrespective of causality were 84.0% and 82.6% for the Beyfortus* and placebo group, respectively. The majority of AEs were mild or moderate in severity.

Most commonly reported adverse events (>10% of subjects in either treatment group) for the Beyfortus* and placebo group, respectively:
- Upper respiratory tract infection (31.8% vs. 29.9%)
- Nasopharyngitis (19.0% vs. 21.0%)
- Pyrexia (11.8% vs. 10.3%)

The rates of serious adverse events (SAEs), irrespective of causality, were comparable between Beyfortus* and placebo (7.6% and 10.5%). No SAEs were determined to be related to Beyfortus*.

Most commonly reported SAEs (≥0.5% of subjects in either treatment group) for the Beyfortus* and placebo group, respectively:
- Bronchiolitis (1.3% vs. 2.6%)
- Pneumonia (0.7% vs. 0.9%)
- Gastroenteritis (0.6% vs. 0.4%)
- LRTI (0.6% vs. 0.8%)
- Bronchitis (0.5% vs. 1.0%)
- Urinary tract infection (0.3% vs. 0.5%)
- RSV bronchiolitis (0.2% vs. 0.9%)
- Inguinal hernia (<0.1% vs. 0.5%)

In the study of 918 infants at higher risk of severe RSV disease entering their first RSV season, the safety profile of Beyfortus* (n=614) was similar to palivizumab (n=304) and consistent with that seen in studies in healthy term and preterm infants ≥29 weeks GA (Study 3 and MELODY)[1*†]

GA=gestational age; RSV=respiratory syncytial virus.

* Infants at higher risk of severe RSV disease included 196 extremely preterm infants (GA <29 weeks) and 306 infants with chronic lung disease of prematurity, and hemodynamically significant congenital heart disease who were term or preterm.[1]

† There are limited data available in extremely preterm infants (GA <29 weeks) less than 8 weeks of age. No clinical data available in infants with a post-menstrual age (GA at birth plus chronological age) of 32 weeks. Limited data are available in infants with Down syndrome (n=13), cystic fibrosis (n=5), congenital airway anomalies (n=9), and neuromuscular disease (n=0; not evaluated in clinical trials).[1]

Administering Beyfortus®

A **single administration** based on infant's weight at the time of receiving Beyfortus*[1]

<5 kg
1 x 50 mg dose

Dosing in infants with a body weight between 1.0 and 1.6 kg is based on extrapolation.

≥5 kg
1 x 100 mg dose

Please see the product monograph for complete dosing and administration recommendations

Available as a ready-to-use pre-filled syringe[1]

Intramuscular injection, preferably in the anterolateral aspect of the thigh*

When applicable, Beyfortus* can be **administered concomitantly** with childhood vaccines[1†]

* The gluteal muscle should not be used routinely as an injection site because of the risk of damage to the sciatic nerve.[1]

† Beyfortus* should not be mixed with any vaccine in the same syringe or vial. When administered concomitantly with injectable vaccines, they should be given with separate syringes and at different injection sites. Please see the product monograph for complete information regarding drug interactions.[1]

Important safety information

Clinical information

Safety and efficacy in children older than 24 months of age have not been established. Safety and efficacy in infants with body weight below 1.6 kg have not been established. Dosing in infants with a body weight from 1.0 kg to <1.6 kg is based on extrapolation. The efficacy in infants who remain vulnerable to severe RSV disease during their first or second RSV season has not been directly established and is based on extrapolation of exposure only.

There is limited information available in extremely preterm infants (Gestational Age [GA] <29 weeks) less than 8 weeks of age, and no clinical data are available in infants with a postmenstrual age (gestational age at birth plus chronological age) of 32 weeks. Limited data are available in infants with Down syndrome (n=13), cystic fibrosis (n=5), congenital airway anomalies (n=9), and neuromuscular disease (n=0; not evaluated in clinical trials).

Not indicated in the geriatric population (≥65 years of age).

Relevant warnings and precautions

- Should be given with caution to individuals with thrombocytopenia, any coagulation disorder or to individuals on anticoagulation therapy.
- Serious hypersensitivity reactions, including anaphylaxis, have been observed rarely with other IgG1 monoclonal antibodies. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration and initiate appropriate medicinal products and/or supportive therapy.
- In some individuals with protein-losing conditions, an increased clearance of nirsevimab was observed in clinical trials. Nirsevimab may not provide the same level of protection in individuals with significant protein loss.
- Pregnant and nursing women: not indicated for adults.

For more information

Please refer to the Product Monograph at https://www.sanofi.com/assets/countries/canada/docs/products/vaccines/beyfortus-en.pdf for important information relating to adverse events, drug interactions, dosing and conditions of clinical use. The Product Monograph is also available by calling 1-800-265-7927.

References: 1. Beyfortus® Product Monograph, June 14, 2024. **2.** Bianchini S, et al. *Microorganisms* 2020;8:2048. doi: 10.3390/microorganisms8122048. **3.** Pisesky A, et al. *PLoS One* 2016;11(3):e0150416. doi: 10.1371/journal.pone.0150416. **4.** An Advisory Committee Statement (ACS) National Advisory Committee on Immunization (NACI). Statement on the prevention of respiratory syncytial virus (RSV) disease in infants. Available at: https://www.canada.ca/content/dam/phac-aspc/documents/services/publications/vaccines-immunization/national-advisory-committee-immunization-statement-prevention-respiratory-syncytial-virus-disease-infants/naci-statement-2024-05-17.pdf. Accessed: May 27, 2024. **5.** Summary of the National Advisory Committee on Immunization (NACI) Statement of May 17, 2024. Statement on the prevention of respiratory syncytial virus (RSV) disease in infants. Available at: https://www.canada.ca/content/dam/phac-aspc/documents/services/publications/vaccines-immunization/national-advisory-committee-immunization-summary-statement-prevention-respiratory-syncytial-virus-disease-infants/naci-summary-2024-05-17.pdf. Accessed: July 17, 2024. **6.** Protocol for: Griffin MP, Yuan Y, Takas T, et al. Single-dose nirsevimab for prevention of RSV in preterm infants. *N Engl J Med* 2020;383:415–25. **7.** Protocol for: Hammitt LL, Dagan R, Yuan Y, et al. Nirsevimab for prevention of RSV in healthy late-preterm and term infants. *N Engl J Med* 2022;386:837–46. **8.** Data on file. Sanofi Pasteur Limited, 2023. **9.** Obando-Pacheco, et al. *J Infect Dis* 2018;217:1356–64. **10.** Griffin MP, et al. *N Engl J Med* 2020;383:415–25. doi: 10.1056/NEJMoa1913556. **11.** Drysdale SB, et al. Nirsevimab for Prevention of Hospitalizations Due to RSV in Infants. *N Engl J Med* 2023;389(26):2425–35. **12.** Data on File.

Beyfortus® (nirsevimab)

Scan and visit Sanofi Campus to learn more!

When RSV season is here, Beyfortus® is at hand.

Beyfortus® (nirsevimab) reduced the relative risk of medically attended RSV LRTI, inclusive of hospitalization, in infants compared to placebo.[1]

Beyfortus® may be publicly funded in your province or territory (with criteria). Please refer to your local public health unit for further information.[1,2]

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Beyfortus® (nirsevimab)