

# **Beyfortus (nirsevimab-alip)**

## **Category:**

Best Biotechnology Product

## **Company Name:**

AstraZeneca and Sanofi

## **Product/Solution Name:**

Beyfortus (nirsevimab-alip)

## **Compound/Tech Name:**

nirsevimab

## **Trade Name:**

Beyfortus

## **Corporate Name:**

Beyfortus

## **Date of Approval:**

2023-07-17

## **Indications:**

Beyfortus® (nirsevimab-alip) is a long-acting antibody approved in the United States (US) for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease (LRTD) in newborns and infants born during or entering their first RSV season, and for children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.

Beyfortus was the first long-acting monoclonal antibody approved in the US for the prevention of RSV LRTD in a broad infant population, from preterm or immunocompromised infants to those born full-term and healthy. The single dose can be administered directly to infants as an intramuscular injection, providing fast-acting protection with demonstrated efficacy and safety for the nation's youngest, most vulnerable population.

Beyfortus is currently approved in more than 50 markets and was granted regulatory designations to facilitate expedited development by several major regulatory agencies around the world, including Breakthrough Therapy Designation from the US Food and Drug Administration (FDA).

Beyfortus received FDA approval in July 2023 following a unanimous vote by the Antimicrobial Drugs Advisory Committee (AMDAC). Furthermore, Beyfortus is the first monoclonal antibody to be recommended by the US Advisory Committee on Immunization Practices (ACIP) for broad infant use and was included in the Vaccines for Children program supporting equitable access in the US.

During the 2023-2024 RSV season, Beyfortus demonstrated over 90% effectiveness against RSV-associated hospitalization among infants in the US in their first RSV season, with similar outcomes in other major markets, and a noteworthy 50,000 hospitalisations were avoided globally.(1) Preclinical, clinical, and real-world evidence supporting Beyfortus has been published in more than 30 publications across high-impact journals including The New England Journal of Medicine.

Beyfortus is developed and commercialized in partnership by AstraZeneca and Sanofi.

## **Therapeutic Areas:**

Respiratory syncytial virus  
Infectious diseases  
Pediatric immunization

## **General Information File Document upload:**

[\*\*Beyfortus Brochure.pdf\*\*](#)  
[\*\*Beyfortus Prescribing Information.pdf\*\*](#)

## **Background information and need for drug / device:**

Prior to the development of Beyfortus, there were up to 80,000 RSV-related infant hospitalizations in the US each year.(2) That was 80,000 babies fighting to breathe with hundreds of thousands more seeking medical attention without hospitalization.

RSV is one of the most common respiratory viruses among infants and young children.(3,4) While the majority of cases don't progress beyond mild, cold-like symptoms, RSV can quickly become severe and progress to a lower respiratory tract infection, such as bronchiolitis and pneumonia.(3,4) In fact, RSV is the leading cause of hospitalization in infants under 12 months, averaging 16 times higher than the annual rate for influenza in the US.(5,6) The burden of disease is significant, with an estimated 590,000 medically attended RSV lower respiratory tract infections in the US each

year.(7) Approximately 75% of infants hospitalized for RSV are born at term and have no underlying conditions, demonstrating the widespread impact and unpredictability of the virus across a broad population.(8-10)

RSV causes annual seasonal epidemics worldwide.(11-13) and two out of three infants are infected with RSV during their first year of life and almost all children are infected by their second birthday.(4,14) In the US alone, infant RSV treatment costs \$709.6 million annually.(15)

Even with more than 60 years of research, the scientific community has struggled to develop new preventive options in the RSV field.(16) Until recently, RSV prevention was limited to high-risk infants with pre-existing conditions-leaving most infants unprotected from this virus.(16,17) The 2022-2023 RSV season, in particular, took a record toll, likely due to a reduction in preventive public health measures as COVID-19 precautions eased.(18,19)

Following those unprecedented levels of illness and hospitalizations, the development of Beyfortus represents a significant breakthrough and innovation to protect infants from serious RSV disease.

## **Background File Document upload:**

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[\*\*AstraZenecacom\\_Advancing the Science of RSV.pdf\*\*](#)

[\*\*Beyfortuscom\\_What is RSV.pdf\*\*](#)

## **History of the development of the solution/product:**

The story of Beyfortus began in the mid-2000s with the identification and optimization of nirsevimab, an antibody that binds with high affinity to the site Ø of the prefusion conformation of the RSV fusion (F) protein. Nirsevimab was substantially more potent and more effective at binding the F protein than previously studied antibodies. Nirsevimab employs YTE technology, which enhances binding of IgG1 and prolongs serum half-life, more than tripling the longevity of nirsevimab in serum and enabling once-per-season dosing.(20)

Extensive discovery and preclinical efforts set the stage for Beyfortus' robust clinical development program that spanned three pivotal late-stage clinical trials over nearly a decade. Clinical trials consistently showed that a single dose of Beyfortus protected infants for at least five months, the duration of a typical RSV season, and demonstrated approximately 70-80% efficacy against medically attended RSV lower respiratory tract infection (MA RSV LRTI).(21-24)

The clinical program included:

- Trial 03, a Phase IIb randomized, double-blind, placebo-controlled, multicenter clinical trial that included 1,453 preterm infants entering their first RSV season. Among infants treated with Beyfortus, 25 (2.6%) experienced MA RSV LRTI compared with 46 (9.5%) infants who received placebo. Beyfortus reduced the risk of MA RSV LRTI by ~70% relative to placebo.(21,23)
- MELODY (Trial 04), a Phase III randomized, double-blind, placebo-controlled, multicenter clinical trial that included 3,012 term and late preterm infants. Among the primary cohort infants (1490) treated with Beyfortus, 12 (1.2%) experienced MA RSV LRTI compared with 25 (5.0%) infants who received placebo. Beyfortus reduced the risk of MA RSV LRTI by ~75% relative to placebo.(21,22,25)
- MEDLEY (Trial 05), a Phase II/III randomized, double-blind, active (palivizumab)-controlled, multicenter trial that supported the use of Beyfortus in children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season. In addition to safety, the pharmacokinetic data provided evidence for the use of Beyfortus to prevent MA RSV LRTI in this population.(24-26)
- Pooled analyses reinforced the effectiveness of Beyfortus, reducing the risk of MA RSV LRTI in infants by ~80% compared to placebo, as well as reducing the risk of RSV LRTI hospitalization by 77% and very severe RSV by 86%. (27)

The robust clinical study program included a diverse infant population, including studies in immunocompromised, high-risk populations and Native American populations, who are disproportionately impacted by higher rates of RSV.

Researchers worked closely with regulatory bodies to design optimal, yet flexible programs regarding dose optimization and quality of evidence, to build the pathway for broad access and widespread approval. Despite significant roadblocks during the pandemic, the research team acted quickly, working closely with regulators to optimize program delivery and implement health tools including telehealth for remote patient monitoring, home health visits, and online apps to stay on track and ensure robust oversight of enrollees.

Beyfortus has revolutionized the space, paving the way for other long-acting antibody drugs, including clesrovimab, as a new standard of prevention and for passive immunization as an approach across therapeutic areas, potentially enabling future protection strategies.

## **Development File Document upload:**

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[Hammit\\_N Engl J Med\\_2022.pdf](#)  
[Muller\\_N Engl J Med\\_2023.pdf](#)  
[Zhu\\_J Infect Dis\\_2018.pdf](#)

**Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition:**

The innovation behind Beyfortus was driven by nirsevimab's high potency combined with the YTE technology enabling once per season dosing, and the ability to protect for an entire season. Notably, in HARMONIE, a close to real-world setting Phase IIIb trial, Beyfortus reduced the risk of RSV LRTI hospitalization by 83%.(28)

In the first RSV season following Beyfortus' commercial launch, 1.9 million doses were supplied globally, marking the fastest pediatric immunization uptake on record. Two years post launch, Beyfortus secured its place as the second biggest biologic by volume, tripling the doses delivered in 2024 to 6 million+ doses, compared to 2023. During the 2023-2024 US respiratory virus season, Beyfortus showed impressive impact with real-world reports demonstrating 89% efficacy against MA RSV acute respiratory illness and 93% efficacy against RSV-associated hospitalization, with similar evidence reported globally.(1,29,30,31)

To get there, AstraZeneca and Sanofi worked closely with the CDC to establish a pathway for broad access for a monoclonal antibody. Beyfortus-the first passive immunization on the CDC's vaccine schedule and first monoclonal antibody implemented \"at scale\"-dramatically changed the RSV landscape for babies regardless of health status. ACIP's unanimous recommendation means Beyfortus is available with no out-of-pocket cost to families-enabling true practice-changing care.

The 2024-2025 respiratory virus season was the first season with widespread availability of Beyfortus in the US Initial real-world reports continue to reinforce Beyfortus' efficacy, with the VISION Vaccine Effectiveness Network reporting a 79% reduction in RSV-associated hospitalization and an 82% reduction in RSV-associated intensive care admissions.(32) Compared to the 2018-2020 respiratory virus season, Beyfortus significantly reduced RSV-associated hospitalization rates in infants by 43% in the 2024-2025 season.(33)

Following the approval of Beyfortus in 2023, Galicia, a region in northwestern Spain, enacted a universal immunization program using Beyfortus, where results showed RSV LRTI hospitalizations were reduced by nearly 90%.(34) Prof. Federico Martín-Torres, MD, PhD, a trial investigator and head of pediatrics at Hospital Clínico Universitario de Santiago de Compostela, said, \"The infant wards and ICUs were almost empty this past winter virus season. Unlike prior years, there were very few young infants with bronchiolitis in the hospital.\" In advance of the 2024 RSV season, Chile was the first country in the southern hemisphere to implement a universal immunization strategy

against RSV. In a retrospective observational study, now published in The Lancet, Beyfortus reduced RSV-related LRTI hospitalizations by 78%, effectively averting 30 cases of RSV per 1000 infants and resulting in zero RSV-related deaths. (35)

Beyfortus has consistently proven itself as an effective RSV immunization, with approximately 10 million infants globally receiving Beyfortus to date. Imagine, a world where pediatric RSV-associated hospitalization is confined to history-driven by paradigm-shifting innovations that protect the resiliency of our healthcare systems and improve the lives of millions.

### **Innovation File Document upload:**

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[Moline\\_JAMA Pediatrics\\_2025.pdf](#)  
[Torres\\_Lancet Infect Dis\\_2025.pdf](#)

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