

Beyfortus® immunization to protect infants from RSV has begun

- Six out of 10 infants and newborns in Canada will have access to the protective antibody Beyfortus® for the first time this season
- Access to Beyfortus® includes infants in remote communities most impacted by respiratory syncytial virus (RSV), in all three territories and northern Quebec and Ontario
- Beyfortus® demonstrated the ability to reduce the risk of RSV lower respiratory tract infections by 74.5%, including hospitalizations in infants entering their first RSV seasonⁱ

TORONTO, Oct. 28, 2024 /CNW/ - Sanofi is pleased to announce Beyfortus® (nirsevimab) will be broadly available for babies born in Ontario, Quebec, Nunavut, Northwest Territories, and the Yukon this fall. The administration of this immunization to infants has begun. Beyfortus® is the first long-acting antibody approved in Canada for the prevention of RSV lower respiratory tract disease in newborns and infants through their first RSV season.ⁱⁱ As RSV circulates seasonally between November and April, causing a high burden of bronchiolitis, pneumonia and hospitalizations in infants and newborns, this timely availability aims to help safeguard the most vulnerable populations during this critical period. With the ongoing challenges posed by RSV, Sanofi is committed to increasing access to this immunization across Canada.



"We understand the concerns parents face during RSV season, and we are dedicated to providing new solutions to protect all babies," said Delphine Lansac, General Manager of Vaccines at Sanofi. "The availability of Beyfortus® is a significant step forward in our mission to protect infant health and to help alleviate the burden on the healthcare system during respiratory illness season."

Beyfortus® will be provided in hospital prior to discharge for babies born during RSV season and is available through primary care providers or public health in Quebec, Ontario, Nunavut, Northwest Territories, and the Yukon for infants born prior to RSV season. Beyfortus® is publicly funded and available free of charge in these jurisdictions. Healthcare providers can contact their local health authority to obtain more information about Beyfortus®.

The National Advisory Committee on Immunization (NACI) and Quebec's National Institute of Excellence in Health and Social Services (INESSS) recommended Beyfortus® to protect newborns and infants from RSV.^{iii,iv} Health Canada issued a Notice of Compliance for Beyfortus® in April 2023.

About RSV

RSV, a highly contagious virus, can lead to respiratory illness in babies, including lung infections such as bronchiolitis and pneumonia.^v Approximately 2 out of 3 infants are infected by RSV by their first birthday and almost all infants are infected by the age of 2.^{vi} Infants under 1 year are on average almost 16 times more likely to be hospitalized for RSV than for influenza.^{vii} The majority of RSV hospitalizations occur in infants without risk factors. A recent study showed among infants hospitalized for RSV, 80% were previously healthy and born at term.^{viii} As highlighted by NACI, each year, between 10% and 20% of RSV cases among healthy infants require medical care including physician office, urgent care, emergency room visits and hospitalizations.^{ix} Until now, only a small fraction of infants born in Canada have been eligible to receive RSV protection.

About Beyfortus®

Beyfortus® is the first immunization designed for all infants to help prevent RSV lower respiratory tract disease through their first RSV season. Beyfortus® is also indicated for children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season. Beyfortus® offers timely protection against RSV lower respiratory tract disease lasting at least 5 months, to coincide with the RSV season.

As a long-acting antibody provided directly to newborns and infants in a single dose, Beyfortu[®] offers rapid protection to help prevent lower respiratory tract disease caused by RSV without requiring activation of the immune system.

Beyfortu[®] demonstrated statistically significant efficacy in reducing the relative risk of respiratory syncytial virus lower respiratory tract infections, including hospitalizations, by 74.5% vs. placebo in term and late preterm infants (gestational age greater than or equal to 35 weeks) entering their first RSV season (95% CI: 49.6-87.1; $p < 0.0001$).^x

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 the world, 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.

In Canada, we employ over 2,000 people. We invest 20% of our revenue annually in biopharma research (representing \$1.2 billion CAD in R&D investment over the last decade) creating jobs, business, and opportunities throughout the country. We are also on track to deliver over \$2 billion CAD in new infrastructure investments by 2028.

In 2024, we are celebrating 110 years of heritage dedicated to developing innovative health solutions for Canadians. What started as a small laboratory in May of 1914, recognized for having advanced some of the greatest contributions to public health, both nationally and globally, has evolved to become the largest biomanufacturing facility in Canada.

Sanofi is listed on (EURONEXT: SAN) and (NASDAQ: SNY)

ⁱ BEYFORTUS[®] Product Monograph, Sanofi Pasteur Limited, June 14, 2024.

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ⁱⁱⁱ An Advisory Statement, National Advisory Committee on Immunization (NACI), Statement on the prevention of Respiratory Syncytial Virus (RSV) disease in infants, April 2024.

^{iv} Institut national d'excellence en santé et en services sociaux: BEYFORTUS^{MC}: Prévention des infections graves par le virus respiratoire syncytial chez l'enfant.

^v Public Health Agency of Canada. Accessed 21 February 2024. [Respiratory syncytial virus \(RSV\): Canadian Immunization Guide - Canada.ca](#)

^{vi} Simoes EAF. *Lancet* 1999; 354:847-852

^{vii} Demont C et al. *BMC Infect Dis* 2021; 21(1) : 730, Sanchez-Luna M et al. *Curr Med Res Opin* 2016; 32(4) : 693-698, Kobayashi Y et al. *J Infect Dis* 2022; 226 :386-395, Yu J et al. *Emerg Infect Dis* 2019; 25(6) : 1127-1135, Thwaites R et al. *Eur J Pediatr* 2020; 179(5): 791-799, Arriola C et al. *J Pediatric Infect Dis Soc* 2020; 8(12): 2048.

^{viii} Pisesky et al. *PloS one* 11.3 (2016): e0150416

^{ix} Abrams EM, Doyon-Plourde P, Davis P, Brousseau N, Irwin A, Siu W, et al. Burden of disease of respiratory syncytial virus in infants, young children and pregnant women and people. *Canada Communicable Disease Report*. 2024 Feb;50(1/2):1-15. <https://doi.org/10.14745/ccdr.v50i12a01>.

^x BEYFORTUS[®] Product Monograph, Sanofi Pasteur Limited, June 14, 2024.

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