

The National Advisory Committee on Immunization recommends BEYFORTUS® to protect all infants against RSV

- The National Advisory Committee on Immunization (NACI) strongly recommends working towards a universal Respiratory Syncytial Virus (RSV) immunization program using BEYFORTUS® (nirsevimab).ⁱ
- BEYFORTUS® is the first long-acting antibody approved in Canada for the prevention of RSV lower respiratory tract disease in neonates and infants through their first RSV season.ⁱⁱ
- BEYFORTUS® is also approved for children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.ⁱⁱⁱ

TORONTO, May 21, 2024 /CNW/ - The National Advisory Committee on Immunization issued a recommendation for BEYFORTUS® (nirsevimab) to be used for the prevention of RSV. The committee has presented two strong recommendations for the delivery of BEYFORTUS® to all Canadian infants that could be implemented through established systems and programs.



NACI recommends a universal RSV immunization program using BEYFORTUS® for all infant protection due to the significant burden of disease in infants from RSV and impacts of RSV on the healthcare system, parents and caregivers. This preferential recommendation for BEYFORTUS® is due to its protective efficacy, potential duration of effect and once-per-season dosing compared to other treatment options.^{iv}

NACI also recommends RSV immunization programs using BEYFORTUS® to prevent severe RSV disease. In this approach, NACI has two priority groups. The first group includes infants born before or during their first RSV season, or entering their second RSV season who are at increased risk of severe disease, or whose access to treatment may be complex. The second priority group includes all infants under 8 months of age entering their first RSV season.^v

Delphine Lansac

General Manager, Vaccines Canada, Sanofi

"I am pleased that NACI recognizes the benefits of BEYFORTUS® to protect all infants from RSV. This dangerous illness affects the most vulnerable among us with devastating impacts each year and parents and physicians have long been seeking this preventative option. No baby should be left at risk and no parent should have to realize the fear of their baby experiencing a severe RSV infection."

Dr. Christine Palmay

MD, CCFP, FCP

"NACI's most recent statement regarding prevention of RSV in infants marks a pivotal step towards enhancing the best form of medicine: prevention. As a society, we have a duty to protect those most at risk. Arguably, infants and children are at the top of this list. As a health care provider, I have seen firsthand the devastating effects of RSV, including hospitalization requiring severe interventions, long term health complications and most tragically, death. In the community, RSV infections have plagued countless families who endlessly need to seek medical attention and feel the strain associated with constantly caregiving for their sick children. The option to have a preventative immunization is a game changer and offers a tool to protect our precious babies and children from RSV. As we rebuild a medical system post pandemic, proactive care in the form of prevention is the only way to move forward."

BEYFORTUS® received Notice of Compliance from Health Canada in April 2023. Additionally, it was approved by the FDA in the United States in July 2023, the European Union in October 2022 and in Great Britain in November 2022. Regulatory applications are also currently under review in several other countries.

Sanofi is working with provincial authorities to make BEYFORTUS[®] available to a broad cohort of infants for the 2024-25 RSV season.

About RSV

RSV, a highly contagious virus, can lead to respiratory illness in babies, including lung infections such as bronchiolitis and pneumonia.^{vi} 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.^{vii} Infants under 1 year are on average almost 16 times more likely to be hospitalized for RSV than for influenza.^{viii} 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.^{ix} 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.^x Currently, only a small fraction of infants born in Canada have access to RSV protection.

About BEYFORTUS[®]

BEYFORTUS[®] is a single-dose, long-acting antibody designed to help prevent RSV lower respiratory tract disease (LRTD) for infants during 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.

BEYFORTUS[®] is administered directly to neonates and infants as a single dose and offers rapid protection via an antibody to help prevent LRTD caused by RSV, without requiring activation of the immune system. BEYFORTUS[®] administration can be timed to the start of the RSV season.

In March 2017, Sanofi and AstraZeneca announced an agreement to develop and commercialize BEYFORTUS[®]. Under the terms of the agreement, AstraZeneca leads development and manufacturing activities, and Sanofi leads commercialization activities and records revenues. Under the terms of the global agreement, Sanofi made an upfront payment of €120m, has paid development and regulatory milestones of €120m and €25m in sales-related milestones. Sanofi will pay up to a further €350m upon achievement of additional regulatory and sales-related milestones. The two companies share costs and profits in all territories except in the U.S. where Sanofi consolidates 100% of the economic benefits in its Business Operating Income.

About Sanofi

Sanofi is an innovative global healthcare company, driven by one purpose: we chase the miracles of science to improve people's lives. Our team, across some 100 countries, 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, including two new vaccine manufacturing facilities at our Toronto Campus.

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 An Advisory Statement, National Advisory Committee on Immunization (NACI), Statement on the prevention of Respiratory Syncytial Virus (RSV) disease in infants, 17 May, 2024. [naci-statement-2024-05-17.pdf \(canada.ca\)](#)

ⁱⁱ BEYFORTUS[™] Product Monograph. Sanofi Pasteur Limited. March 14, 2024.

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^{iv} An Advisory Statement, National Advisory Committee on Immunization (NACI), Statement on the prevention of Respiratory Syncytial Virus (RSV) disease in infants, 17 May, 2024. [naci-statement-2024-05-17.pdf \(canada.ca\)](#)

^v An Advisory Statement, National Advisory Committee on Immunization (NACI), Statement on the prevention of Respiratory Syncytial Virus (RSV) disease in infants, 17 May, 2024. [naci-statement-2024-05-17.pdf \(canada.ca\)](#)

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

vii Simoes EAF. *Lancet* 1999; 354:847-852

viii 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.

ix Pisesky et al. *PloS one* 11.3 (2016): e0150416

x 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>.

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