

Ontario Ministry of Health Announces a Universal Public Program with Beyfortus® this RSV Season

TORONTO, July 25, 2024 /CNW/ - The Ontario Ministry of Health has announced a universal public program with Beyfortus® (nirsevimab) for all newborns and infants born in 2024 and through the 2024-2025 RSV season. This also includes some high-risk children up to 24 months old. This is the first publicly funded broad infant program in Ontario offering protection to all newborns and infants entering their first RSV season. RSV is one of the most common respiratory viruses in babies that can lead to lung infections such as bronchiolitis and pneumonia.i

In May, the National Advisory Committee on Immunization (NACI) recommended working towards a universal RSV immunization program with Beyfortus® to prevent severe RSV disease in infants, due to the significant burden of disease in all infants from RSV and the impacts of RSV on the Canadian health system.ii According to NACI, RSV infects "almost all children by the age of 2 years old."iii Offering broad infant protection is needed as most 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.iv

Delphine Lansac

General Manager, Vaccines, Sanofi Canada

"Today's announcement by the Government of Ontario is a significant milestone. Providing universal access to Beyfortus® to help protect all infants in Ontario means that parents can focus on the joys of a new baby and worry less about experiencing a severe RSV infection. This new program builds on our 110-year heritage as a committed partner supporting public health in Canada. Our objective continues to be protecting the health of Canadians with innovative solutions and introducing Beyfortus® is a step forward to protect babies and make a positive difference for families and the healthcare system."

The Honourable Sylvia Jones

Ontario Deputy Premier and Minister of Health

"Our government is taking steps to ensure Ontarians of all ages have the tools they need to be prepared and keep their loved ones safe and healthy ahead of respiratory virus season. Our government is working with our partners to significantly expand Ontario's RSV program, to make it easier for families to connect to the care they need, improving health outcomes and reducing the number of hospitalizations and ICU admissions resulting from RSV."

Dr. Eddy Lau

Pediatrician, St. Joseph's Health Centre, Unity Health,
Assistant Professor of Pediatrics, University of Toronto

"RSV infection is one of the highest burdens on pediatric healthcare during the fall and winter seasons. Two winters ago, it was the first time in decades where our inpatient hospital capacity was strained to the point where infants needed ICU level care in community hospitals in Ontario. Since that time, RSV has continued to be one of the most significant infections putting infants and children in hospital. The availability of a single dose RSV prevention strategy will result in a significant decrease in infant illness and hospitalization."

Health Canada issued a Notice of Compliance for Beyfortus® in April 2023. Additionally, it was approved by the FDA in the United States in July 2023 and the European Union in October 2022.

About Beyfortus®

Beyfortus® is a single-dose, long-acting antibody designed to help prevent RSV lower respiratory tract disease (LRTD) for newborns and 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 newborns 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

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

ⁱⁱ 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 \(canada.ca\)](#)

ⁱⁱⁱ 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 \(canada.ca\)](#)

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

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