

## Quebec Ministry of Health Announces Universal Public Program with Beyfortus® this Upcoming RSV Season

TORONTO, May 31, 2024 /CNW/ - The Quebec Ministry of Health has announced a universal public program with Beyfortus® (Nirsevimab) for all newborns and infants six months of age and younger for the 2024-25 Respiratory Syncytial Virus (RSV) season. This is the first publicly funded broad infant program in Canada offering a preventative immunization for RSV.

*"This is a huge step forward." - Dr. Earl Rubin, Pediatric Infectious Diseases Specialist, MUHC*



The public program will also cover newborns and infants with health conditions that put them at increased risk of complications, including those born premature or living in isolated communities up to 8 months of age and high-risk newborns and infants up to 8 months of age during their first RSV season or under 19 months of age during their second RSV season.<sup>i</sup>

According to Quebec's National Institute of Excellence in Health and Social Services, the increasing demand on emergency services over the past few years and the emergence of new viral strains like COVID-19 demonstrate the need to protect all newborns and infants from RSV.<sup>ii</sup>

### **Delphine Lansac**

General Manager, Vaccines, Canada

*"This is a historic moment in Quebec where babies can be protected from a seasonal virus that can have truly devastating impacts. Parents and healthcare providers have been seeking preventative measures for a long time and the burden on the healthcare system has only continued to grow over the last several years. Now is the time to protect our most vulnerable from RSV."*

### **Dr. Earl Rubin**

Pediatric Infectious Diseases Specialist

*"Coming off the heels of the post-pandemic huge RSV seasons, dealing with our triple-demic issues (of Influenza, RSV and Covid), and superimposed on the many decades of known seasonal surges of RSV, this announcement for Nirsevimab provides the opportunity to protect all infants against severe RSV, and not just the high-risk premature babies and those with serious respiratory or cardiac conditions. This product, and roll out to the population, will not only decrease medically attended visits due to RSV infection (clinics, ER etc.), but it will also ease the growing demand for admission to hospital. RSV is the number one reason for hospital bed occupancy in hospitals that look after children during the late fall and early winter seasons. This is a huge step forward."*

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, the European Union in October 2022 and in Great Britain in November 2022. Regulatory applications are also currently under review in several other countries.

Quebec's National Institute of Excellence in Health and Social Services (INESSS) recommends Beyfortus® to be used for the prevention of RSV lower respiratory tract disease (LRTD) in all newborns and infants aged 8 months and younger.<sup>iii</sup> The INESSS Standing Committee on Deliberation – Reimbursement and Access unanimously agrees that Beyfortus® provides significant clinical benefits compared to placebo in reducing lower respiratory tract infections that require medical assistance as well as hospitalization due to RSV infection, in the healthy, full-term, or premature pediatric population during the first RSV season.<sup>iv</sup>

### **About RSV**

RSV, a highly contagious virus, can lead to respiratory illness in babies, including lung infections such as bronchiolitis and pneumonia.<sup>v</sup> 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.<sup>vi</sup> Infants under 1 year are on average almost 16 times more likely to be hospitalized for RSV than for influenza.<sup>[vii]</sup> 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.<sup>viii</sup>

### **About Beyfortus<sup>®</sup>**

Beyfortus<sup>®</sup> is a single-dose, long-acting antibody designed to help prevent RSV lower respiratory tract disease (LRTD) for neonates and infants during their first RSV season. Beyfortus<sup>®</sup> is also indicated for children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season. Beyfortus<sup>®</sup> offers timely protection against RSV lower respiratory tract disease lasting at least 5 months, to coincide with the RSV season.

Beyfortus<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup>. 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.

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<sup>i</sup> Régis de l'assurance maladie : Nirsevimab. Accessed 27 May 2024. [Liste des médicaments\\_Établissement – en vigueur le 23 mai 2024 \(gouv.qc.ca\)](#)

<sup>ii</sup> Institut national d'excellence en santé et en services sociaux: BEYFORTUS<sup>MC</sup>: Prévention des infections graves par le virus respiratoire syncytial chez l'enfant. Accessed 11 April 2024 [Extrait d'avis au ministre sur Beyfortus \(inesss.qc.ca\)](#)

<sup>iii</sup> Institut national d'excellence en santé et en services sociaux : BEYFORTUS<sup>MC</sup> : Prévention des infections graves par le virus respiratoire syncytial chez l'enfant. Consulté le 11 avril 2024. [Extrait d'avis au ministre sur Beyfortus \(inesss.qc.ca\)](#)

<sup>iv</sup> Institut national d'excellence en santé et en services sociaux : BEYFORTUS<sup>MC</sup> : Prévention des infections graves par le virus respiratoire syncytial chez l'enfant. Consulté le 11 avril 2024. [Extrait d'avis au ministre sur Beyfortus \(inesss.qc.ca\)](#)

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

<sup>vi</sup> Simoes EAF. *Lancet* 1999; 354:847-852

<sup>vii</sup> 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.

<sup>viii</sup> Pisesky et al. *PloS one* 11.3 (2016): e0150416

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