News Releases

Quebec's INESSS recommends BEYFORTUS® for the prevention of RSV for all infants 8 months of age and younger(1)

- BEYFORTUS® (nirsevimab) is the first long-acting antibody approved in Canada for the prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract disease in neonates and infants through their first RSV season.[i]
- BEYFORTUS® is also approved for children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.[ii]
- According to INESSS, increasing demand on emergency services shows the need for all infant protection from RSV.[iii]

TORONTO, April 18, 2024 /CNW/ - 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 neonates and infants aged 8 months and younger. Furthermore, the INESSS Standing Committee on Deliberation – Reimbursement and Access unanimously agree 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. The Committee also recognizes the therapeutic value of BEYFORTUS® in the population for whom the risk of developing a serious infection persists for a second RSV season.[iv]

Delphine Lansac
General Manager, Vaccines Canada, Sanofi
"Parents and physicians who experience the impacts of RSV annually have been waiting for a preventative option that can cover the entire infant population and protect our most vulnerable. I believe every baby deserves to be protected against RSV and this recommendation for BEYFORTUS® marks an important milestone towards achieving that goal in Quebec. Now is the time to protect all infants against this devastating illness."

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.

Sanofi is working with Quebec 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.[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] According to INESSS, 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.[ix] 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 neonates 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 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.

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[1] Per INESSS, newborns and infants whose mothers received a vaccine for RSV prevention, and who were born more than 2 weeks after the administration of the vaccine, are not eligible to receive nirsevimab for the current or upcoming season.

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

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

[iii] Institut national d'excellence en santé et en services sociaux: BEYFORTUS[MC]: 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)

[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. Accessed 11 April 2024 Extrait d'avis au ministre sur Beyfortus (inesss.qc.ca)

[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] Institut national d'excellence en santé et en services sociaux: BEYFORTUS[MC]: 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)

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