News Releases

Health Canada approves BEYFORTUS™ (nirsevimab) for the prevention of RSV disease in infants

- BEYFORTUS™ (nirsevimab) is the first and only single-dose immunization designed for the prevention of RSV disease in newborns and infants, including those born healthy, at term or preterm, or with specific health conditions[1]
- Clinical trial data show BEYFORTUS™ is effective in reducing medically attended RSV infections including hospitalizations[1]

TORONTO, April 24, 2023 /CNW/ - Health Canada has issued a Notice of Compliance (NOC) approving BEYFORTUS™ (nirsevimab) for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease (LRTD) in newborns and infants during their first RSV season, and children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.[1]

RSV is a common and highly contagious seasonal respiratory virus infecting almost all children by two years of age.[2] RSV usually causes mild symptoms but can cause severe illness, including bronchiolitis and pneumonia that may lead to hospitalization or even death.[1] The virus is most common during the winter, but it may begin earlier or last longer in certain parts of the country.[1] RSV is a leading cause of infant hospitalizations (approximately 79%),[3] including infants born at term with no underlying health conditions.[4,5,6,7,8]

> ***Dr. Steven Moss, MD, FRCPC, DipABPed***
> Associate Professor of Pediatrics, University of Toronto, American Board of Pediatrics Certified and Toronto-based Community Pediatrician
> *"Respiratory Syncytial Virus significantly impacts infants and children whom I care for in community and hospital settings. I am excited to hear that nirsevimab obtained Health Canada approval."*

The approval was based upon a BEYFORTUS™ clinical development program spanning three pivotal late-stage clinical trials, including results from the Phase 3 MELODY trial recently published in the New England Journal of Medicine.[9]

> ***Jason Lee***
> Head of Vaccines Medical Affairs, Sanofi Canada
> *"Today is a historical day for RSV prevention as decades of research and development culminate in Canada's approval of the first immunization against RSV disease. BEYFORTUS™, designed using a long-acting mAB will help meet a vast unmet need in RSV prevention, providing parents with an option to protect their infants during the first RSV season."*

Sanofi is committed to making BEYFORTUS™ available to newborns and infants for the upcoming 2023/2024 RSV season.

About RSV

RSV is the most common cause of LRTD, including bronchiolitis and pneumonia, in infants. In Canada, RSV is a leading cause of hospitalizations in infants, with children under the age of 2 being 14 times more likely to be hospitalized due to RSV than influenza.[4,5] All infants are potentially at risk of developing a severe RSV infection.[6,7,8] Most hospitalizations for RSV occur in healthy infants born at term.[3,10] RSV also places a burden on the health system, with most hospitalized infants needing supplemental oxygen and some requiring ICU admission.[11,12]

About BEYFORTUS™ (nirsevimab)

BEYFORTUS™ is approved by Health Canada for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in newborns and infants during their first RSV season, and children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.[1]

BEYFORTUS™, an immunizing agent and a long-acting antibody designed for all infants for protection against LRTD from birth through their first RSV season with a single dose, is developed jointly by Sanofi and AstraZeneca.

BEYFORTUS™ has been developed to offer newborns and infants direct RSV protection via an antibody to help prevent LRTD caused by RSV. Monoclonal antibodies do not require the activation of the immune system to help offer timely, rapid, and direct protection against the disease.

In March 2017, Sanofi and AstraZeneca entered into an agreement to develop and commercialize BEYFORTUS™. Under the terms of the agreement, AstraZeneca leads development and manufacturing activities, and Sanofi leads commercialization activities.

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 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, Sanofi employs approximately 2,000 people and in 2022, we invested more than $145 million in R&D in Canada, creating jobs, business, and opportunity throughout the country.

REFERENCES

1 BEYFORTUS™ Product Monograph. AstraZeneca Canada. April 19, 2023.

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3 Hall CB, et al. Pediatrics 2013;132(2);e34a–38

4 Schanzer DL, et al. Influenza Other Respir Viruses 2018;12:113–21; doi: 10.1111/irv.12497

5 Data extracted from the Canadian Discharge Abstract Database from 2003 to 2014 using a regression model to estimate respiratory hospitalizations attributable to influenza, RSV and other respiratory viruses.

6 Arriola CS, et al. J Pediatric Infect Dis Soc 2020;9(5):587–95

7 Pisesky A, et al. Incidence of Hospitalization for Respiratory Syncytial Virus Infection amongst Children in Ontario, Canada: A
Population-Based Study Using Validated Health Administrative Data. 2016 Mar 9;11(3):e0150416. doi: 10.1371/journal.pone.0150416

8 Buchan SA, et al. Pediatr Infect Dis J 2019 Apr;38(4):362–69

9 Muller W, et al. Nirsevimab for Prevention of RSV in Term and Late-Preterm Infants. 2023 Apr 5; DOI: 10.1056/NEJMc2214773

10 Data from a 5-year, prospective, population-based surveillance of children hospitalized with RSV between October 2000 and
March 2005. Among 559 RSV-hospitalized infants aged <24 months, 79% were previously healthy

11 Mitchell I, et al. Can Respir J 2017; Article ID 4521302, https://doi.org/10.1155/2017/4521302

12 A prospective, observational, survey-based analysis of the burden of RSV. Infants included in the study were <1 year of age and
were hospitalized with a confirmed diagnosis of RSV/LRTI (N=67)

SOURCE Sanofi Canada

For further information: Media Relations: Augustine Fischer, 289 260 4165, Augustine.fischer@sanofi.com; Kendra Stephenson, 289 894 0828, kstephenson@getproof.com