News Releases

Health Canada accepts nirsevimab regulatory submission for infant RSV

- Nirsevimab is the first investigational long-acting antibody designed for all infants to help protect against respiratory syncytial virus (RSV) throughout their first RSV season with a single dose
- Health Canada has accepted the file for review with a regulatory decision expected in Q4 of 2023
- Nirsevimab has already been approved by the European Commission and the UK as the first and only broadly protective option against RSV for newborns and infants

TORONTO, Jan. 18, 2023 /CNW/ - Health Canada has accepted a New Drug Submission (NDS) for nirsevimab, the first investigational single-dose long-acting antibody designed for all infants to help protect against medically attended lower respiratory tract infections (LRTI) throughout their first respiratory syncytial virus (RSV) season. Nirsevimab is being developed by Sanofi and AstraZeneca.

According to the National Advisory Committee on Immunization (NACI), "RSV infects almost all infants by 2 years of age."[1] Nirsevimab is an immunization designed for all infants to provide direct prophylactic RSV protection.

> ***Jean-Pierre Baylet***
> General Manager, Vaccines, Sanofi Canada
> *"The recent spikes in bronchiolitis and hospitalizations caused by RSV infection in Canada demonstrate the urgent need for a preventative option that can help protect all infants. We are pleased to receive this regulatory filing acceptance and remain confident in nirsevimab's potential, if approved, to change the current RSV prevention paradigm as a single-dose option that can offer sustained protection to all Canadian infants throughout the season."*

The NDS is based on results from the Phase 3 MELODY trial, Phase 2/3 MEDLEY trial, and Phase 2b trial which studied the safety and efficacy of a single dose of nirsevimab against LRTI due to RSV for the RSV season.

Nirsevimab was recently approved by the Medicines and Healthcare products Regulatory Agency in the United Kingdom and by the European Commission, following a positive opinion from the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP).

Nirsevimab is an investigational product that is not currently authorized for sale in Canada.

About RSV

RSV is a common, contagious virus that causes seasonal epidemics of lower respiratory tract infections (LRTI). In Canada RSV is the leading cause of respiratory hospitalizations and on average causes 14 times more hospitalizations than influenza in infants under the age of 2.[2] Globally, in 2019, there were 33 million RSV-associated acute lower respiratory infection episodes, 3.6 million RSV-associated acute lower respiratory infection hospital admissions, 26,300 RSV-associated acute lower respiratory infection in-hospital deaths, and 101,400 RSV-attributable overall deaths in children aged 0–60 months.[3,6] In recent months, there has been a resurgence of RSV following the easing of COVID-19 public health measures.[7,8] Most hospitalizations for RSV occur in otherwise healthy infants born at term.[9,10] Medically attended LRTIs are associated with increased costs to the healthcare system.[11]

About nirsevimab

Nirsevimab is an investigational long-acting antibody designed to help protect all infants for the RSV season with a single dose. Due to its extended half-life technology, nirsevimab is being developed as a single dose for all infants experiencing their first RSV season and infants with specific conditions, such as congenital heart disease or chronic lung disease, entering their first and second RSV season.[12-14]

Nirsevimab is an immunization designed to provide direct prophylactic RSV protection to all infants via an antibody to help prevent LRTI caused by RSV. Monoclonal antibodies do not require the activation of the immune system to help offer rapid and direct protection against disease.[15]

In March 2017, Sanofi and AstraZeneca announced an agreement to develop and commercialize nirsevimab. Under the terms of the agreement, AstraZeneca leads all development and manufacturing activities and Sanofi will lead commercialization activities and record revenues.

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.

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