

Nirsevimab shows positive topline results in RSV Phase 2/3 MEDLEY trial

- * Respiratory syncytial virus (RSV) is the leading cause of hospitalization in all infants^{1,2}
- * Nirsevimab is being investigated as a first-in-class single dose immunization to provide protection for all infants entering their first RSV season
- * MEDLEY is the third pivotal trial to report positive data for nirsevimab; regulatory submissions planned for the first half of 2022

PARIS – June 28, 2021 - In positive topline results from the Phase 2/3 MEDLEY trial, nirsevimab showed a similar safety and tolerability profile compared to palivizumab when administered to preterm infants or those with chronic lung disease (CLD) or congenital heart disease (CHD) entering their first respiratory syncytial virus (RSV) season.³ Safety and tolerability were assessed by the occurrence of all treatment emergent adverse events (TEAEs) and treatment emergent serious adverse events (TESAEs).

RSV, a seasonal virus that typically circulates in autumn through spring in temperate regions, is the most common cause of lower respiratory tract infections (LRTI) and the leading cause of hospitalizations in all infants.^{1,2,4}

“These data for nirsevimab are important as they show a safety and tolerability profile comparable to the only available preventative option against lower respiratory tract infections caused by RSV for preterm infants and those with health conditions,” said Dr. Joseph Domachowske, Professor of Pediatrics and Professor of Microbiology and Immunology at the State University of New York, Upstate Medical Center and MEDLEY trial primary investigator. “Given the typical RSV season lasts nearly five months, there is a potential advantage to providing a preventative option that could help protect all infants with one dose for the entire season.”

MEDLEY is the third pivotal trial to report positive data for nirsevimab. In April, Sanofi [reported](#) that nirsevimab met its primary endpoint of achieving a statistically significant reduction of LRTI caused by RSV in healthy preterm and term infants in the Phase 3 MELODY trial. Coupled with recently published [Phase 2b trial](#) results, MELODY and MEDLEY results are part of a robust body of evidence demonstrating the potential of nirsevimab to provide RSV protection to all infants. Results from the MELODY and MEDLEY trials will be presented at forthcoming scientific congresses and, along with the Phase 2b results, will form the basis of global regulatory submissions planned for 2022.

“RSV is the major remaining pediatric infectious disease with no preventative option available to all infants,” said Jean-François Toussaint, Global Head of Research and Development, Sanofi Pasteur. “We believe nirsevimab has the potential to become an important and innovative routine immunization for all infants – those born prematurely or at term, healthy or with health conditions.”

“RSV is the leading cause of hospitalizations in infants,” said Mene Pangalos, Executive Vice President, BioPharmaceuticals R&D, AstraZeneca. “These results, combined with the recent positive efficacy outcome of our MELODY Phase 3 trial and our Phase 2b data, contribute to the body of evidence demonstrating nirsevimab’s potential to protect all infants against RSV with one dose. We look forward to sharing the results with regulators.”

Nirsevimab, being developed in partnership with AstraZeneca, is the first investigational extended half-life monoclonal antibody (mAb) aiming to protect all infants entering their first RSV season, when they are at highest risk for severe RSV disease.⁵⁻⁷ With nirsevimab, the goal is to provide rapid and direct protection to the infant through a single immunization.

Nirsevimab is designed to be administered from birth to infants born during the RSV season or at the season’s start for infants entering their first RSV season. In contrast to other options for RSV under development, such as maternal immunization, the aim of nirsevimab is to offer protection when needed to all infants entering their first season.

About the Phase 2/3 MEDLEY clinical trial

MEDLEY is a Phase 2/3, randomized, double-blind, palivizumab-controlled trial with the primary objective to evaluate the safety and tolerability of nirsevimab compared to palivizumab when administered to preterm infants entering their first respiratory syncytial virus (RSV) season and children with CLD and CHD entering their first and second RSV season.³ Safety is assessed by monitoring the occurrence of TEAEs and TESAEs through 360 days post-dose. Between July 2019 and May 2021 approximately 925 infants entering their first RSV season were dosed with either nirsevimab or palivizumab.

The evaluation of nirsevimab was carried out earlier than anticipated, based on sufficient enrollment, allowing for the assessment of nirsevimab’s safety and tolerability versus palivizumab in infants followed through their first RSV season. The trial is ongoing to collect additional safety data in toddlers with CLD or CHD dosed prior to the second season. Results from the MEDLEY trial will be presented at a forthcoming scientific congress.

About RSV

RSV is a common, contagious virus that infects the respiratory tract, causing millions of hospitalizations globally in infants, and is the most common cause of bronchiolitis and pneumonia in children younger than one year.^{1,5,8-12} Hospitalization rates due to RSV

infection are consistently highest in the first year of life – with infants under one year representing 75% of RSV hospitalizations in children under 5 years.^{8,13,14} Most hospitalizations for RSV occur in otherwise healthy infants born at term.^{8,15} Moreover, medically-attended LRTIs are associated with increased costs to the healthcare system.¹⁶

About nirsevimab

Nirsevimab is an investigational extended half-life RSV mAb being developed as a passive immunization for the prevention of LRTI caused by RSV. It is designed to protect all infants experiencing their first RSV season and infants with congenital heart disease or chronic lung disease entering their first and second RSV season.^{3,17}

Nirsevimab is developed with the goal of providing RSV protection via an antibody given directly to an infant to help prevent LRTI caused by RSV, unlike active immunization, where a person's immune system is activated to prevent or fight infection through a vaccine.¹⁸ Passive immunization could offer rapid protection.¹⁸

In March 2017, AstraZeneca and Sanofi announced an [agreement](#) to develop and commercialize nirsevimab. Under the terms of the agreement, AstraZeneca leads all development activity through initial approvals and retains manufacturing activities and Sanofi will lead commercialization activities. Nirsevimab is currently under clinical investigation and its safety and efficacy have not been reviewed by any regulatory authority.

Editor's note: In January 2021, nirsevimab received the [Promising Innovative Medicine \(PIM\) Designation](#) from the UK Medicines and Healthcare Products Regulatory Agency (MHRA) and was also granted the Breakthrough Therapy Designation (BTD) by the China Center for Drug Evaluation (CDE) under the National Medical Products Administration. In February 2019, the US Food and Drug Administration granted [Breakthrough Therapy Designation](#) for nirsevimab for the prevention of LRTI caused by RSV, and the European Medicines Agency (EMA) granted access to its [PRiority MEdicines \(PRIME\) scheme](#) for the same indication. In Japan, nirsevimab was also selected by the Japan Agency for Medical Research and Development (AMED) as “a medicine for prioritized development” under the Project for Drug Selection to Promote New Drug Development in Pediatrics.

About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

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