Press Release

FDA Advisory Committee unanimously recommends nirsevimab as first immunization against RSV disease for all infants

- Nirsevimab would be the first immunization specifically designed to protect all infants through their first RSV season, if approved
- Across all clinical trials, a single dose of nirsevimab delivered high, consistent and sustained efficacy and favorable safety against RSV disease
- The FDA has indicated it will work to expedite its review; Sanofi remains committed to delivering nirsevimab in time for the 2023-2024 RSV season

Paris, June 8, 2023. The U.S. Food and Drug Administration (FDA) Antimicrobial Drugs Advisory Committee (AMDAC) voted unanimously 21 to 0 that Sanofi and AstraZeneca's nirsevimab has a favorable benefit risk profile for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease (LRTD) in newborns and infants born during or entering their first RSV season. The Committee also voted 19 to 2 in support of nirsevimab's favorable benefit risk profile for children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.

Thomas Triomphe
Executive Vice President, Vaccines, Sanofi
"Most babies hospitalized with RSV are born at term and healthy, which is why interventions specifically designed to protect all infants are likely to result in the greatest impact. We are encouraged by the Advisory Committee's positive vote based on the compelling clinical development program supporting nirsevimab and its breakthrough potential to reduce the magnitude of annual RSV burden."

Iskra Reic
Executive Vice President, Vaccines and Immune Therapies, AstraZeneca
"We are delighted that the Antimicrobial Drugs Advisory Committee has unanimously recognized the favorable benefit risk profile of nirsevimab as the first preventative option against RSV for a broad infant population. Nirsevimab builds on AstraZeneca's strong science, leadership in RSV and commitment to addressing the needs of the most vulnerable. We look forward to continuing to work with the FDA to complete their expedited review, and we hope to see nirsevimab available as soon as possible given the significant burden of RSV in infants."

Dr William Muller
Associate Professor, Pediatrics, Northwestern University Feinberg School of Medicine and Scientific Director, Clinical and Community Trials, Ann & Robert H. Lurie Children's Hospital of Chicago, Illinois
"RSV remains the most common cause of bronchiolitis and pneumonia in infants, and the inability to predict which infants will develop severe RSV disease leads to uncertainty for new parents and for physicians. The innovation of nirsevimab as a long-acting antibody that can be conveniently administered to a broad infant population with a single dose at the time protection is most needed is a significant public health advancement that could have far-reaching impact on the well-being of our families and healthcare systems in the U.S."

If approved, nirsevimab would be the first immunization specifically designed to protect all infants through their first RSV season, including those born healthy at term or preterm, or with specific health conditions that make them vulnerable to RSV disease. The single dose can be administered at the beginning of the RSV season or at birth for those born during the RSV season.

The FDA accepted the Biologics License Application (BLA) for nirsevimab in 2022 and the agency has indicated it will work to expedite its review. The Prescription Drug User Fee Act date is in the third quarter of 2023. If approved by that time, nirsevimab will be available in the U.S. ahead of the 2023-2024 RSV season.

The AMDAC based its recommendation on the robust nirsevimab 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. Across all clinical endpoints, a single dose of nirsevimab demonstrated high and consistent efficacy against RSV LRTD sustained through the entire RSV season. Nirsevimab was well tolerated with a favorable safety profile that was consistent across all clinical trials. The overall rates of adverse events were comparable between nirsevimab and placebo and the majority of adverse events were mild or moderate in severity. The most common adverse events were rash, fever and injection site reactions.

AMDAC reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of infectious diseases and disorders and makes appropriate recommendations to the Commissioner of Food and Drugs. The AMDAC's recommendation, while not binding, will be considered by the FDA during its review of the BLA for nirsevimab.

About RSV

RSV is a very contagious virus that can lead to serious respiratory illness for infants, according to the Centers for Disease Control and Prevention (CDC). RSV symptoms can include runny nose, coughing, sneezing, fever, decrease in appetite, and wheezing.[1] Two out of three infants are infected with RSV during their first year of life and almost all infants are infected by their second birthday.[1,2] In the U.S., RSV is the leading cause of hospitalization in infants under 12 months, averaging 16 times higher than the annual rate for influenza.[3,4] Approximately 75% of infants hospitalized for RSV are born healthy and at term with no underlying conditions.[5] Each year in the U.S., there are an estimated 590,000 RSV disease cases in infants under one requiring medical care, including physician office, urgent care, emergency room visits and hospitalizations.[6]

About nirsevimab

In the U.S., nirsevimab is an investigational single-dose long-acting antibody designed to protect all infants through their first RSV season and for children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.

Nirsevimab, provided directly to newborns and infants as a single dose, offers RSV protection via an antibody to help prevent lower respiratory tract disease caused by RSV. Monoclonal antibodies do not require the activation of the immune system to help offer timely, rapid and direct protection against disease.[7]

In March 2017, Sanofi and AstraZeneca announced an agreement to develop and commercialize nirsevimab. 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 €55m and will pay up to a further €440m upon achievement of certain 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.

Nirsevimab has been granted special designations to facilitate expedited development by several regulatory agencies around the world. These include Breakthrough Therapy Designation and Priority Review designation by the China Center for Drug Evaluation under the National Medical Products Administration; Breakthrough Therapy Designation from the FDA; access granted to the European Medicines Agency (EMA) PRIority MEdicines (PRIME) scheme and EMA accelerated assessment; Promising Innovative Medicine designation by the UK Medicines and Healthcare products Regulatory Agency; and named "a medicine for prioritized development" under the

Project for Drug Selection to Promote New Drug Development in Pediatrics by the Japan Agency for Medical Research and Development.

Nirsevimab has been granted marketing authorization in the European Union, Great Britain and Canada for the prevention of RSV lower respiratory tract disease in newborns and infants from birth through their first RSV season and is currently undergoing regulatory review in the U.S. In Canada, nirsevimab is also approved for children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season and such indication is under review at the EMA level.

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.

Sanofi is listed on EURONEXT: SAN and NASDAQ: SNY

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