Press Release
India

Sanofi receives marketing authorization for Beyfortus® in India to protect infants & children against Respiratory Syncytial Virus (RSV)

- Multiple studies have highlighted RSV as the most prevalent respiratory virus in India*
- Beyfortus (nirsevimab) is the first monoclonal antibody approved to protect all infants born during or entering their 1st RSV season

Mumbai, July 31, 2024. Sanofi (India) announced that on 10th June 2024 it has received marketing authorization approval from the Central Drugs Standard Control Organization (CDSCO) for Beyfortus in India. Beyfortus contains the monoclonal antibody nirsevimab in a prefilled injection used 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. It is also administered in children up to 24 months of age, who remain vulnerable to severe RSV disease through their second RSV season.

RSV is a highly contagious virus that can lead to serious respiratory illness for infants[i]. Two out of three infants are infected with RSV during their first year of life and almost all children are infected by their second birthday. [ii]In addition to being the most common cause of LRTD such as bronchiolitis and pneumonia in infants[iii], RSV is also a leading cause of hospitalization in infants worldwide, with most hospitalizations occurring in healthy infants born at term. [ivvvivii] In 2019, there were approximately 33 million cases of acute lower respiratory infections globally, leading to more than 3 million hospitalizations, and it was estimated that there were 26,300 in-hospital deaths of children younger than 5 years.[viii]

Preeti Futnani

General Manager – Sanofi Vaccines (India)

"Prevention of RSV in India is still an unmet medical need. This makes the approval of Beyfortus a landmark moment for Sanofi in India. We are prioritizing this potential game-changer to make Beyfortus available for all Indian parents to help protect their babies during their first and second RSV seasons."

Dr. Kuharaj Mahenthiran

Country Medical Head, Sanofi Vaccines (India)

"Data gathered from all geographical regions of India (from 1970 to 2020) to assess the burden of respiratory viruses and their prevalence, found RSV to be the most prevalent respiratory virus (29%) followed by Influenza A[ix]. The CDSCO approval for Beyfortus was based on a clinical

program spanning three pivotal late-stage clinical trials. Across all clinical endpoints, a single dose of Beyfortus demonstrated high and consistent efficacy against RSV LRTD in all infant populations studied. These included babies born healthy at term, late preterm or preterm, or with specific health conditions that make them vulnerable to severe RSV disease. Beyfortus was also well tolerated with a favorable safety profile that was consistent across all clinical trials."

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.
For more information about the terms of Sanofi's financial agreements, refer to Sanofi's corporate website.

Beyfortus has been approved for use in the European Union, the US, China, Japan, and many other countries around the world.

About Beyfortus
Beyfortus (nirsevimab) is the first immunization designed for all infants for protection against RSV through their first RSV season, including for those born healthy at term or preterm, or with specific health conditions that make them vulnerable to RSV disease. Beyfortus is also designed to protect children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.
As a long-acting antibody provided directly to newborns and infants as a single dose, Beyfortus 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.

Sanofi in India
As Sanofi India, we are in a great place to make a difference. Present in India for nearly seven decades, we have earned the trust of our customers and stakeholders for our commitment to promoting health. As we chase the miracles of science to improve people's lives, we continue to engage across the entire health spectrum from prevention with vaccines to wellness, treatment, patient support & capacity building.

Our India Charitable Access Program (InCAP) is the country's longest running humanitarian program providing free treatment to people afflicted with Lysosomal Storage Disorders. We conduct clinical trials here so that India can have quicker access to the latest from our global pipeline. Our world-class manufacturing site in Goa produces for people in India and 60+ other countries. Sanofi has located one of its four global talent hubs in Hyderabad, India, from where wide range of services are provided globally.

Recognized by the 'Top® Employers Institute' – a global authority that honours excellence in people practices since 2019, our local entities include Sanofi India Limited (SIL - listed entity), Sanofi Healthcare India Pvt. Ltd. (SHIPL) and Sanofi Consumer Healthcare India Limited (SCHIL).

Visit us at www.sanofi.in and www.sanofiindialtd.com, or connect with us on LinkedIn and Twitter.

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 the world, 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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