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Sanofi receives marketing authorisation for Beyfortus in India to protect children against Respiratory Syncytial Virus

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Beyfortus is the first monoclonal antibody approved to protect all infants born during or entering their 1st RSV season



Sanofi (India) has received marketing authorisation approval from the Central Drugs Standard Control Organisation (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.

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.

Preeti Futnani, General Manager – Sanofi Vaccines (India) said, “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 prioritising this potential game-changer to make Beyfortus available for all Indian parents to help protect their babies during their first and second RSV seasons.”

According to 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 Aix. The CDSCO approval for Beyfortus was based on a clinical programme 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 commercialisation activities and records revenues.

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