BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Malaysia approves Sanofi and AstraZeneca's BeyfortusÃ?Â® (nirsevimab)

November 24, 2025 | News

BeyfortusÃ?Â® (nirsevimab) is an available option designed to protect all infants against respiratory syncytial virus (RSV)



Sanofi and AstraZeneca's Beyfortus (Nirsevimab) is now approved (KKLIU 3697 / EXP 16.05.2026) by the National Pharmaceutical Regulatory Agency (NPRA) and is available for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in newborns and infants born during or entering their first RSV season.

RSV is predominantly seen in infants less than 1 year old and infected children below 2 years old had a high hospitalisation rate of 84.5%. As a tropical climate country, RSV circulation in Malaysia is seen throughout the year with distinct peaks.

The approval was based on results from the extensive Beyfortus clinical development programme spanning across broad infant population from pre-term, heathy full-term and those with underlying comorbidities. Across all clinical endpoints, a single dose of Beyfortus demonstrated high and consistent efficacy against RSV disease sustained for at least six months. Beyfortus was well tolerated with a favourable safety profile that was consistent across all clinical trials and real world evidence. The overall rates of adverse events were comparable between Beyfortus and placebo and the majority of adverse events were mild or moderate in severity.

In temperate countries, the single administration of Beyfortus was developed to correspond with the beginning of the RSV season for babies born prior to the season or at birth for those born during the RSV season. In clinical trials, Beyfortus helped prevent RSV disease requiring medical care in all infant populations studied, including those born healthy, at term or preterm, or with specific health conditions that make them vulnerable to severe RSV disease. RSV disease requiring medical care

included physician office, urgent care, emergency room visits and hospitalisations.