Press Release

Beyfortus public health advantage bolstered by first real-world comparison of infant vs maternal RSV immunization programs

- Late-breaking data show infant respiratory syncytial virus (RSV) hospitalizations reduced by 69% in Spain following Beyfortus-only immunization targeted to all infants and 26.7% in the UK following RSVpreF-only maternal vaccination
- Newly presented durability data show Beyfortus sustained efficacy of 83% through six months in babies born before or during the RSV season

Paris, May 29, 2025. An immunization program implemented in Spain using Beyfortus cut infant hospitalizations due to RSV by 69.0% during the 2024-2025 RSV season compared to the 2022-2023 season, according to data presented at the 43rd Annual Meeting of the European Society for Paediatric Infectious Diseases (ESPID) in Bucharest, Romania. The real-world analysis also showed that a program in the UK using only the RSVpreF maternal vaccine reduced infant RSV hospitalizations in infants by 26.7% over those same RSV seasons.

Sanofi's observational, retrospective REACH study is the first multi-country public health impact analysis of infant RSV prevention programs. These late-breaking data will be presented for the first time today during an oral session (Session 09: Late Breaking) from 2:00 – 3:30 pm EEST at ESPID, which is taking place from May 26-30, 2025.

Other data from Sanofi at ESPID include new durability data from the HARMONIE Phase 3b clinical study, now published in *The Lancet Child & Adolescent Health*, that demonstrates Beyfortus reduced RSV hospitalizations in infants by 82.7% (95% CI: 67.8 to 91.5; p<0.0001) through six months (180 days) compared to no intervention, exceeding the typical length of the five-month RSV season. The high efficacy of 83.2% previously reported in the primary analysis was sustained over the longer follow-up period with no evidence of waning protection in infants born before or during the RSV season. Beyfortus maintained a favorable safety profile, consistent with clinical study results. Those results will be shared in an oral presentation on Friday, May 30 from 10:40 – 10:50 EEST (Oral Presentation Session 10: Preventing RSV).

> ***Thomas Triomphe***
> Executive Vice President, Vaccines
> *"The six-month data from HARMONIE show Beyfortus' protection exceeded the typical five-month RSV season. This is important because half of infant RSV hospitalizations occur in older babies born before the RSV season begins. These data demonstrating high, sustained efficacy, combined with real-world public health impact data, underscore how Beyfortus provides proven protection against the number one cause of lower respiratory tract disease in all infants."*

Additional late-breaking data for Beyfortus at ESPID 2025 (Poster presentation #EV1006) reinforce Beyfortus as cost-effective in preventing RSV disease in infants, with results showing Beyfortus prevents more medically attended RSV cases when compared with clesrovimab, another antibody in development.

Beyfortus has amassed real-world data in over 40 studies spanning four continents and more than 250,000 immunized infants – the largest body of public health impact data for infant RSV protection across countries, population groups and healthcare settings. With more than six million infants immunized, Beyfortus is well accepted by parents and providers and remains the only option that can offer RSV protection designed for all infants with proven high, sustained efficacy, favorable safety and public health impact demonstrated in the real world.

About RSV
RSV is a highly contagious virus that can lead to serious respiratory illness for infants. 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. RSV is the most common cause of lower respiratory tract disease, including bronchiolitis and pneumonia, in infants. It is also a leading cause of hospitalization in infants worldwide, with most hospitalizations for RSV occurring in healthy infants born at term. Globally, in 2019, there were approximately 33 million cases of acute lower respiratory infections leading to more than three million hospitalizations in children younger than five years. RSV-related direct medical costs, globally — including hospital, outpatient and follow-up care — were estimated at c.€5 billion in 2017.

About Beyfortus
Beyfortus is the first immunization designed for all infants for protection against RSV disease through their first RSV season, including for those born before or during the RSV season, healthy at term or preterm, or with specific health conditions. 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 and direct protection to help prevent lower respiratory tract disease caused by RSV without requiring activation of the immune system. Beyfortus administration can be timed to coincide with the RSV season.

Beyfortus has been approved for use in the US, the EU, China, Japan, and many other countries around the world. Special designations to facilitate expedited development of Beyfortus were achieved in several countries, including breakthrough therapy designation and fast track designation in the US; PRIority MEdicines (PRIME) and accelerated assessment in the EU; "a medicine for prioritized development" in Japan, and breakthrough therapy designation and priority review designation in China.

About REACH
The REACH study was performed on the LOGEX RTI Observatory, ran by healthcare analytics company LOGEX, and used administrative and microbiology data from multiple hospital sites across Spain and the UK. Data collection is ongoing through May 2025, with current results reflecting three consecutive RSV seasons from June 2022 through the end of March 2025. Hospitals report RSV hospitalizations from the current season as well as historical seasons for each country separately. No RSV prevention program was in place for the 2022-23 RSV season.

About HARMONIE
The **H**ospit**a**lized **R**SV **Mon**oclonal Ant**i**body Pr**e**vention (HARMONIE) study is a large European Phase 3b clinical trial conducted in multi-country, close to real-world conditions to reinforce the efficacy and safety of Beyfortus for the prevention of RSV-related hospitalizations in infants up to 12 months of age who are not eligible to receive palivizumab.

The trial opened at nearly 250 sites and enrolled more than 8,000 infants born with a gestational age of 29 weeks or greater during the 2022-2023 RSV season. Primary results from the study published in *The New England Journal of Medicine* (NEJM) confirmed efficacy of 83.2% (95% CI 67.8 to 92.0; P<0.001) for Beyfortus against RSV-related hospitalizations and efficacy of 75.7% (95% CI: 32.8 to 92.9; P=0.004) against very severe RSV lower respiratory tract disease compared to no RSV intervention (standard of care) through the RSV season.

About Sanofi
Sanofi is an R&D driven, AI-powered biopharma company committed to improving people's lives and creating compelling growth. We apply our deep understanding of the immune system to invent medicines and vaccines that treat and protect millions of people around the world, with an innovative pipeline that could benefit millions more. Our team is guided by one purpose: we chase the miracles of science to improve people's lives; this inspires us to drive progress and

deliver positive impact for our people and the communities we serve, by addressing the most urgent healthcare, environmental, and societal challenges of our time.

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