Shortage of recently approved Beyfortus™ (nirsevimab-alip) due to high demand

- Currently, there is a nationwide shortage of Sanofi's Beyfortus (nirsevimab-alip), a monoclonal antibody used in newborns and infants to protect against respiratory syncytial virus (RSV) disease due to increased demand.

- Beyfortus is available as both a 50 mg/0,5 mL and a 100 mg/1 mL single dose pre-filled syringe. Dosage depends on age, weight, and indication. Using two 50 mg strengths in place of a 100 mg strength has not been studied and is not approved or recommended. Supply constraints mainly impact the 100 mg strength.

- Beyfortus is on allocation with supply being distributed based on historical orders. Sanofi is working with their manufacturing partner, AstraZeneca, to accelerate additional supply and explore a number of actions to extend the manufacturing network.

- RSV is a seasonal disease that occurs between October and April each year and typically causes respiratory illness such as runny nose, coughing, sneezing, fever, wheezing). In more serious cases it can cause bronchiolitis and pneumonia. RSV is the most common cause of hospitalization in infants and can cause serious illness and death in infants and young children. Each year in the U.S., an estimated 58,000-80,000 children younger than 5 years are hospitalized due to RSV infection.

- Beyfortus was approved in July 2023 and is indicated for the prevention of RSV lower respiratory tract disease in neonates and infants born during or entering their first RSV season and in children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season. Beyfortus must be administered by a healthcare provider.

- At this time, there is no information on how long the shortage will last and when additional supply will be available. The Drug Safety Team will continue to monitor Beyfortus and provide updates when available.