Beyfortus™ (nirsevimab-alip) – New drug approval

- On July 17, 2023, the FDA announced the approval of Sanofi and AstraZeneca's Beyfortus (nirsevimab-alip), for the prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract disease in:
    - Neonates and infants born during or entering their first RSV season
    - Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.

- While most infants and young children experience mild, cold-like symptoms, some infants, especially with their first RSV infection, develop lower respiratory tract disease such as pneumonia and bronchiolitis, that often leads to an emergency department or physician office visit.
    - Approximately 1% to 3% of children under 12 months of age in the U.S. are hospitalized each year due to RSV, according to the American Academy of Pediatrics.
    - In most parts of the U.S., RSV circulation is seasonal, typically starting during the fall and peaking in the winter; it is transmitted from person to person through close contact with someone who is infected.

- Beyfortus is a monoclonal antibody with activity against RSV. It is the first monoclonal antibody approved to protect all infants through their first RSV season.

- The efficacy of Beyfortus was supported by three studies (Trials 03, 04, and 05). The key measure of efficacy was the incidence of medically attended RSV lower respiratory tract infection (MA RSV LRTI), evaluated during the 150 days after Beyfortus administration. MA RSV LRTI included all health care provider visits (physician office, urgent care, emergency room visits and hospitalization) for lower respiratory tract disease with worsening clinical severity and a positive RSV test. Trials 03 and 04 were randomized, double-blind, placebo-controlled studies.
    - Trial 03 included 1,453 preterm infants who were born during or entering their first RSV season. Of the 1,453 preterm infants in the trial, 969 received a single dose of Beyfortus and 484 received placebo. Among infants who were treated with Beyfortus, 25 (2.6%) experienced MA RSV LRTI compared with 46 (9.5%) infants who received placebo. Beyfortus reduced the risk of MA RSV LRTI by approximately 70% relative to placebo ($p < 0.001$).
    - For Trial 04, the primary analysis group within the trial included 1,490 term and late preterm infants, 994 of whom received a single dose of Beyfortus and 496 of whom received placebo. Among infants who were treated with Beyfortus, 12 (1.2%) experienced MA RSV LRTI compared with 25 (5.0%) infants who received placebo Beyfortus reduced the risk of MA RSV LRTI by approximately 75% relative to placebo ($p < 0.001$).
    - Trial 05, a randomized, double-blind, active (palivizumab)-controlled study, supported the use of Beyfortus in children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season. The trial enrolled 925 preterm infants and infants with chronic lung disease of prematurity or congenital heart disease. The safety and pharmacokinetic data from Trial 05 provided evidence for the use of Beyfortus to prevent MA RSV LRTI in this population.

- Warnings and precautions for Beyfortus include hypersensitivity including anaphylaxis and use in individuals with clinically significant bleeding disorders.

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- The most common adverse reactions with Beyfortus use were rash and injection site reactions.
- For neonates and infants born during or entering the RSV season, Beyfortus should be administered starting from birth. For infants born outside the RSV season, Beyfortus should be administered once prior to the start of the RSV season considering duration of protection provided by Beyfortus.
- The recommended dosage of Beyfortus for neonates and infants born during or entering their first RSV season is based on body weight and is administered as a single intramuscular (IM) injection.
    - For neonates and infants less than 5 kg, the dose is 50 mg. For neonates and infants 5 kg and greater, the dose is 100 mg.
- For children up to 24 months of age who remain at increased risk for severe RSV disease in their second RSV season, the recommended dosage of Beyfortus is a single 200 mg dose administered as two IM injections (2 x 100 mg).
- Refer to the Beyfortus drug label for additional dosing and administration recommendations.
- AstraZeneca and Sanofi plan to launch Beyfortus ahead of the upcoming 2023-2024 RSV season. Beyfortus will be available as 50 mg/0.5 mL and 100 mg/mL single-dose pre-filled syringes.

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