Arexvy® (respiratory syncytial virus vaccine) – Expanded indication

- On June 7, 2024, GSK announced the FDA approval of Arexvy (respiratory syncytial virus vaccine), for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 50 through 59 years of age who are at increased risk for LRTD caused by RSV.

- Arexvy is the first RSV vaccine approved in individuals 50 through 59 years of age at increased risk for LRTD.

- Arexvy is also approved for active immunization for the prevention of LRTD caused by RSV in individuals 60 years of age and older.

- The approval of Arexvy for the expanded indication was based on a randomized study in 343 individuals 50 through 59 years of age with an increased risk of LRTD caused by RSV due to certain chronic medical conditions (chronic pulmonary disease, chronic cardiovascular disease, diabetes, chronic kidney, or liver disease). Patients were randomized to Arexvy or saline placebo. A comparator group of individuals 60 years and older also received Arexvy. Effectiveness in individuals 50 through 59 years of age was assessed by a comparison of RSV neutralizing antibody responses induced by Arexvy in this age group to antibody responses of individuals 60 years of age and older.

    — The neutralizing antibody responses to RSV-A and RSV-B subtypes in individuals 50 through 59 years of age with chronic medical conditions met the criteria for immunobridging.

- The most commonly reported adverse reactions (≥ 10%) with Arexvy use in individuals 50 through 59 years of age were injection site pain, fatigue, myalgia, headache, arthralgia, erythema, and swelling.

- Arexvy is administered as a single dose (0.5 mL) as an intramuscular injection.