Arexvy (respiratory syncytial virus vaccine, adjuvanted) – New vaccine approval

- On May 3, 2023, the FDA announced the approval of GSK's Arexvy (respiratory syncytial virus vaccine, adjuvanted), for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older.

- Arexvy is the first vaccine approved for RSV.

- RSV is a highly contagious virus that causes infections of the lungs and breathing passages in individuals of all age groups. RSV circulation is seasonal, typically starting during the fall and peaking in the winter. In older adults, RSV is a common cause of LRTD, which affects the lungs and can cause life-threatening pneumonia and bronchiolitis.

    — According to the CDC, each year in the U.S., RSV leads to approximately 60,000 to 120,000 hospitalizations and 6,000 to 10,000 deaths among adults 65 years of age and older.

- The efficacy of Arexvy was established in an ongoing randomized, placebo-controlled, observer-blind clinical study in adults 60 years of age and older. The primary population for efficacy analysis included 24,960 participants randomized equally to receive 1 dose of Arexvy or placebo. At the time of the primary efficacy analysis, participants had been followed for the development of RSV-associated LRTD for up to 10 months. The primary objective was to demonstrate the efficacy of Arexvy in the prevention of a first episode of confirmed RSV-A and/or B-associated LRTD during the first RSV season.

    — Compared with placebo, Arexvy significantly reduced the risk of developing RSV-associated LRTD by 82.6% (96.95% CI: 57.9, 94.1), which met the pre-specified success criterion for the primary study objective.
    — Additionally, Arexvy significantly reduced the risk of developing severe RSV-associated LRTD by 94.1% (95% CI: 62.4, 99.9).

- In a separate concomitant administration, open-label study, patients 60 years of age and older received 1 dose of Arexvy and Fluarix Quadrivalent (FDA-approved influenza vaccine) at month 0 (n = 442) or 1 dose of Fluarix Quadrivalent at month 0 followed by a dose of Arexvy at month 1 (n = 443).

    — There was no evidence for interference in the immune response to any of the antigens contained in both concomitantly administered vaccines.
    — Data are not available for concomitant administration with other vaccines.

- Warnings and precautions for Arexvy include preventing and managing allergic vaccine reactions; syncope; and altered immunocompetence.

- The most commonly reported solicited local adverse reaction (≥ 10%) with Arexvy use was injection site pain. The most commonly reported solicited systemic adverse reactions (≥ 10%) with Arexvy use were fatigue, myalgia, headache, and arthralgia.

- The FDA is requiring GSK to conduct a post-marketing study to assess the signals of serious risks for Guillain-Barré syndrome and acute disseminated encephalomyelitis.

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

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- GSK plans to launch Arexvy before the 2023/2024 RSV season. Arexvy will be available as a single-dose vial of lyophilized antigen component to be reconstituted with the accompanying vial of adjuvant suspension component.
    - In June 2023, the CDC's Advisory Committee on Immunization Practices (ACIP) will make recommendations on the appropriate use of the vaccine.