Audenz™ (Influenza A [H5N1] Monovalent Vaccine, Adjuvanted) – New drug approval

- On January 31, 2020, the FDA approved Seqirus' Audenz (Influenza A [H5N1] Monovalent Vaccine, Adjuvanted), for active immunization for the prevention of disease caused by the influenza A virus H5N1 subtype contained in the vaccine. Audenz is approved for use in persons 6 months of age and older at increased risk of exposure to the influenza A H5N1 virus subtype contained in the vaccine.

    — Use in persons 6 months through 17 years of age is approved under accelerated approval based on the immune response elicited by Audenz. Effectiveness of the seasonal vaccine made by the same process has not been confirmed for this age group. Continued approval for use in this age group may be contingent upon verification and description of clinical benefit in confirmatory trials.

- The influenza antigen contained in Audenz is manufactured according to the same process as that used to produce the antigens contained in Flucelvax® and Flucelvax Quadrivalent (Influenza Vaccine), which are unadjuvanted seasonal influenza vaccines licensed in the U.S. Effectiveness of Audenz was demonstrated based on serum hemagglutination-inhibition (HI) antibody responses to Audenz and effectiveness of Flucelvax, including a demonstration of efficacy of Flucelvax in the prevention of influenza disease in adults 18 through 49 years of age.

- The immunological efficacy of Audenz was evaluated in a randomized, observer-blind, placebo-controlled study in 3,196 adults 18 years of age and older. Patients received either two doses of Audenz or saline placebo, 21 days apart. HI titers were assessed according to prespecified criteria for the proportion of patients with seroconversion and the proportion of patients with a post-vaccination HI titer ≥ 1:40.

    — In adults 18 through 64 years of age, the seroconversion rate was 79.9% (95% CI: 77.4, 82.3) and 0.3% (95% CI: 0.0, 1.6) for Audenz and placebo, respectively. The percentage of patients with a HI titer ≥ 1:40 was 95.0% (95% CI: 93.4, 96.2) and 8.5% (95% CI: 5.9, 12.1), respectively.
    — In adults 65 years of age and older, the seroconversion rate was 54.0% (95% CI: 51.0, 57.0) and 1.7% (95% CI: 0.6, 3.7) for Audenz and placebo, respectively. The percentage of patients with a HI titer ≥ 1:40 was 85.7% (95% CI: 83.3, 87.9) and 20.8% (95% CI: 16.6, 25.8), respectively.

- In addition, an immunological study was conducted in an observer-blind study in 289 children 6 months through 17 years of age.

    — The overall seroconversion rate was 96% (97.5% CI: 93, 98). The percentage of patients with a HI titer ≥ 1:40 was 96% (97.5% CI: 92, 98).

- Warnings and precautions for Audenz include hypersensitivity reactions, Guillain-Barré syndrome, and limitations of vaccine effectiveness.

- The most common adverse reactions (≥ 10%) with Audenz use in adults 18 through 64 years of age were injection site pain, fatigue, headache, malaise, myalgia, arthralgia, and nausea. The most common adverse reactions (≥ 10%) with Audenz use in adults 65 years of age and older were injection site pain, fatigue, malaise, headache, and arthralgia.

- The most common adverse reactions (≥ 10%) with Audenz use in infants and children, 6 months through 5 years of age, were tenderness, irritability, sleepiness, change in eating habits, and fever.

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The most common adverse reactions (≥ 10%) with Audenz use in children 6 through 17 years of age, were injection site pain, myalgia, fatigue, malaise, headache, loss of appetite, nausea, and arthralgia.

- Audenz should be administered intramuscularly as two doses, 21 days apart.
- Seqirus' launch plans for Audenz are pending. Audenz will be available as a 0.5 mL injectable emulsion supplied in a prefilled single-dose syringe.