Indian Health Service
National Pharmacy and Therapeutics Committee
Medication Update

May 4, 2023

FDA Approves First Ever Vaccine for Respiratory Syncytial Virus (RSV)

On May 3rd 2023, the U.S. Food and Drug Administration approved Arexvy®, the first respiratory syncytial virus (RSV) vaccine approved for use in the United States. **Arexvy® is approved for the prevention of lower respiratory tract disease caused by RSV in individuals 60 years of age and older.**

Background:

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 lower respiratory tract disease (LRTD), which affects the lungs and can cause life-threatening pneumonia and bronchiolitis. According to the U.S. Centers for Disease Control and Prevention, each year in the U.S., RSV leads to approximately 60,000-120,000 hospitalizations and 6,000-10,000 deaths among adults 65 years of age and older.

Safety and Efficacy Data:

The safety and effectiveness of Arexvy® is based on the FDA's analysis of data from an ongoing, randomized, placebo-controlled clinical study conducted in the U.S. and internationally in individuals 60 years of age and older. The main clinical study of Arexvy® was designed to assess the safety and effectiveness of a single dose administered to individuals 60 years of age and older. Participants will remain in the study through three RSV seasons to assess the duration of effectiveness and the safety and effectiveness of repeat vaccination. Data for a single dose of Arexvy® from the first RSV season of the study were available for the FDA's analysis.

In this study, approximately 12,500 participants have received Arexvy® and 12,500 participants have received a placebo. Among the participants who have received Arexvy® compared to the participants who have received a placebo, the vaccine significantly reduced the risk of developing RSV-associated LRTD by 82.6% and reduced the risk of developing severe RSV-associated LRTD by 94.1%.

Among a subset of these clinical trial participants, the most commonly reported side effects by individuals who received Arexvy® were injection site pain, fatigue, muscle pain, headache and joint stiffness/pain. Among all clinical trial participants, atrial fibrillation within 30 days of vaccination was reported in 10 participants who received Arexvy® and 4 participants who received placebo.

In two other studies, approximately 2,500 participants 60 years of age and older received Arexvy®. In one of these studies, in which some participants received Arexvy® concomitantly with an FDA-approved influenza vaccine, two participants developed acute disseminated encephalomyelitis (ADEM), a rare type of inflammation that affects the brain and spinal cord, seven and 22 days, respectively, after receiving Arexvy® and the influenza vaccine. One of the participants who developed ADEM died. In the other study, one participant developed Guillain-Barré syndrome (a rare disorder in which the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis) nine days after receiving Arexvy®.

The FDA is requiring the company to conduct a postmarketing study to assess the signals of serious risks for Guillain-Barré syndrome and ADEM. In addition, although not an FDA requirement, the company has committed to assess atrial fibrillation in the postmarketing study.

Agency Considerations:

At the upcoming meeting in August 2023, the Indian Health Service (IHS) National Pharmacy and Therapeutics Committee (NPTC) will be reviewing “Prevention of RSV”, including this newly approved vaccine. Following the August meeting, clinical guidance and formulary implications from the Committee’s decision will be disseminated to the field.

Notably, in 2011, the NPTC voted to add “all Advisory Committee on Immunization Practices (ACIP) recommended vaccines for routine use.” The RSV vaccine manufacturer announced that in June 2023, the ACIP will make recommendations on the appropriate use of the vaccine in the United States. The manufacturer also announced the vaccine will be available for older adults before the 2023-2024 RSV season, which typically starts ahead of the winter months.[2]

References:
1. U.S. Food and Drug Administration, FDA Approves First Respiratory Syncytial Virus (RSV) Vaccine. Published online May 3, 2023
2. GlaxoSmithKline, US FDA approves GSK’s Arexvy, the world’s first respiratory syncytial virus (RSV) vaccine for older adults, Published online May 3, 2023.