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RSV Vaccine Abrysvo Approved for Individuals 60 Years and Older

Brian Park, PharmD | June 1, 2023

Abrysvo is expected to be available in the third quarter of 2023.

Credit: Getty Images.

The Food and Drug Administration (FDA) has approved Abrysvo™ (respiratory syncytial virus vaccine) for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older.

Abrysvo is an unadjuvanted bivalent vaccine containing recombinant RSV prefusion F (preF) A and RSV preF B. The approval was based on data from the randomized, double-blind, placebo-controlled phase 3 RENOIR study (ClinicalTrials.gov Identifier: NCT05035212), which assessed the efficacy and safety of Abrysvo in the prevention of RSV-associated LRTD in adults 60 years of age and older. Patients were randomly assigned to receive Abrysvo (n=17,197) or placebo (n=17,186).

The coprimary endpoints were vaccine efficacy against the first episode of RSV-associated LRTD with at least 2 or at least 3 symptoms. Vaccine efficacy for Abrysvo was reported to be 66.7% (96.66% CI, 28.8-85.8) against RSV-associated LRTD with at least 2 symptoms (11 cases in the vaccine group vs 33 cases in the placebo arm). Vaccine efficacy was reported to be 85.7% (96.66% CI, 32.0-98.7) against RSV-associated LRTD with at least 3 symptoms (2 cases in the vaccine group vs 14 cases in the placebo arm). The median duration of follow-up for efficacy was 7 months.

The most commonly reported solicited local and systemic adverse reactions (incidence at least 10%) were fatigue (15.5%), headache (12.8%), pain at the injection site (10.5%), and muscle pain (10.1%).

“This past RSV season demonstrated the serious consequences and potential health risks this virus poses for older adults,” said Edward E. Walsh, MD, Professor of Medicine, University of Rochester Medical Center, and principal RENOIR investigator. “Today’s FDA approval of Abrysvo recognizes significant scientific progress, and importantly helps

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Abrysvo is supplied in a kit containing a vial of lyophilized antigen component, a prefilled syringe containing diluent and a vial adapter. The lyophilized antigen component should be reconstituted with the accompanying sterile water diluent component to form a single dose that is administered intramuscularly.

Abrysvo is expected to be available in the third quarter of 2023.

References:

1. US FDA approves Abrysvo™, Pfizer's vaccine for the prevention of respiratory syncytial virus (RSV) in older adults. News release. Pfizer. May 31, 2023. Accessed June 1, 2023. https://www.businesswire.com/news/home/20230530005660/en/U.S.-FDA-Approves-ABRYSVO%E2%84%A2-Pfizer%E2%80%99s-Vaccine-for-the-Prevention-of-Respiratory-Syncytial-Virus-RSV-in-Older-Adults.
2. Package insert. Pfizer; 2023. Accessed June 1, 2023. https://labeling.pfizer.com/ShowLabeling.aspx?id=19589.

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