

Abrysvo™ (respiratory syncytial virus vaccine) – New vaccine approval

- On May 31, 2023, [Pfizer announced](#) the FDA approval of [Abrysvo \(respiratory syncytial virus vaccine\)](#), 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.
- Abrysvo is the second vaccine approved for RSV in this patient population. The FDA approved GSK's [Arexvy \(respiratory syncytial virus vaccine, adjuvanted\)](#), on May 3rd.
- The efficacy of Abrysvo was established in a randomized, double-blind, placebo-controlled study in individuals 60 years of age and older. Participants were randomized to receive Abrysvo or placebo. The evaluable efficacy population included 32,614 patients. Vaccine efficacy against RSV-LRTD, defined as the relative risk reduction of first episode of RSV-LRTD in the Abrysvo group compared to the placebo group in the first RSV season, was assessed.
 - The study met the pre-specified success criteria for demonstration of efficacy of Abrysvo for the primary objectives of prevention of RSV-LRTD with ≥ 2 symptoms and prevention of RSV-LRTD with ≥ 3 symptoms.

Efficacy endpoint	Abrysvo N = 16,306 n	Placebo N = 16,308 n	Vaccine efficacy (%) (96.66% CI)
First episode of RSV-associated lower respiratory tract disease with ≥ 2 symptoms	11	33	66.7 (28.8, 85.8)
First episode of RSV-associated lower respiratory tract disease with ≥ 3 symptoms	2	14	85.7 (32.0, 98.7)

- Warnings and precautions for Abrysvo include management of acute allergic reactions; syncope; altered immunocompetence; and limitations of vaccine effectiveness.
- The most commonly reported solicited local and systemic adverse reactions ($\geq 10\%$) with Abrysvo use were fatigue, headache, pain at the injection site, and muscle pain.
- The recommended dose of Abrysvo is a single dose (approximately 0.5 mL) administered intramuscularly.
- The CDC's Advisory Committee on Immunization Practices (ACIP) will meet on June 21, 2023, to discuss recommendations for the appropriate use of RSV vaccines in older adults.
 - Pending the outcome of this meeting, Pfizer anticipates supply availability in 3Q 2023 ahead of the anticipated RSV season this fall.