RSV VACCINE INFORMATION

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Respiratory syncytial virus (RSV) is a virus that can infect the respiratory tract and lungs of patients. Typically, this virus causes cold-like symptoms, such as a runny nose, congestion, sore throat, sneezing, and coughing. In most adults and older children, these symptoms are mild, and patients will typically recover within 1 to 2 weeks. However, RSV can lead to more severe symptoms in high-risk populations, such as fever, difficulty breathing, severe coughing, or wheezing. In severe cases, RSV can lead to serious complications, including hospitalization or death.

WHY ADULTS?

Patients who are considered to be at high risk of developing RSV include children 1-year-old or younger, older adults, and those who are immunocompromised. According to the Centers for Disease Control and Prevention (CDC), between 60,000 and 160,000 older adults are hospitalized yearly and between 6,000 and 10,000 older adults die yearly due to RSV in the United States. RSV is especially dangerous for adults older than 60-years-old, as well as those with chronic heart or lung disease, those with weakened immune systems, and those living in nursing homes or long-term care facilities. To protect these high risk patients, it is important to practice good hand hygiene, clean surfaces that are touched frequently, and stay home when you are sick. Along with this, there are now two RSV vaccines that have been approved by the U.S Food and Drug Administration (FDA) and recommended by the CDC.

INDICATION

- Arexvy is approved and indicated for adults 60 years and older.
- Abrysvo is approved and indicated for adults 60 years and older. It is also approved for pregnant individuals at 32 through 36 weeks gestational age to pass on protection to child from birth through 6 months.

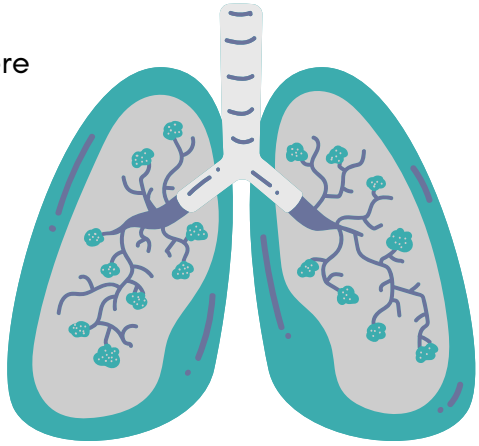
COST

- Arexvy and Abrysvo are available at local retail pharmacies without a prescription.
- Arexvy and Abrysvo are covered for patients with Medicaid and Medicare part D at no cost. Arexvy and Abrysvo may be covered for patients with commercial insurance at no cost, if the vaccine is given at an in-network retail pharmacy.

EFFICACY

Arexvy was compared to placebo in a phase 3, randomized, placebo controlled, observer-blind study in 17 countries. The study will be ongoing for 36 months but the initial approval is based on the primary analysis which was completed after a median of 6.7 months of patient follow-up.

The study included adults aged 60 and older who were not immunocompromised and did not have unstable pre-existing chronic disease. Patients were excluded if they had confirmed acute respiratory illness within the first 15 days after vaccination.



The primary objective was to prevent the first episode of confirmed RSV-A or B- associated lower respiratory tract disease (LRTD).

Compared with placebo, Arexvy reduced the risk of developing RSV-associated LRTD by 82.6% (96.95% CI [57.9,94.10]). The highest impact was seen in adults aged 70 and over and those with at least 1 comorbidity of interest (Table 1). Vaccine efficacy against RSV-A associated LRTD cases was 84.6% (95% CI [32.1,98.3]) and RSV B-associated LRTD cases was 80.9% (95% CI [49.4,94.3]). Compared with placebo, Arexvy reduced the risk of developing severe RSV-associated LRTD by 94.1% (95%CI [62.4,99.9]).

Table 1: First RSV-associated LRTD overall, by age and co-morbidity subgroups

Subgroup	AREXVY			Placebo			% Efficacy (CI)
	N	n	Incidence Rate per 1,000 Person-Years	N	n	Incidence Rate per 1,000 Person-Years	
Overall (≥60 years)	12,466	7	1.0	12,494	40	5.8	82.6 (57.9, 94.1)
60-69 years	6,963	4	1.0	6,979	21	5.5	81.0 (43.6, 95.3)
70-79 years	4,487	1	0.4	4,487	16	6.5	93.8 (60.2, 99.9)
Participants with 1+ comorbidity of interest	4,937	1	0.4	4,861	18	6.6	94.6 (65.0, 99.9)

Abrysvo was also studied in an ongoing phase 3, randomized, placebo-controlled, double-blind study in individuals 60 years of age and older. Study participants will be followed for two RSV seasons but results were presented after one RSV season due to meeting the pre-specified success criteria for efficacy. RSV-associated LRTD with ⩾ 2 symptoms was seen in 11 patients with Abrysvo compared to 33 patients with placebo showing vaccine efficacy of 66.7% (96.66% CI 28.8,85.8). RSV-associated

EFFICACY (CONTINUED)

LRTD with ⩾ 3 symptoms was seen in 2 patients with Abrysvo compared to 14 patients with placebo showing vaccine efficacy of 85.7% (96.66% CI 32.0, 98.7).

Abrysvo was compared to placebo in a phase 3, randomized, placebo controlled study evaluating the efficacy to prevent RSV-associated LRTD and severe RSV-LRTD in infants where the mother received the vaccine while pregnant. The study met the criteria for vaccine efficacy for reducing severe LRTD due to RSV at all timepoints to within 180 days. They did not meet the criteria for reducing LRTD due to RSV but improvement was seen after 90 days through 180 days after birth.

Table 2: Vaccine efficacy of Abrysvo against severe LRTD caused by RSV - infants from birth through 6 months of age

Time Period	Abrysvo Number of Cases N=1572	Placebo Number of Cases N=1539	VE (%) (CI)
90 days	1	11	91.1 (38.8, 99.8)
180 days	6	25	76.5 (41.3, 92.1)

Table 3: Vaccine efficacy of Abrysvo against LRTD caused by RSV - infants from birth through 6 months of age

Time Period	Abrysvo Number of Cases N=1572	Placebo Number of Cases N=1539	VE (%) (CI)
90 days	14	21	34.7 (-34.6, 69.3)
180 days	24	55	57.3 (29.8, 74.7)

SAFETY

For Arexvy, the most commonly reported adverse reactions (⩾10%) were pain at the injection site (60.9%), fatigue (33.6%), myalgia (28.9%), headache (27.2%) and arthralgia (18.1%).

For Abrysvo, adverse effects were studied in patients age 60 and older as well as pregnant patients. The most commonly reported adverse reactions in pregnant patients were patient at the injection site (40.6%), headache (31%), muscle pain (26.5%) and nausea (20%). For those age 60 and older, the most common adverse reactions were fatigue (15.5%), headache (12.8%), pain at the injection site (10.5%) and muscle pain (10.1%).

In one study, Arexvy was given with Fluarix or 1 month after Fluarix. There was no evidence for interference in the immune response.

*References for this handout are available upon request.