RSVPreF3 (Arexvy®)[3]

Classification
RSV Vaccine

Pharmacology
Induces an immune response against RSVpreF3 that protects against LRTD caused by RSV.

Indication
Active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus in individuals 60 years of age and older.

Dosage/Administration
A single 0.5 mL intramuscular injection. There are currently no recommendations for repeat vaccination.

Supplied as two vials, a lyophilized antigen component (a sterile white powder) that is to be reconstituted and an accompanying adjuvant suspension component (an opalescent, colorless to pale brownish sterile liquid) that will be used to reconstitute the lyophilized antigen component.

Use in Special Populations
Pregnancy: Not approved for use in patients <60 years of age. Clinical trial data found an increase in preterm births with the RSVPreF3 antigen.

Lactation: It is Unknown whether Arexvy is secreted in human milk, no data is available to assess the effects of Arexvy on breastfed infants or on milk production/excretion. Provider discretion should be used when evaluating the decision to breastfeed post-vaccination.

Pediatric Use: Not approved for use in patients <60 years of age. Evidence from an animal model strongly suggests that AREXVY would be unsafe in individuals younger than 2 years of age because of an increased risk of enhanced respiratory

disease. It was not studied for safety and effectiveness in individuals 2-17 years of age.

Geriatric Use: Approved for use in individuals 60 years of age and older.

Contraindication

Do not administer AREXVY to anyone with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of AREXVY.

Component list

- RSVPreF3 antigen
- MPL
- QS-21
- Trehalose
- Sodium Chloride
- Potassium dihydrogen phosphate
- Dipotassium phosphate
- Polysorbate
- Disodium phosphate anhydrous
- DOPC
- Cholesterol

Precautions

Preventing and managing allergic vaccine reactions: It is recommended that appropriate medical supervision and treatment be available to manage possible anaphylactic reactions following administration of Arexvy.

Syncope: It is recommended to take appropriate measures to avoid injury from fainting due to possible risk of Syncope in association with the administration of injectable vaccines.

Altered immunocompetence: In immunocompromised persons, Arexvy may produce a diminished immune response.

Adverse Effects

The most common adverse effects were identified as injection site pain (60.9%), fatigue (33.6%), myalgia (28.9%), headache (27.2%), and arthralgia (18.1%).

In study 1, serious adverse events with onset within 6 months following vaccination were reported at similar rates in participants who received AREXVY (4.2%) or placebo (4.0%). Serious events of atrial fibrillation were reported in 13 participants who received AREXVY and 15 participants who received placebo within 6 months after vaccination. The currently available information on the atrial fibrillation is insufficient to determine a causal relationship to the vaccine.

Serious adverse events were reported in 3 patients in study 2 and study 3; Guillain-Barré syndrome beginning 9 days after AREXVY vaccination was reported in a participant enrolled in a study site in Japan; Acute disseminated encephalomyelitis was reported in 2 participants enrolled in a study site in South Africa; the onset of the symptoms was 7- and 22-days post vaccination, respectively. One event was fatal and the other non-fatal. These participants received AREXVY concomitantly with FLUARIX QUADRIVALENT.

Monitoring

Immediate supervision after administration of the vaccination is recommended due to potential risk of allergic vaccine reactions and syncope. Any adverse events believed to have resulted from Arexvy should be reported to the Vaccine Adverse Event Reporting System.

Interactions

Immunosuppressant agents: Immunosuppressant agents may diminish the immunological response to Arexvy. Immunocompromised participants were excluded from the study.

No evidence was found to indicate reduced efficacy when given in combination with Fluarix quadrivalent. In Study 3, an open-label, Phase 3, clinical study conducted in New Zealand, Panama, and South Africa, participants 60 years of age and older received 1 dose of AREXVY and FLUARIX QUADRIVALENT at Month 0 (n = 442) or 1 dose of FLUARIX QUADRIVALENT at Month 0 followed by a dose of AREXVY at Month 1 (n = 443).

There was no evidence for interference in the immune response to any of the antigens contained in both concomitantly administered vaccines. The criteria for non-inferiority of the immune responses in the control versus "co-administration" group were met as the 2-sided 95% confidence interval upper limits on the group geometric mean titer ratios were below 1.5 for the RSV-A neutralizing antibodies and haemagglutinin inhibition antibodies against the strains Flu A/Hong Kong/H3N2, Flu A/Victoria/H1N1, Flu B/Phuket/Yamagata, and Flu B/Washington/Victoria.

There is no data available on the concomitant administration with other vaccines.

Efficacy

Compared with placebo, Arexvy significantly reduced the risk of developing RSV-associated LRTD by 82.6% (96.95% CI [57.9, 94.1]) in participants 60 years of age and older, which met the pre-specified success criterion for the primary study objective. The median duration of efficacy follow-up was 6.7 months.

Table 2. Efficacy Analysis: First Respiratory Syncytial Virus-associated Lower Respiratory Tract Disease Overall, by Age and Co-morbidity Subgroups in Study 1[a] (Modified Exposed Set)

	AREXVY			Placebo			
Subgroup	N	n	Incidence Rate per 1,000 Person-Years	N	n	Incidence Rate per 1,000 Person-Years	% Efficacy (CI)[b]
Overall (≥60 years)	12,466	7	1.0	12,494	40	5.8	82.6 (57.9, 94.1)
60 to 69 years	6,963	4	1.0	6,979	21	5.5	81.0 (43.6, 95.3)
70 to 79 years	4,487	1	0.4	4,487	16	6.5	93.8 (60.2, 99.9)
Participants with at least 1 comorbidity of interest	4,937	1	0.4	4,861	18	6.6	94.6 (65.9, 99.9)

(The above table is from the Arexvy Package insert)

One case of severe RSV-associated LRTD in the group that received Arexvy and 17 cases in the group that received placebo were reported, amongst which 2 cases required supportive therapy. Compared with placebo, Arexvy significantly reduced the risk of developing severe RSV-associated LRTD by 94.1% (95% CI [62.4, 99.9]) in participants 60 years of age and older.

Dosage Forms/Cost (AWP)[1]

IM, Single dose vial to be reconstituted with supplied diluent. Packaged in carton of 10 doses.

Pricing from Morris and Dickson: **$**336.00/dose, $3360.00/box of 10 doses

Safety Considerations

Look Alike-Sound Alike: Abrysvo (RSVpreF)

Summary/Conclusion

Arexvy is FDA approved for prevention of RSV-LRTD in adults ≥ 60-year-old. The data from the clinical trials is robust and targets an appropriate population for RSV-LRTD and would be applicable to numerous state hospital patients. The side effect profile is favorable and is one of two new novel vaccinations against RSV-LRTD.

Recommendation

Add both Arexvy and Abrysvo to the formulary. The prevention of RSV-LRTD in the State Hospital system would prove majorly beneficial. Despite Arexvy's more limited target population it would still be beneficial to have a secondary, cheaper, option should Abrysvo encounter supply issues or the additional indication of vaccination in pregnant individuals at 32-36 weeks gestational age is not needed.

Arexvy vs Abrysvo at a Glance

Medication	**Arexvy (RSVPreF3)**	**Abrysvo (RSVpreF)**
Cost	$336.00/dose[1]	$354.00/dose[2]
Population	≥ 60-year-old[3]	≥ 60-year-old and pregnant individuals at 32-36 weeks gestational age[4]
Route and form	IM, single dose vial to be reconstituted[3]	IM, single dose vial to be reconstituted[4]
Storage	2-8°C[3]	2-8°C[4]
Effectiveness	82.6% efficacy in reducing the risk of developing RSV-LRTD in patients ≥ 60-year-old.[3]	76.5% Vaccine Efficacy against severe RSV-LRTED in Infants from birth through 6 months of age.[4] 85.7% vaccine effectiveness in preventing RSV-LRTD with ≥3 symptoms in patients ≥ 60-year-old.[4]

References

1. Morris & Dickson. (12/18/2023) Arexvy product information. https://www.mdwebportal.net/mdwp/ProductInfo.aspx?id=%20J5eMCrNe8yLXTHzzCMKFwwXYXrRzJneHeUdXauNfCsw=&item=296996
2. Morris & Dickson. (12/18/2023) Abrysvo product information. https://www.mdwebportal.net/mdwp/ProductInfo.aspx?id=%20J5eMCrNe8yLXTHzzCMKFwwXYXrRzJneHeUdXauNfCsw=&item=296566
3. Arexvy (RSVpreF3) [package insert]. Durham, NC: GlaxoSmithKline Biologicals; 2023
4. Abrysvo (RSVPreF) [package insert]. New York, NY: Pfizer Inc; 2023

Date: 12/18/2023
Prepared by: Tyler Stromberg PharmD
Reviewed by: Kasey Leggette Peña, PharmD, BCPP