GSK’s RSVPreF3 OA Vaccine (AREXVY)

AREXVY was approved by FDA on May 3, 2023, and is indicated for the prevention of LRTD caused by RSV in adults 60 and older, as a single dose.

ACIP June 21, 2023

Leonard Friedland, MD
Vice President, Scientific Affairs and Public Health
Presentation Overview

Efficacy and safety results over 2 full RSV seasons from pivotal Phase 3 Study

- 1 dose of AREXVY provides durable efficacy against RSV-associated LRTD over 2 full RSV seasons, including against severe RSV disease, in adults with underlying comorbidities, and across advancing ages
- 2nd dose 12 months after 1st dose does not appear to confer additional efficacy in overall population

Immunogenicity and safety results from 2 co-administration trials with influenza vaccines (adjuvanted, high dose)

- AREXVY can be administered with all types of commonly used influenza vaccines

LRTD: lower respiratory tract disease

Presentation by GSK at ACIP June 21, 2023
Pivotal Efficacy and Safety Study (AReSVi-006): Results Through 2 Full RSV Seasons

Phase 3, randomized, placebo-controlled, multi-country study to demonstrate efficacy and safety of single and annual revaccination doses in adults 60 years and older
Ongoing AReSVi-006 Phase 3 Trial Design
Randomized, placebo-controlled, observer-blind, multi-country efficacy study

Adults ≥ 60 years
N = 24,966

Study Initiated May 2021 (Northern hemisphere)

Season 1
2021 – 2022

AREXVY
N = 12,467

Placebo
N = 12,499

End of S1 Analysis Apr 2022

Season 2
2022 – 2023

AREXVY
(annual group, dose 2)

Placebo
(AREXVY single dose)

Mid-S2 Analysis Nov 2022

Season 3
2023 – 2024

AREXVY
(annual group, dose 3)

Placebo
(AREXVY single dose)

End of S2 Analysis Mar 2023

Confirmatory secondary endpoint: Evaluate efficacy of AREXVY in prevention of RSV*-LRTD† in adults ≥ 60 YOA over 2 seasons, following a single dose of AREXVY and following annual revaccination dose
- All RSV-LRTD cases adjudicated by independent external adjudication committee
- Success criterion: lower limit of 2-sided 97.5% CI for vaccine efficacy > 20%

*RT-PCR confirmed; †LRTD defined as ≥ 2 lower respiratory symptoms/signs for ≥ 24 hours including ≥1 lower respiratory sign OR ≥ 3 lower respiratory symptoms for ≥ 24 hours; RT-PCR: reverse transcriptase polymerase chain reaction

Presentation by GSK at ACIP June 21, 2023
### AReSVi-006 Case Definitions

#### ARI

- **Symptoms or signs**
  - Fever/feverishness
  - Fatigue
  - Body aches
  - Headache
  - Decreased appetite
  - OR
  - ≥ 2 respiratory symptoms or signs
  - OR
  - ≥ 1 respiratory and 1 systemic symptom or sign for at least 24 hours

#### Respiratory symptoms or signs

- **Upper respiratory symptoms or signs**
  - Nasal congestion
  - Sore throat

- **Lower respiratory symptoms**
  - Sputum
  - Cough
  - Dyspnea

#### Systemic symptoms or signs

- **Symptoms or signs**
  - Fatigue
  - Body aches
  - Headache
  - Decreased appetite

#### Respiratory symptoms or signs

- **Lower respiratory signs**
  - Wheezing
  - Crackles/rhonchi
  - Tachypnea
  - Hypoxemia
  - O2 supplement

### LRTD*

- **≥ 2 lower respiratory symptoms or signs (≥ 1 sign)**
  - OR
  - ≥ 3 lower respiratory symptoms for at least 24 hours

#### Lower respiratory symptoms

- Sputum
- Cough
- Dyspnea

#### Lower respiratory signs

- Wheezing
- Crackles/rhonchi
- Tachypnea
- Hypoxemia
- O2 supplement

#### Severe LRTD*

- **≥ 2 lower respiratory signs**
  - OR
  - episode preventing normal, everyday activities

#### Lower respiratory signs

- Wheezing
- Crackles/rhonchi
- Tachypnea
- Hypoxemia
- O2 supplement

*USPI case definitions
AREXVY Produces Durable Vaccine Efficacy Against RSV-LRTD Over 2 Full Seasons

<table>
<thead>
<tr>
<th>Median Follow-Up (months)</th>
<th>AREXVY</th>
<th>Placebo</th>
<th>VE (95% CI)</th>
<th>VE (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of events</td>
<td></td>
<td>W/o season as covariate</td>
<td>W/ season as covariate</td>
</tr>
<tr>
<td><strong>Single Dose</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Season 1*</td>
<td>6.7</td>
<td>7 / 12,466</td>
<td>40 / 12,494</td>
<td>82.6% (57.9, 94.1)</td>
</tr>
<tr>
<td>VE 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mid Season 2</td>
<td>14</td>
<td>15 / 12,469</td>
<td>85 / 12,498</td>
<td>80.9% (66.7, 89.8)</td>
</tr>
<tr>
<td>Post dose 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Season 2 Only</td>
<td>6.4</td>
<td>20 / 4,991</td>
<td>91 / 10,031</td>
<td>56.1% (28.2, 74.4)</td>
</tr>
<tr>
<td>Post dose 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Season 1 + 2**</td>
<td>18</td>
<td>30 / 12,469</td>
<td>139 / 12,498</td>
<td>74.5% (60.0, 84.5)</td>
</tr>
<tr>
<td>Annual (2 doses, ~12 months apart)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
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<td>91 / 10,031</td>
<td>55.9% (27.9, 74.3)</td>
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<tr>
<td>Post dose 2</td>
<td></td>
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<td>18</td>
<td>30 / 12,469</td>
<td>139 / 12,498</td>
<td>74.5% (60.0, 84.4)</td>
</tr>
</tbody>
</table>

Modified exposed set
*96.95% CI for VE 1; **97.5% CI for Season 1 + 2

Presentation by GSK at ACIP June 21, 2023
**AREXVY Produces Durable Vaccine Efficacy Against RSV-Severe LRTD Over 2 Full Seasons**

<table>
<thead>
<tr>
<th>Median Follow-Up (months)</th>
<th>AREXVY</th>
<th>Placebo</th>
<th>VE (95% CI)</th>
<th>VE (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AREXVY</strong></td>
<td></td>
<td></td>
<td><strong>Placebo</strong></td>
<td></td>
</tr>
<tr>
<td>Number of events</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Single Dose</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Season 1</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VE 1</td>
<td>6.7</td>
<td>1 / 12,466</td>
<td>17 / 12,494</td>
<td><strong>94.1%</strong> (62.4, 99.9)</td>
</tr>
<tr>
<td>Mid Season 2</td>
<td>14</td>
<td>4 / 12,469</td>
<td>33 / 12,498</td>
<td><strong>86.8%</strong># (63.0, 96.6)</td>
</tr>
<tr>
<td>Season 2 Only</td>
<td>6.4</td>
<td>5 / 4,991</td>
<td>28 / 10,031</td>
<td><strong>64.2%</strong> (6.2, 89.2)</td>
</tr>
<tr>
<td>Season 1 + 2**</td>
<td>18</td>
<td>7 / 12,469</td>
<td>48 / 12,498</td>
<td><strong>82.7%</strong># (61.6, 93.4)</td>
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</tr>
<tr>
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<td>6.4</td>
<td>5 / 4,966</td>
<td>28 / 10,031</td>
<td><strong>64.1%</strong> (5.9, 89.2)</td>
</tr>
<tr>
<td><strong>Seasons 1 + 2</strong></td>
<td>18</td>
<td>7 / 12,469</td>
<td>48 / 12,498</td>
<td><strong>82.7%</strong># (61.6, 93.4)</td>
</tr>
</tbody>
</table>

*Modified exposed set
*96.95% CI for VE 1; **97.5% CI for Season 1 + 2

Presentation by GSK at ACIP June 21, 2023
AREXVY Produces Durable Vaccine Efficacy Against RSV-LRTD in Vulnerable Populations Over 2 Full Seasons

<table>
<thead>
<tr>
<th>AREXVY</th>
<th>Placebo</th>
<th>VE (95% CI)</th>
<th>VE (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number of events</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; 1 pre-existing comorbidity of interest</td>
<td>1 / 4,937</td>
<td>18 / 4,861</td>
<td><strong>94.6%</strong> (65.9, 99.9)</td>
</tr>
<tr>
<td>Pre-frail</td>
<td>1 / 4,792</td>
<td>14 / 4,778</td>
<td><strong>92.9%</strong> (53.4, 99.8)</td>
</tr>
<tr>
<td><strong>Season 1</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Median follow-up = 6.7 months)</td>
<td>&gt; 1 pre-existing comorbidity of interest</td>
<td>16 / 4,983</td>
<td>72 / 4,919</td>
</tr>
<tr>
<td>Pre-frail</td>
<td>8 / 4,794</td>
<td>47 / 4,779</td>
<td><strong>80.0%</strong> (57.3, 91.8)</td>
</tr>
<tr>
<td><strong>Single dose over 2 seasons†</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Median follow-up = 18 months)</td>
<td>&gt; 1 pre-existing comorbidity of interest</td>
<td>&gt; 1 pre-existing comorbidity of interest</td>
<td>16 / 4,983</td>
</tr>
<tr>
<td>Pre-frail</td>
<td>8 / 4,794</td>
<td>47 / 4,779</td>
<td><strong>80.0%</strong> (57.3, 91.8)</td>
</tr>
</tbody>
</table>

Vaccine efficacy in frail participants cannot be concluded due to low number of cases accrued.

Comorbidities of interest include chronic obstructive pulmonary disease, asthma, any chronic respiratory or pulmonary disease, and chronic heart failure (cardiorespiratory condition) and diabetes mellitus type 1 or type 2 and advanced liver or renal disease (endocrine or metabolic condition).

*April 2022 analysis; †From 15 days post Dose 1 up to end of Season 2 in Northern Hemisphere
# AREXVY Produces Durable Vaccine Efficacy Against RSV LRTD Across Advancing Ages Over 2 Full Seasons

<table>
<thead>
<tr>
<th></th>
<th>AREXVY</th>
<th>Placebo</th>
<th>Number of events</th>
<th>VE (95% CI)</th>
<th>VE (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Season 1</strong>*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Median follow-up = 6.7 months)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥ 60 YOA***</td>
<td>7 / 12,466</td>
<td>40 / 12,494</td>
<td></td>
<td>82.6% (57.9, 94.1)</td>
<td>82.6% (57.9, 94.1)</td>
</tr>
<tr>
<td>60 – 69 YOA</td>
<td>4 / 6,963</td>
<td>21 / 6,979</td>
<td></td>
<td>81.0% (43.6, 95.3)</td>
<td>81.0% (43.6, 95.3)</td>
</tr>
<tr>
<td>70 – 79 YOA</td>
<td>1 / 4,487</td>
<td>16 / 4,487</td>
<td></td>
<td>93.8% (60.2, 99.9)</td>
<td>93.8% (60.2, 99.9)</td>
</tr>
<tr>
<td><strong>Single dose over 2 seasons†</strong></td>
<td></td>
<td></td>
<td></td>
<td>W/o season as covariate#</td>
<td>W/ season as covariate¶</td>
</tr>
<tr>
<td>(Median follow-up = 18 months)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥ 60 YOA****</td>
<td>30 / 12,469</td>
<td>139 / 12,498</td>
<td></td>
<td>74.5% (60.0, 84.5)</td>
<td>67.2% (48.2, 80.0)</td>
</tr>
<tr>
<td>60 – 69 YOA</td>
<td>17 / 6,963</td>
<td>74 / 6,981</td>
<td></td>
<td>72.9% (53.7, 85.0)</td>
<td>65.4% (40.4, 80.9)</td>
</tr>
<tr>
<td>70 – 79 YOA</td>
<td>9 / 4,489</td>
<td>55 / 4,489</td>
<td></td>
<td>80.7% (60.6, 91.6)</td>
<td>74.9% (48.4, 89.2)</td>
</tr>
</tbody>
</table>

Vaccine efficacy in adults ≥ 80 years of age cannot be concluded due to low number of cases accrued

*April 2022 analysis; ***96.95% CI; ****97.5% CI; YOA: years of age; †From 15 days post Dose 1 up to end of Season 2 in Northern Hemisphere.
# AREXVY Produces Durable Vaccine Efficacy Against RSV-A LRTD and RSV-B LRTD Over 2 Full Seasons

## Table: Vaccine Efficacy (VE) Against RSV-A and RSV-B

<table>
<thead>
<tr>
<th></th>
<th>AREXVY</th>
<th>Placebo</th>
<th>VE (95% CI)</th>
<th>VE (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number of events</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Season 1</strong>&lt;sup&gt;*&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Median follow-up = 6.7 months)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RSV-A</td>
<td>2 / 12,466</td>
<td>13 / 12,494</td>
<td>84.6% (32.1, 98.3)</td>
<td>84.6% (32.1, 98.3)</td>
</tr>
<tr>
<td>RSV-B</td>
<td>5 / 12,466</td>
<td>26 / 12,494</td>
<td>80.9% (49.4, 94.3)</td>
<td>80.9% (49.4, 94.3)</td>
</tr>
<tr>
<td>**Single dose over 2 seasons&lt;/sup&gt;†</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Median follow-up = 18 months)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RSV-A</td>
<td>6 / 12,469</td>
<td>48 / 12,498</td>
<td>85.2%&lt;sup&gt;‡&lt;/sup&gt; (65.4, 94.8)</td>
<td>80.5%&lt;sup&gt;‡&lt;/sup&gt; (54.0, 93.2)</td>
</tr>
<tr>
<td>RSV-B</td>
<td>24 / 12,469</td>
<td>90 / 12,498</td>
<td>68.5%&lt;sup&gt;‡&lt;/sup&gt; (50.2, 80.8)</td>
<td>59.7%&lt;sup&gt;‡&lt;/sup&gt; (35.8, 75.5)</td>
</tr>
</tbody>
</table>

*April 2022 analysis; †From 15 days post Dose 1 up to end of Season 2 in Northern Hemisphere

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Presentation by GSK at ACIP June 21, 2023
Reactogenicity Profile of 2nd Dose in Line with 1st Dose

Solicited AEs Reported Within 4 Days of Vaccination (Solicited Safety Set)

<table>
<thead>
<tr>
<th>Local</th>
<th>Systemic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erythema</td>
<td>AREXVY</td>
</tr>
<tr>
<td>Pain</td>
<td>1 dose AREXVY (1st season)</td>
</tr>
<tr>
<td>Swelling</td>
<td>1 dose AREXVY (1st season) / Placebo (2nd season)</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>AREXVY</td>
</tr>
<tr>
<td>Fatigue</td>
<td>AREXVY</td>
</tr>
<tr>
<td>Fever</td>
<td>AREXVY</td>
</tr>
<tr>
<td>Headache</td>
<td>AREXVY</td>
</tr>
<tr>
<td>Myalgia</td>
<td>AREXVY</td>
</tr>
</tbody>
</table>

AREXVY Season 1 n=879; Placebo Season 1 n=878; 2 doses Season 2 n=326 (received AREXVY in Season 1 and Season 2); 1 dose Season 2 n=345 (received AREXVY in Season 1 and Placebo in Season 2); Placebo Season 2 n=666 (received Placebo in Season 1 and Season 2)
Safety Profile of 2nd Dose in Line with 1st Dose
Unsolicited AEs, SAEs, fatal SAEs, and pIMDs

Unsolicited AEs
Within 30 days

SAEs
Up to 6 months post vaccination

Fatal SAEs
Up to DLP (Season 2)

pIMDs

AREXVY Season 1 n=12,467; Placebo Season 1 n=12,499; 2 doses Season 2 n=4,966 (received AREXVY in Season 1 and Season 2); 1 dose Season 2 n=4,991 (received AREXVY in Season 1 and Placebo in Season 2); Placebo Season 2 n=10,033 (received Placebo in Season 1 and Season 2)

DLP: data lock point; pIMD: potential immune-mediated disease
Influenza Vaccine Co-administration Studies: Immunogenicity and Safety

Open-label, randomized, controlled, multi-country studies to evaluate immune response, safety, and reactogenicity of AREXVY when co-administered with influenza vaccines in adults aged 60 years and above (RSV OA=ADJ-007) or 65 years and above (RSV OA=ADJ-008 and RSV OA=ADJ-017)
Phase 3 Influenza Vaccine Co-Administration Studies: Designs\textsuperscript{1–3}

Open-label, randomized controlled studies evaluating immunogenicity, safety, and reactogenicity of AREXVY co-administered with:

- FLU-QIV (RSV OA=ADJ-007; Southern hemisphere)\textsuperscript{1}
- FLU-QIV-HD (RSV OA=ADJ-008; Northern hemisphere)\textsuperscript{2}
- FLU-aQIV (RSV OA=ADJ-017; Europe)\textsuperscript{3}

# Co-Administration of AREXVY and Licensed FLU-QIV-HD

## Antibody GMT Ratio (Control Over Co-Administration)

<table>
<thead>
<tr>
<th>Antibody</th>
<th>Co-Ad N</th>
<th>Control N</th>
<th>GMT Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flu A/Darwin H3N2</td>
<td>458</td>
<td>441</td>
<td>0.98 (0.84, 1.14)</td>
</tr>
<tr>
<td>Flu A/Victoria H1N1</td>
<td>452</td>
<td>435</td>
<td>0.93 (0.80, 1.08)</td>
</tr>
<tr>
<td>Flu B/Austria/Victoria</td>
<td>458</td>
<td>441</td>
<td>0.95 (0.88, 1.03)</td>
</tr>
<tr>
<td>Flu B/Phuket/Yamagata</td>
<td>456</td>
<td>441</td>
<td>0.92 (0.84, 1.02)</td>
</tr>
<tr>
<td>RSV-A*</td>
<td>459</td>
<td>358</td>
<td>1.18 (1.04, 1.35)</td>
</tr>
<tr>
<td>RSV-B</td>
<td>459</td>
<td>357</td>
<td>1.02 (0.89, 1.16)</td>
</tr>
</tbody>
</table>

### Success Criteria:
Upper limit ≤ 1.5 of 2-sided 95% CI for Group GMT Ratio (Control Group divided by Co-Ad Group) for RSV vaccine and for each of FLU vaccine strains.

*RSV-A preliminary, final results pending

Flu response evaluated using HI and RSV response evaluated using NAb (ED 60); HI: Hemagglutination
Co-Administration of AREXVY and Licensed Flu-Adjuvanted QIV

**Success Criteria:** Upper limit ≤ 1.5 of 2-sided 95% CI for Group GMT Ratio (Control Group divided by Co-Ad Group) for RSV vaccine and for each of FLU vaccine strains

*Lower HI titers observed than expected, investigation ongoing; **RSV-A preliminary, final results pending
Flu response evaluated using HI and RSV response evaluated using NAb (ED 60); HI: Hemagglutination

<table>
<thead>
<tr>
<th>Antibody</th>
<th>Co-Ad N</th>
<th>Control N</th>
<th>GMT Ratio (Control Over Co-Administration) 1 Month After Vaccination Per Protocol Set</th>
<th>GMT Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flu A/Darwin H3N2*</td>
<td>433</td>
<td>402</td>
<td>1.31 (1.13, 1.52)</td>
<td></td>
</tr>
<tr>
<td>Flu A/Victoria H1N1</td>
<td>424</td>
<td>398</td>
<td>1.03 (0.91, 1.18)</td>
<td></td>
</tr>
<tr>
<td>Flu B/Austria/Victoria</td>
<td>433</td>
<td>402</td>
<td>0.97 (0.89, 1.05)</td>
<td></td>
</tr>
<tr>
<td>Flu B/Phuket/Yamagata</td>
<td>432</td>
<td>402</td>
<td>1.04 (0.95, 1.12)</td>
<td></td>
</tr>
<tr>
<td>RSV-A**</td>
<td>475</td>
<td>377</td>
<td>0.98 (0.87, 1.11)</td>
<td></td>
</tr>
<tr>
<td>RSV-B</td>
<td>473</td>
<td>377</td>
<td>1.16 (1.03, 1.31)</td>
<td></td>
</tr>
</tbody>
</table>

RSV OA=ADJ-017: FLU aQIV

Presentation by GSK at ACIP June 21, 2023
Modified Set: Solicited Local AEs Within 4 Days Post Vaccination

Grade 3: > 100 mm for erythema and swelling; Grade 3 pain: significant pain at rest; prevents normal everyday activities.

Fever: temperature ≥ 38.0°C/100.4°F by any route (oral, axillary or tympanic); Grade 3 fever: > 39.0°C/102.2°F.

Grade 3 headache, fatigue, myalgia, arthralgia: preventing normal activity
Exposed Set: Solicited Local AEs Within 7 Days Post Vaccination

**FLU-aQIV**
- Erythema: 51.7%
- Pain: 44.8%
- Swelling: 4.3%

**AREXVY**
- Erythema: 65.9%
- Pain: 58.8%
- Swelling: 0%

Grade 3: > 100 mm for erythema and swelling; Grade 3 pain: significant pain at rest; prevents normal everyday activities. Fever: temperature ≥ 38.0 C/100.4 F by any route (oral, axillary or tympanic); Grade 3 fever: > 39.0 C/102.2 F. Grade 3 headache, fatigue, myalgia, arthralgia: preventing normal activity.
Modified Set: Solicited Systemic AEs Within 4 Days Post Vaccination

Grade 3: >100 mm for erythema and swelling. Grade 3 pain: significant pain at rest; prevents normal everyday activities.

Fever: temperature ≥ 38.0°C/100.4°F by any route (oral, axillary or tympanic); Grade 3 fever: > 39.0°C/102.2°F.

Grade 3 headache, fatigue, myalgia, arthralgia: preventing normal activity

Presentation by GSK at ACIP June 21, 2023
Exosed Set: Solicited Systemic AEs Within 7 Days Post Vaccination

**Solicited Systemic Adverse Events**

- **Arthralgia**
- **Fatigue**
- **Fever**
- **Headache**
- **Myalgia**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Co-Ad Visit 1</th>
<th>FLU Visit 1</th>
<th>AREXVY Visit 1</th>
<th>Co-Ad Visit 2</th>
<th>FLU Visit 1</th>
<th>AREXVY Visit 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arthralgia</td>
<td>25.8%</td>
<td>15.6%</td>
<td>17.1%</td>
<td>0.2%</td>
<td>0.2%</td>
<td>0.2%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>45.7%</td>
<td>28.7%</td>
<td>29.9%</td>
<td>0.2%</td>
<td>0.2%</td>
<td>0.2%</td>
</tr>
<tr>
<td>Fever</td>
<td>2.1%</td>
<td>0.2%</td>
<td>0.2%</td>
<td>2.1%</td>
<td>0.2%</td>
<td>0.2%</td>
</tr>
<tr>
<td>Headache</td>
<td>32.2%</td>
<td>19.5%</td>
<td>23.7%</td>
<td>0.2%</td>
<td>0.2%</td>
<td>0.2%</td>
</tr>
<tr>
<td>Myalgia</td>
<td>39.0%</td>
<td>23.0%</td>
<td>31.9%</td>
<td>0.2%</td>
<td>0.2%</td>
<td>0.2%</td>
</tr>
</tbody>
</table>

**Grade 3:**
- >100 mm for erythema and swelling.
- Grade 3 pain: significant pain at rest; prevents normal everyday activities.
- Grade 3 headache, fatigue, myalgia, arthralgia: preventing normal activity

Presentation by GSK at ACIP June 21, 2023
Summary of Findings

1. A single dose of AREXVY provides durable efficacy against RSV-associated LRTD for 2 full RSV seasons, including against severe RSV disease, in adults with underlying comorbidities, and across advancing ages.

2. Revaccination after 12 months does not appear to confer additional efficacy benefit for overall population; future data will inform optimal timing of revaccination.

3. AREXVY can be administered with all types of commonly used influenza vaccines.

4. Reactogenicity and safety profiles of the second dose are consistent with the first dose; important for future revaccination consideration.

5. Across all studies, no new cases of GBS, ADEM, or other neuroinflammatory demyelinating disorders were reported with additional exposure.
**AReSVi-004 Phase 3 Trial Design**

**Primary objective:** Evaluate humoral immune response following 1-dose primary schedule up to 12 months post-dose 1*

**Key secondary objectives:** Evaluate humoral and CMI† responses following 1-dose primary schedule and revaccination doses, up to study end (Month 36)

**Safety monitoring:** Throughout study

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*Primary endpoints: NAb geometric mean titers (RSV-A and RSV-B) at Day 1 (pre-vaccination), D31, M6, and M12 post-dose 1; †CMI response in terms of frequency of RSVPreF3-specific CD4+ and/or CD8+ T-cells expressing at least 2 activation markers. CD: cluster of differentiation; CMI: cell-mediated immune

Immunogenicity Overview Through Month 18 Post Vaccination

**RSV-A Serum Neutralization Titers**
- 1 dose vs. 2 doses
- Timepoint (days): D0, M6, M12, M18
- GMT (ED60) levels:
  - D0: ~10X
  - M6: ~6X
  - M12: ~3X
  - M18: **~2.4X**

**RSV-B Serum Neutralization Titers**
- 1 dose vs. 2 doses
- Timepoint (days): D0, M6, M12, M18
- GMT (ED60) levels:
  - D0: **~8X**
  - M6: ~4X
  - M12: **~2X**
  - M18: **~3X**

**RSVPreF3-specific CD4+ T-cells**
- 1 dose vs. 2 doses
- Timepoint (days): D0, M6, M12, M18
- RSVPreF3 CD4+ T-cells, /10^6 cells (GM)

*RSV-A preliminary, final results pending
**versus before vaccination 1; CD4+ T-cells expressing ≥2 activation markers including ≥1 cytokine among CD40L, 4-1BB, IL-2, TNF-α, IFN-γ, IL-13, IL-17 (events/10^6 cells; by intracellular staining). ED: Estimated Dilution; ED60: serum dilution inducing 60% inhibition in plaque-forming units; GMT: geometric mean titer; IL: interleukin; TNF: tumor necrosis factor