

## **Investor Science Event**

#### Getting ahead of respiratory syncytial virus disease in older adults IDWeek 2022, 19 - 23, October 2022, Washington, DC

Conference call and webcast for investors and analysts

### **Cautionary statement regarding forward-looking statements**

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A number of adjusted measures are used to report the performance of our business, which are non-IFRS measures. These measures are defined and reconciliations to the nearest IFRS measure are available in our second quarter 2022 earnings release and Annual Report on Form 20-F for FY 2021.

All outlooks, ambitions, and considerations should be read together with pages 5-7 of the stock-exchange announcement relating to an update to investors dated 23 June 2021, paragraph 19 of Part 7 of the Circular to shareholders relating to the demerger of Haleon plc dated 1 June 2022 and the Guidance, assumptions and cautionary statements in the Q2 2022 earnings release.

Basis of preparation: GSK satisfied the formal criteria according to IFRS 5 for treating Consumer Healthcare as a 'Discontinued operation' effective from 30 June 2022. The amounts presented in this presentation for continuing operations and Adjusted results excludes the Consumer Healthcare business discontinued operation. Comparative figures have been restated on a consistent basis. Earnings per share, Adjusted earnings per share and Dividends per share have been adjusted to reflect the GSK Share Consolidation on 18 July 2022.









Dr Phil Dormitzer SVP, Global Head, Vaccines R&D





Roger Connor President, Vaccines and Global Health



Luke Miels Chief Commercial Officer



### Why we're here Agenda

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Innovation leadership in vaccines Dr Tony Wood



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21 October 2022



# Innovation leadership in vaccines

Dr Tony Wood, Chief Scientific Officer

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### A new biopharma company

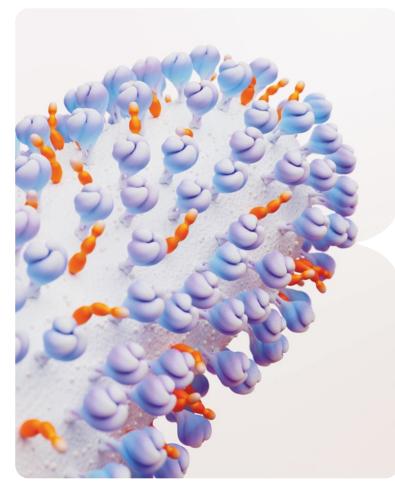
Uniting science, technology, and talent to get ahead of disease together



\*Includes high-potential late-stage pipeline assets and internally/externally sourced assets consistent with R&D focus on the science of the immune system and human genetics.

### **Innovation in vaccines**

IDWeek 2022, 19-23 October 2022, Washington, DC



<sup>1.</sup> Respiratory syncytial virus.

Potential best-in-class clinical profile for novel RSV<sup>1</sup> vaccine candidate in older adults

- 94.1% reduction in severe RSV disease in older adults
- 82.6% overall vaccine efficacy in older adults
- Favourable safety profile
- Co-administration of RSV vaccine candidate with influenza vaccines in older adults

Extending vaccines leadership position in shingles prevention

*Shingrix* duration of protection against shingles extends to 10 years

### RSV data: the highlight of strong year of vaccines R&D delivery

# Exceptional

and consistent phase III results for RSV<sup>1</sup> vaccine candidate in older adults

# Regulatory

approvals achieved including *Priorix* for MMR<sup>2</sup> (US); *Boostrix* maternal<sup>3</sup> (US), *Menveo* liquid (US)

## Advanced

novel vaccine candidates to FTIH including mRNA flu; mRNA COVID; Therapeutic HSV<sup>4</sup>; HPV-9

# Affinivax

acquisition strengthens portfolio, adds key MAPS<sup>5</sup> technology

# Significant

news flow expected over balance of 2022 including late-stage readout on MenABCWY

FTIH: first time in human

1. Respiratory syncytial virus, 2. Measles, mumps, and rubella, 3. Boostrix was approved for immunisation during pregnancy for the prevention of whooping cough in new-born infants 4. Herpes Simplex Virus, 5. Multiple Antigen Presenting System, a trademark of Affinivax, Inc.

### RSV programme leveraged unique vaccines R&D capabilities

#### Focus on science of immune system to both treat and prevent disease

- Leadership in infectious diseases
- One capital allocation approach
- One Development organisation
- Broadest suite of platform technologies



#### Advanced technology platforms are central to our R&D approach

- Proprietary adjuvanted
   RSV vaccine candidate, building on *Shingrix* heritage
- Excellence in clinical trial design and execution based on infectious disease leadership and capabilities
- Potential best-in-class phase III data for RSV vaccine candidate in older adults

21 October 2022



## **Prevention of RSV in older adults**

#### Dr Phil Dormitzer, Senior Vice President and Global Head, Vaccines R&D

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Significant unmet medical need and disease burden

Currently, no vaccine or specific treatment for adults

# >1 billion aged 60+ at risk of annual exposure to RSV

- Common contagious virus
- Older adults and those with underlying medical conditions at increased health risk
- Can exacerbate medical conditions such as COPD<sup>1</sup>, asthma, chronic heart failure, and diabetes
- Increases risk of severe outcomes (pneumonia, hospitalisation, death)
- Associated with substantial clinical and economic burden<sup>2,3,4</sup>
- Immune response after RSV natural infection is not long-lasting, and re-infections occur throughout life<sup>5,6</sup>

**420**k

Hospitalisations Developed countries

177k

Hospitalisations US (65+ years) **29**K

Deaths Developed countries

14k Deaths

US (65+ years)

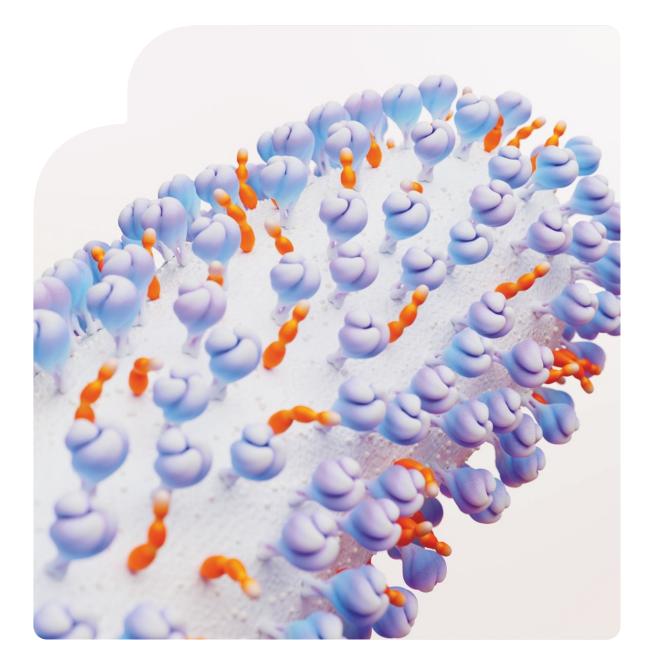
1. Chronic obstructive pulmonary disease, 2. CDC, 2020. RSV in older adults and adults with chronic medical conditions. <u>https://www.cdc.gov/rsv/high-risk/older-adults.html</u> (accessed November 2021); 3. Amand C et al. BMC Health Serv Res 2018;18:294. 4. Falsey AR et al. N Engl J Med 2005;352:1749–1759; 5. Graham BS. Immunol Rev 2011;239:149–166. 6. Anderson LJ et al. Vaccine 2013;31S:B209–B215.

# Designing a potentially effective RSV vaccine for older adults

### Vaccines R&D strategic priorities

- Proteins +/- adjuvant
- mRNA platform
- MAPS/bacterial technology

Hypothesis: combine viral surface antigen with adjuvant to deliver very high efficacy in older adults



### **RSV candidate vaccine for older adults**

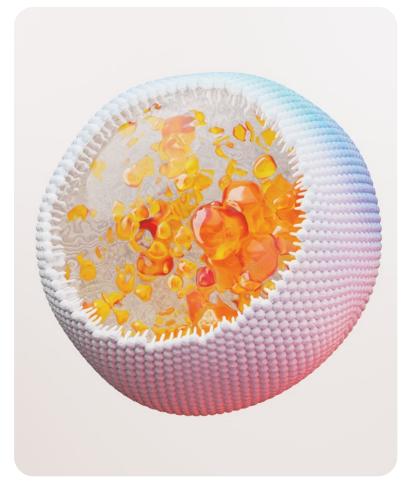
Designed to protect vulnerable adults against RSV disease

#### **RSVPreF3** antigen

- Engineered to preferentially maintain the pre-fusion conformation and display potent neutralizing epitopes<sup>1</sup>
- Induction / boosting of neutralising antibodies to enhance inhibition of viral replication<sup>2,3</sup>

#### AS01<sub>E</sub>

- Boosts cellular immune response and restores the RSVPreF3 CD4+ T-cell level in older adults to a similar range as that of young adults<sup>4,5</sup>
- Defective T-cell responses may contribute to severe disease progression in older adults<sup>6</sup>



1. Graham BS et al. Curr Opin Immunol 2015;35:30–38 ; 2. GSK, 2020. Press release. <u>https://www.gsk.com/en-gb/media/press-releases/gsk-presents-positive-clinical-data-on-maternal-and-older-adults-rsv-candidate-vaccines/</u> (accessed Nov 2021); 3. Boyoglu-Barnum S et al. Front Immunol 2019;10:1675; 4. Guiñazú JR et al., Open Forum Infectious Diseases, 2020:7 (Supp 1), S188-S189. <u>https://academic.oup.com/ofid/article/7/Supplement\_1/S188/6058593</u>; 5. GSK Investor update: RSV older adults and maternal vaccine candidates. Data presented at ID Week 2020, Oct 2020. <u>https://www.gsk.com/media/6184/gsk\_id-week-rsv-analyst-presentation-22-oct-2020.pdf</u>; 6. Openshaw PJM, et al. Annu Rev Immunol 2017;35:501–32; 7. Ruckwardt TJ et al. Immunity Rev 2019;51:429-442; 6. Cherukuri A et al. Clin Vaccine Immunol 2013; 20:239-247.

### Comprehensive clinical programme targeted to adults at greatest risk

Phase	Trial	Population	Comment	Status
Phase I/II	RSV OA=ADJ-002 NCT03814590	Adults and older adults, 18-40 or 60-80 years old	First-in-human (Phase I) Safety, immunogenicity, formulation and dosing selection (Phase II)	Complete
Phase II	RSV OA=ADJ-011 NCT04657198	Adults ≥60 years old	Persistence and safety and immunogenicity of revaccination	Complete
Phase III	RSV OA=ADJ-007 NCT04841577	Adults ≥60 years old	Safety, reactogenicity, immunogenicity when co-administered with FLU-QIV <sup>1</sup>	Complete; results to be presente at IDWeek 2022
Phase III	AReSVi-004 NCT04732871	Adults ≥60 years old	Safety, reactogenicity, immunogenicity, persistence & revaccination	Active, not recruiting; results presented at IDWeek 2022
Phase III	AReSVi-006 NCT04886596	Adults ≥60 years old	Pivotal efficacy study	Active, not recruiting; primary endpoint met. results presented at IDWeek 2022
Phase III	AReSVi-009 NCT05059301	Adults ≥60 years old	Safety and reactogenicity of three lots of RSVPreF3 OA as a single dose	Active, not recruiting; primary endpoint met

Number of participants recruited into RSV older adult vaccine candidate trials

>29k

Note: RSV '002 and '006 had independent data monitoring committee oversight. 1. Seasonal quadrivalent influenza vaccine.

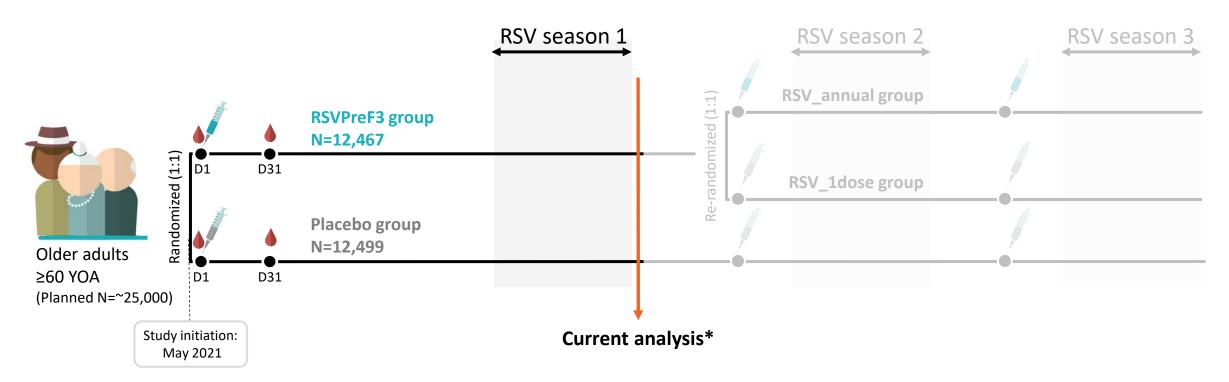


# AReSVi-006 phase III results and potential impact

#### Dr Michael Ison, Professor of Medicine and Surgery, Northwestern Medicine

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# **Methods:** Ongoing, phase 3, randomized, observer-blind, placebo-controlled, multi-country study (NCT04886596)

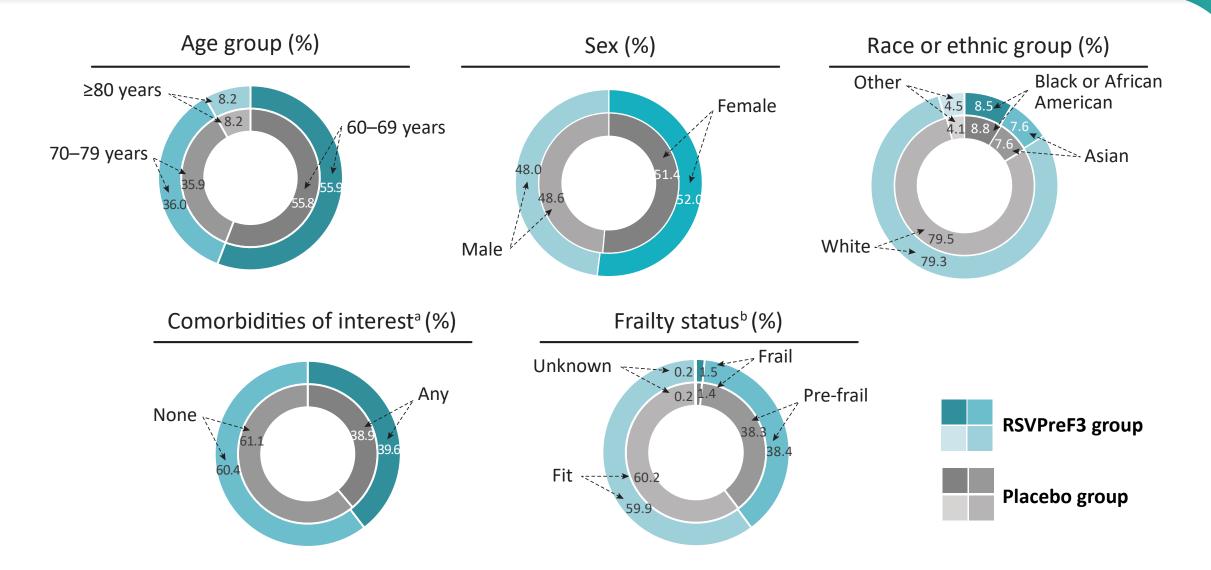


**Primary endpoint:** VE of a single dose of RSVPreF3 OA in preventing RSV-LRTD in adults ≥60 YOA during the first RSV season (criterion: lower limit of the 2-sided confidence interval [CI] for VE >20%)

**Secondary endpoints:** VE against severe RSV-LRTD, RSV-ARI, RSV-LRTD and RSV-ARI by RSV subtype (RSV-A and RSV-B), RSV-LRTD by age, baseline comorbidity and frailty status, reactogenicity and safety

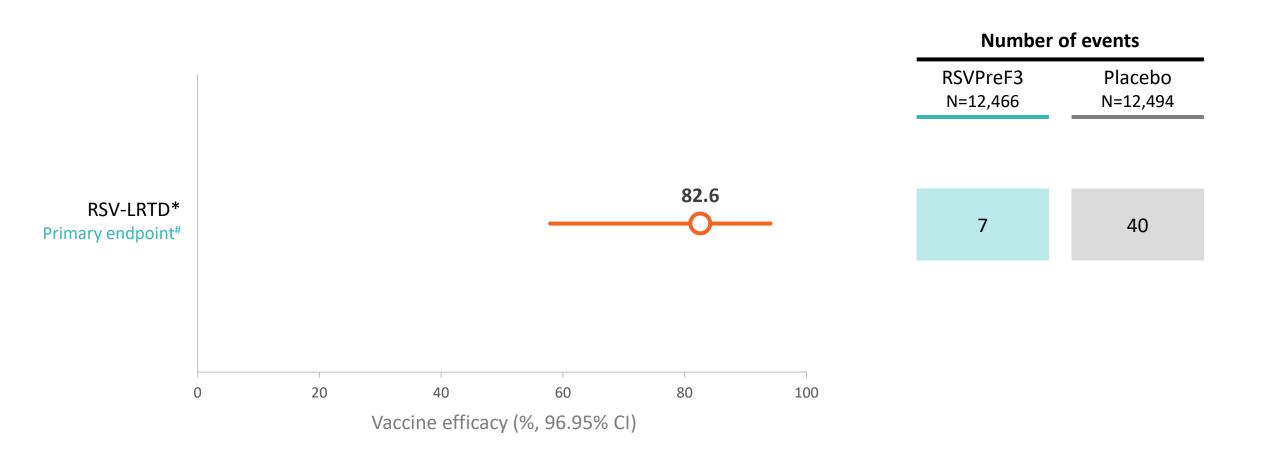
<sup>=</sup> blood sampling; D, day; YOA, years of age; VE, vaccine efficacy; LRTD, lower respiratory tract disease; ARI, acute respiratory infection; N, number of participants in the exposed set. \*up to VE data lock point (11 Apr 2022). Note: RSV season is defined as 1 Oct 1 to 30 Apr in the Northern Hemisphere and 1 Mar to 30 Sep in the Southern Hemisphere.

#### **Results:** Demographic characteristics were similar between groups



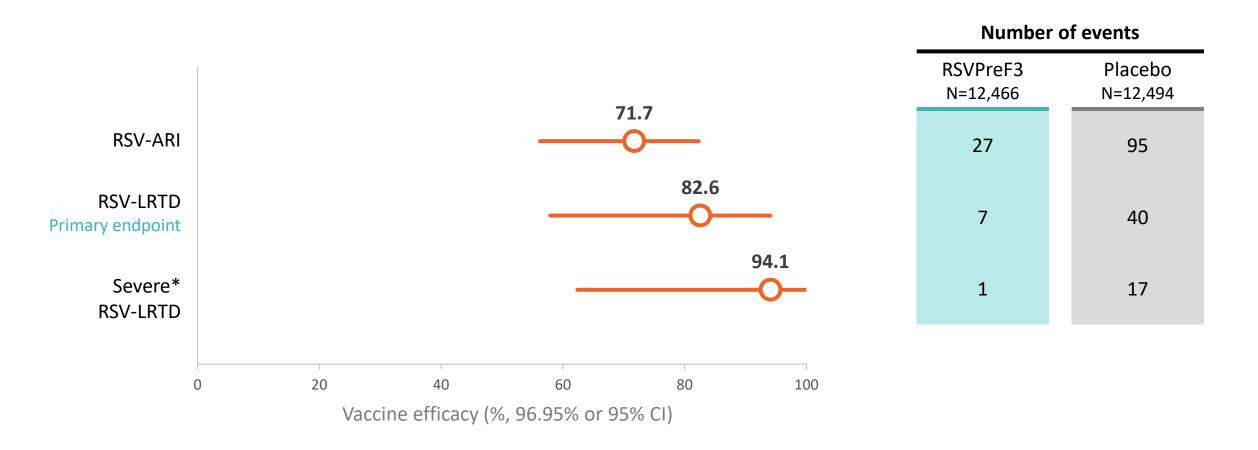
<sup>a</sup>Comorbidities of interest included chronic obstructive pulmonary disease (COPD), asthma, any chronic respiratory/pulmonary disease, chronic heart failure, diabetes mellitus type 1 or type 2 and advanced liver or renal disease. <sup>b</sup>Assessed using a gait speed test: frail, walking speed <0.4 m/s or not able to perform the test; pre-frail, walking speed 0.4–0.99 m/s; fit, walking speed ≥1 m/s.

#### **Results:** The primary endpoint (vaccine efficacy against RSV-LRTD) was demonstrated



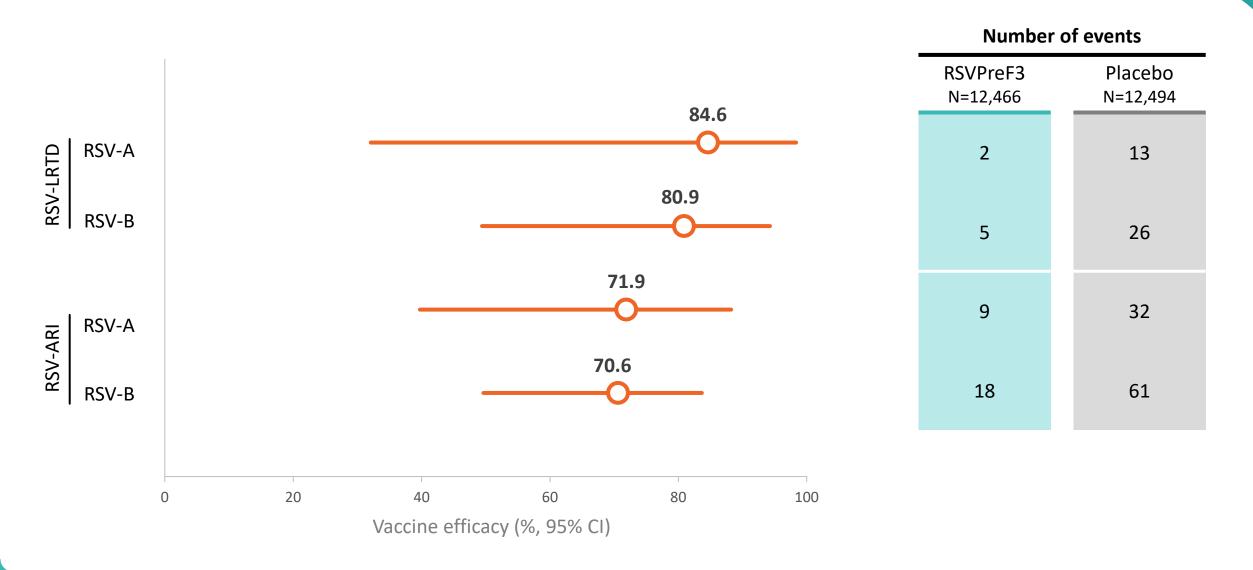
\*An event meeting the case definition of LRTD (Presence of: ≥2 lower respiratory symptoms/signs for ≥24 hours including ≥1 lower respiratory sign OR ≥3 lower respiratory symptoms for ≥24 hours)
 with ≥1 RSV-positive swab detected by quantitative reverse transcription-polymerase chain reaction (qRT-PCR). #criterion: the lower limit of the 2-sided CI for VE >20%. N, number of participants in the modified exposed set (mES). RSV etiology was confirmed by qRT-PCR. All RSV-LRTDs were confirmed by an external adjudication committee.

# **Results:** A single dose of RSVPreF3 OA is highly efficacious against the full spectrum of RSV disease, from RSV-ARI to severe RSV-LRTD



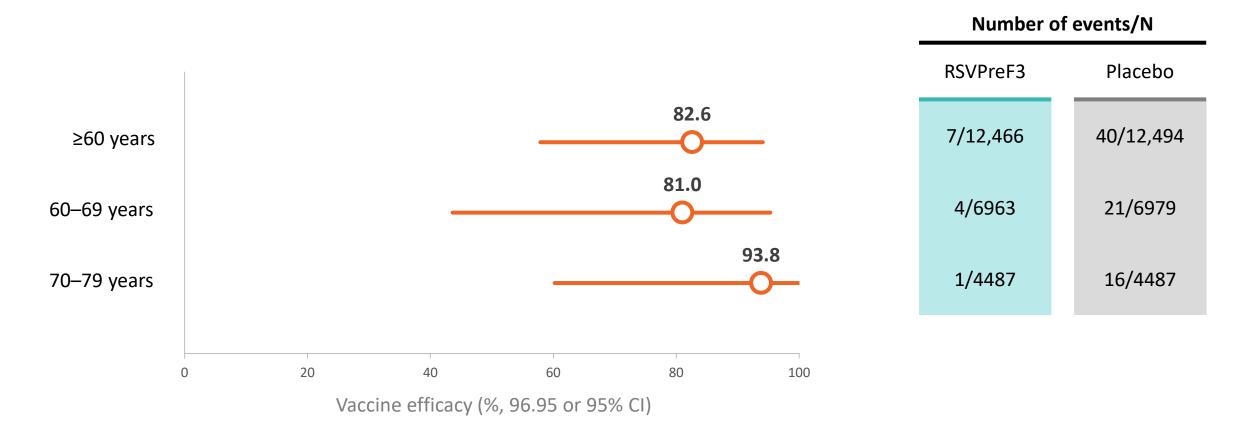
**N**, number of participants in the mES. RSV etiology was confirmed by qRT-PCR. All RSV-LRTDs were confirmed by an external adjudication committee. Error bars represent 96.95% CI for the primary endpoint and 95% CI for other endpoints. \*Severe disease according to either of the 2 case definitions (definition 1 based on clinical signs/investigator assessment or definition 2 based on supportive therapy). All 18 severe cases met case definition 1; 2 of the 18 cases were confirmed by the adjudication committee as also meeting case definition 2 (group allocation still blinded). In addition to these 19 2 cases, another 2 needed oxygen supplementation but were not confirmed by the adjudication committee as meeting case definition 2 at the time of the efficacy data lock point.

#### **Results:** Consistently high VE was observed regardless of RSV subtype



**N**, number of participants in the mES. RSV etiology was confirmed by qRT-PCR. All RSV-LRTDs were confirmed by an external adjudication committee. Error bars represent 95% Cl. **Note**: RSV subtype 20 was unknown for 1 RSV-LRTD and 2 RSV-ARI episodes.

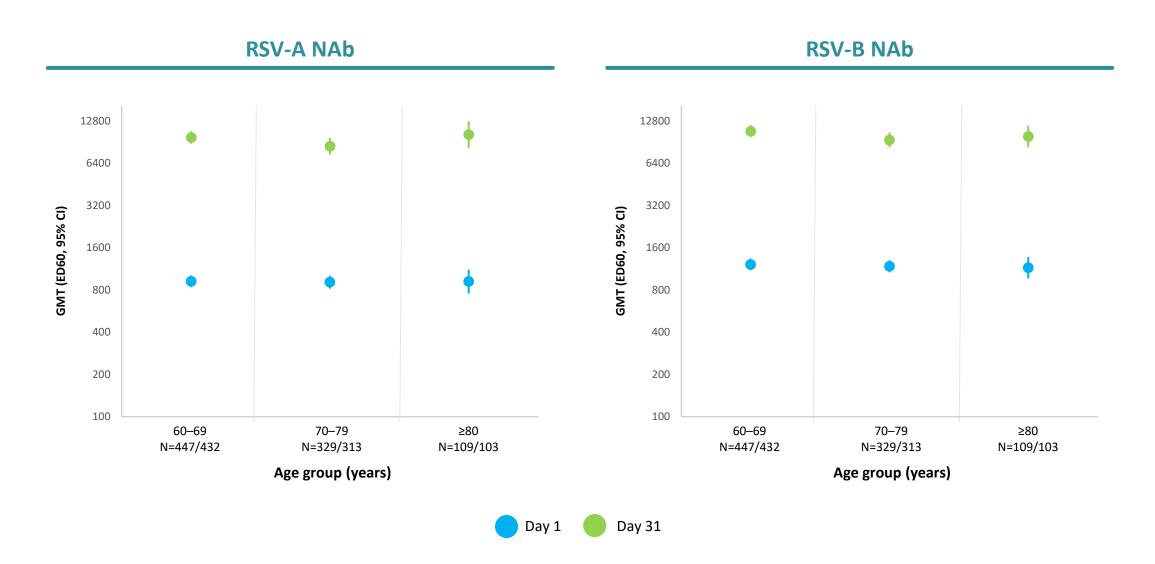
#### **Results:** High VE against RSV-LRTD was seen across different age groups



Note: VE in adults ≥80 years was inconclusive due to too few cases (2/1016 in RSVPreF3 vs 3/1028 in Placebo)

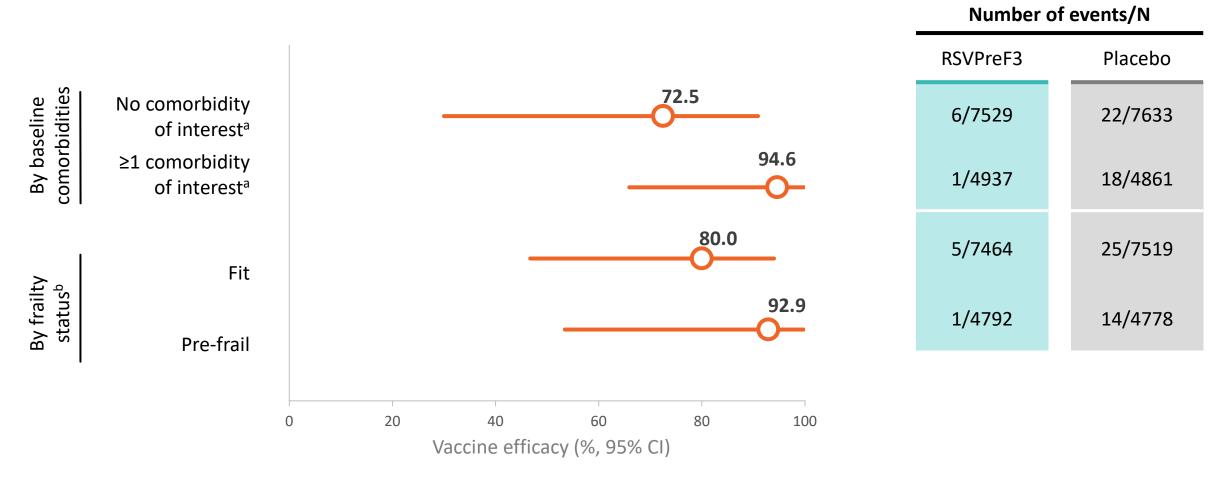
**N**, number of participants in the mES. RSV etiology was confirmed by qRT-PCR. All RSV-LRTDs were confirmed by an external adjudication committee. Error bars represent 96.95% CI for the primary endpoint (≥60 years) and 95% CI for other endpoints.

#### **Results**: Robust immune response to RSV-A and RSV-B regardless of age



ED, estimated dilution; ED60, serum dilution inducing 60% inhibition in plaque-forming units; GMT, geometric mean titer; NAb, neutralizing antibody; N, number of participants with available results at day 1/day 31.

**Results**: High VE against RSV-LRTD was observed in participants with pre-existing comorbidities and in pre-frail and fit participants

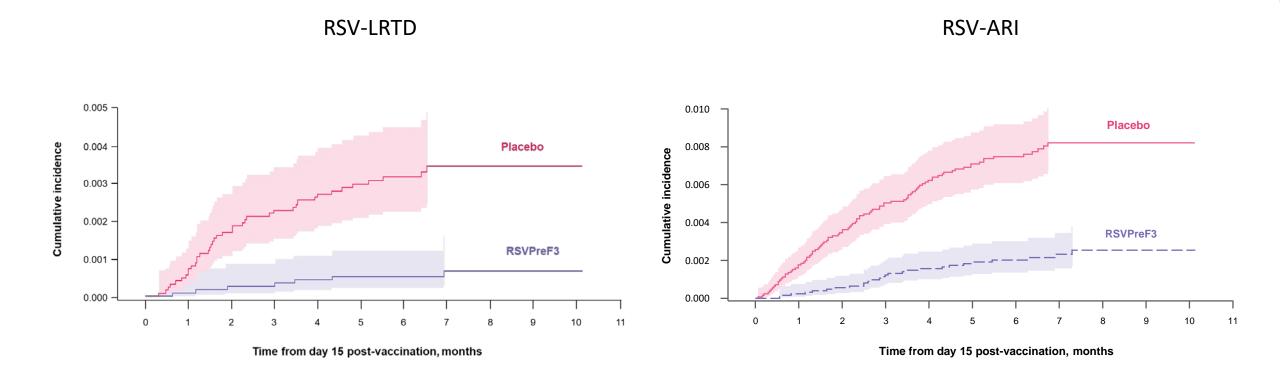


## **Note**: ~39% of participants had comorbidities and ~38% were pre-frail; VE in frail adults was inconclusive due to too few cases and the smaller number of participants (1/189 in RSVPreF3 vs 1/177 in Placebo)

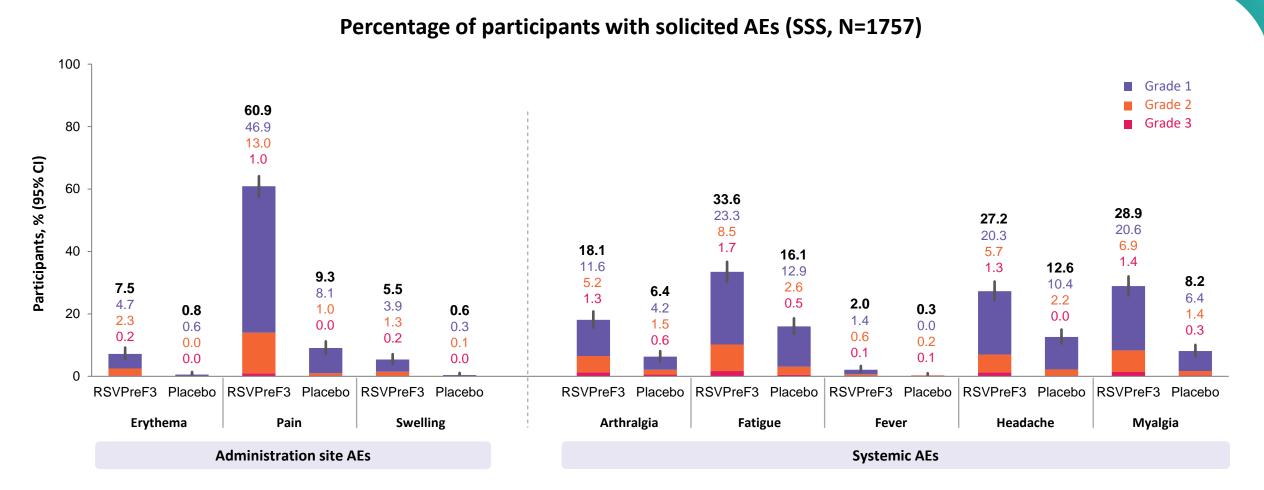
<sup>a</sup>Comorbidities of interest included COPD, asthma, any chronic respiratory/pulmonary disease, chronic heart failure, diabetes mellitus type 1 or type 2 and advanced liver or renal disease. <sup>b</sup>Assessed using a gait speed test: frail, walking speed <0.4 m/s or not able to perform the test; pre-frail, walking speed 0.4–0.99 m/s; fit, walking speed ≥1 m/s. **N**, number of participants in the mES. All RSV cases were confirmed by qRT-PCR. RSV etiology was confirmed by an external adjudication committee. Error bars represent 95% CI.

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**Results:** High VE against RSV-LRTD was observed over the median follow-up period of 6.7 months, supporting efficacy over the course of an RSV season



# **Results:** RSVPreF3 OA was well tolerated, and most solicited AEs were mild or moderate and resolved within the 4-day solicitation period (mean duration: 1–2 days)



No imbalances were observed between the RSVPreF3 OA and Placebo groups in the overall rates of SAEs, vaccination-related SAEs, fatal SAEs, pIMDs or vaccination-related pIMDs

#### Conclusions



The primary endpoint was demonstrated



A single dose of RSVPreF3 OA vaccine is highly efficacious in preventing RSV-ARI, RSV-LRTD and severe RSV-LRTD in adults ≥60 YOA over one RSV season



Vaccine efficacy was similar against RSV-A and RSV-B subtypes and was consistently high in 60–69 and 70–79-year-olds, in pre-frail older adults and in those with comorbidities



RSVPreF3 OA vaccine was well tolerated and had an acceptable safety profile

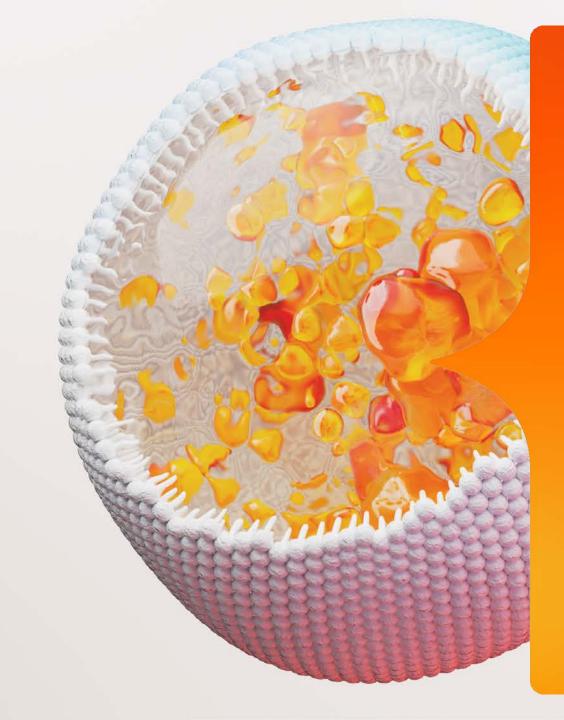


The study is ongoing and will follow participants to evaluate both an annual revaccination schedule and long-term protection over multiple RSV seasons

What do these important data mean when addressing the burden of RSV disease? What do they mean for physicians and for older adults?







How did study investigators determine degree of severity of lower respiratory tract disease? What was the rationale for the clinical study design, specifically with an end point focused on adults with comorbidities?





## **Commercial opportunity**

Roger Connor, President Vaccines and Global Health Luke Miels, Chief Commercial Officer

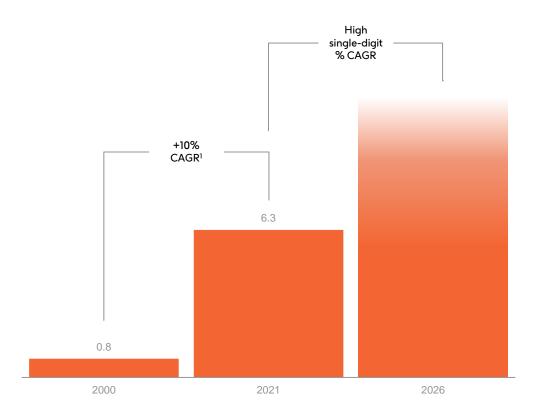
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### A long history of innovation leadership

#### Vaccine leadership

- c.70-year history of vaccine development (introduced polio vaccines in 1950s)
- Broadest portfolio in the industry with 25 vaccines supplied across 160 countries
- >15 new product launches since 2000
- Market leading in multiple categories eg shingles, meningitis, and paediatrics

#### Driving innovative vaccines sales £m<sup>1</sup>



1. Excluding pandemic solutions (flu and COVID-19) and at CER. Please also refer to page 2 of the second quarter 2022 results announcement. All outlooks, targets, ambitions and expectations regarding future performance and the dividend should be read together with the "Guidance, assumptions and cautionary statements" on page 69 of our second quarter 2022 earnings release. 2021-26 CAGR is for the 5 years to 2026, using 2021 as the base year.

### Data at IDWeek 2022 further strengthen GSK's vaccines position

# RSV OA<sup>1</sup> data suggests potential to expand vaccine portfolio for elderly

#### Vaccines approved in growing OA segment

Vaccine	Indication
Shingrix	Herpes zoster (shingles)
Boostrix	Tetanus, diphtheria, and pertussis
Fluarix/ FluLaval QV	Influenza A & B

Havrix/Engerix-B/Twinrix Hepatitis A & B

# *Shingrix* duration data sets new standard for shingles prevention

- Unprecedented high efficacy for 10 years
- Unconstrained supply supports geographic expansion (from 23 countries to >35 by 2024)
- Active LCM<sup>2</sup> (potential label expansion, eg autoimmune disease; fully liquid formulation)
- Confident in ambition to double *Shingrix* sales by 2026<sup>3</sup>, protecting more than 100m adults

### Data offers potential best-in-class profile in the most vulnerable adults Consistent high efficacy

Reduction in severe
disease

94.1%

Efficacy in those with comorbidities

94.6%

Efficacy in those aged 70-79 years

93.8%

Key risk factors are age and comorbidities

- Older adults at increased risk from RSV disease due to reduced immune function
- Those with comorbidities eg cardiovascular, respiratory, and diabetes, are at even higher risk of severe outcomes<sup>1</sup>
- CDC: >90% of hospitalised adults have underlying medical conditions (c.50%: 3+)<sup>1</sup>
- RSV has substantial economic burden with direct medical costs c.\$3bn<sup>2</sup> in US alone<sup>3</sup>

1. Introduction to ACIP's Adult Respiratory Syncytial Virus Work Group: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-06-22-23/01-RSV-Kotton-508.pdf; 2. Herring, W. et al. (2021), Carrico, J et al (2022); 3. Additional impact from lost productivity, long-term health consequences and care costs. Note: Comorbidities included in '006 study included those with pre-existing chronic conditions such as chronic obstructive pulmonary disease, asthma, any chronic respiratory/pulmonary disease, chronic heart failure, diabetes mellitus type-1 or type-2 and advanced liver or renal disease. Around 39% of participants in both the placebo and the vaccine groups had these pre-existing comorbidities.

### RSV OA vaccine candidate represents significant opportunity Q4 2022: US FDA submission acceptance; EU regulatory submission

# Consistent high efficacy offers a best-in-class profile

- 94.1% efficacy against severe RSV disease
- Magnitude of benefit consistent across key subgroups
- Well tolerated
- Builds on GSK legacy of vaccine innovation and respiratory expertise

Substantial unmet need and market opportunity

- Older adults and those with comorbidities at risk of severe outcomes
- One of highest-value unmet needs in infectious disease
- Multi-billion Shingrix-like sales potential

Launch readiness and long-term differentiation

- US launch bulk prepared and ready for swift launch, post approval
- Launch priorities include value-based pricing and raising disease awareness
- Co-administration, annual revaccination, multiseason duration being examined



Endpoint	Case definition
ARI (trigger for swabbing)	<ul> <li>Presence of:</li> <li>at least two respiratory symptoms/signs for at least 24 hours</li> <li>OR</li> <li>at least one respiratory symptom/sign + one systemic symptom/sign for at least 24 hours</li> </ul>
RSV-ARI <sup>a</sup>	An event meeting the case definition of ARI with at least one RSV-positive swab detected by qRT-PCR <sup>b</sup>
LRTD	<ul> <li>Presence of:</li> <li>at least two lower respiratory symptoms/signs for at least 24 hours including at least one lower respiratory sign OR</li> <li>at least three lower respiratory symptoms for at least 24 hours</li> </ul>
RSV-LRTD <sup>a</sup>	An event meeting the case definition of LRTD with at least one RSV-positive swab detected by qRT-PCR <sup>b</sup>
severe RSV-LRTD – Definition 1 – Clinical symptomology <sup>a</sup>	<ul> <li>Presence of an LRTD with at least one of the following criteria:</li> <li>at least two lower respiratory signs</li> <li>an LRTD episode assessed as severe by the investigator<sup>c</sup></li> <li>AND</li> <li>at least one RSV-positive swab detected by qRT-PCR<sup>b</sup></li> </ul>
severe RSV-LRTD – Definition 2 – Supportive therapy <sup>a</sup>	<ul> <li>Presence of an LRTD with at least one of the following criteria<sup>d</sup>:</li> <li>Need for oxygen supplementation<sup>e</sup></li> <li>Need for positive airway pressure therapy (eg CPAP)</li> <li>Need for other types of mechanical ventilation</li> <li>AND</li> <li>with at least one RSV-positive swab detected by qRT-PCR<sup>b</sup></li> </ul>

**CPAP**, continuous positive airway pressure. <sup>a</sup>Throat and/or nasal swab samples collected at ARI visits for qRT-PCR testing were collected within 6D after ARI onset (ie up to D7). In special circumstances (for example in case of suspected COVID-19 infection and pending COVID-19 test result, or self-quarantine) and if it was not possible to perform the ARI visit within 6D after ARI onset (ie within D3 to D7), then the interval for this visit and the site swab collection could be extended up to maximum 14D after ARI onset (ie until D15). Swabs testing positive within this window were considered as related to the ARI. <sup>b</sup>At least 1 swab (self-swab or swab taken by study personnel) positive for RSV-A or RSV-B by qRT-PCR. <sup>c</sup>The investigator graded each ARI as mild, moderate or severe. <sup>d</sup>In case the participant was already receiving any of these for treating/controlling any pre-existing condition, any significant change or adaptation in the used therapy had to be taken into account. <sup>e</sup>Reported by the investigator