

## Breakout 1

# Seasonal respiratory viruses

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Interactive event for investors and analysts. This webinar is being recorded.

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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 the Q1 2023 earnings release and Annual Report on Form 20-F for FY 2022.

All guidance, outlooks, ambitions and expectations should be read together with the Guidance, assumptions and cautionary statements in GSK's Q1 2023 earnings release and the 2022 Annual Report.

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. On 18 July 2022, GSK plc separated its Consumer Healthcare business from the GSK Group to form Haleon, an independent listed company. 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.

# Speakers



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SVP, Global Head,  
Vaccines R&D



**Christi Kelsey**  
SVP, Global Head,  
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# Seasonal respiratory viruses

Respiratory viruses are frequent and cause significant disease worldwide

Respiratory syncytial virus

~330k

annual older adult hospitalisations<sup>1</sup>

- RSV infections can be dangerous for certain adults<sup>2</sup>
- ~177k hospitalisations and 14k deaths in the US each year<sup>3</sup>
- RSV is a stable seasonal virus that can reinfect, but typically circulates as RSV-A or RSV-B

Influenza

~1 billion

people infected annually<sup>4</sup>

- Mild to severe illness that can lead to death<sup>5</sup>
- ~8% of US population gets sick from flu each season<sup>5</sup>
- Complications can include bacterial pneumonia, ear infections, sinus infections and worsening of chronic medical conditions, such as congestive heart failure, asthma, or diabetes<sup>5</sup>

SARS-CoV-2

>750 million

confirmed cases worldwide<sup>6</sup>

- Very contagious and spreads quickly; symptoms feel much like flu, cold, pneumonia<sup>7</sup>
- 6.9 million deaths worldwide<sup>8</sup>
- >1m deaths in the US<sup>9</sup>

1. PubMed. Global Disease Burden Estimates of Respiratory Syncytial Virus-Associated Acute Respiratory Infection in Older Adults in 2015: A Systematic Review and Meta-Analysis. Accessed June 2023. Available at: <https://pubmed.ncbi.nlm.nih.gov/30880339/> 2. Centers for Disease Control and Prevention. Older Adults are at High Risk for Severe RSV Infection. Accessed June 2023. Available here: <https://www.cdc.gov/rsv/factsheet-older-adults.pdf> 3. Falsey AR, et al. N Engl J Med 2005; 352:1749-1759 DOI: 10.1056/NEJMoa043951. Accessed March 2023 4. World Health Organization. WHO launches new global influenza strategy. Accessed June 2023. Available at: <https://www.who.int/news/item/11-03-2019-who-launches-new-global-influenza-strategy> 5. Centers for Disease Control and Prevention. Key Facts About Influenza (Flu). Accessed June 2023. Available at: <https://www.cdc.gov/flu/about/keyfacts.htm> 6. World Health Organization. WHO Coronavirus (COVID-19) Dashboard. Accessed June 2023. Available at: <https://covid19.who.int/> 7. Centers for Disease Control and Prevention. About COVID-19. Accessed June 2023. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/your-health/about-covid-19.html> 8. World Health Organization. WHO Coronavirus (COVID-19) Dashboard. Accessed June 2023. Available at: <https://covid19.who.int/> 9. Nature. Assessing the impact of one million COVID-19 deaths in America: economic and life expectancy losses. Accessed June 2023. Available at: <https://www.nature.com/articles/s41598-023-30077-1>

# Arexvy first-approved respiratory syncytial virus (RSV) vaccine for adults

## Exceptional efficacy for patients aged 60 years or older

Efficacy against RSV LRTD in patients with at least one comorbidity

94.6%

Overall efficacy against RSV-LRTD

82.6%

### >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>

### Arexvy designed to protect vulnerable adults

- RSVPreF3 antigen engineered to preferentially maintain the pre-fusion conformation and display potent neutralising epitopes<sup>7</sup>
- Induction/boosting of neutralising antibodies to enhance inhibition of viral replication<sup>8,9</sup>
- AS01e 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>10,11</sup>
- Defective T-cell responses may contribute to severe disease progression in older adults<sup>12</sup>

Arexvy has potential to deliver multi-billion annual sales

1. Chronic obstructive pulmonary disease 2. CDC, 2020. RSV in older adults and adults with chronic medical conditions. Accessed November 2021. Available at: <https://www.cdc.gov/rsv/high-risk/older-adults.html> 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 7. Graham BS et al. Curr Opin Immunol 2015;35:30–38 8. GSK, 2020. Press release. Accessed November 2021. Available at: <https://www.gsk.com/en-gb/media/press-releases/gsk-presents-positive-clinical-data-on-maternal-and-older-adults-rsv-candidate-vaccines/> 9. Boyoglu-Barnum S et al. Front Immunol 2019;10:1675 10. Guinazú JR et al. Open Forum Infectious Diseases, 2020;7 (Supp 1), S188-S189. Available at: [https://academic.oup.com/ofid/article/7/Supplement\\_1/S188/6058593](https://academic.oup.com/ofid/article/7/Supplement_1/S188/6058593) 11. GSK Investor update: RSV older adults and maternal vaccine candidates. Data presented at ID Week 2020, Oct 2020. Available at: [https://www.gsk.com/media/6184/gsk\\_id-week-rsv-analyst-presentation-22-oct-2020.pdf](https://www.gsk.com/media/6184/gsk_id-week-rsv-analyst-presentation-22-oct-2020.pdf) 12. Openshaw PJM, et al. Annu Rev Immunol 2017;35:501–32

# Arexvy season two data supports multi-season profile

## Clinical evidence builds as launch commences

One dose was efficacious over two complete RSV seasons, including against severe disease

	Overall LRTD VE (95% CI)	Severe LRTD VE (95% CI)
<b>Season 1</b> primary end pt (6.7 months)	<b>82.6%</b> (57.9, 94.1)	<b>94.1%</b> (62.4, 99.9)
<b>Mid Season 2</b> Post dose 1 (14 month)	<b>77.3%</b> (60.2, 87.9)	<b>84.6%</b> (56.4, 96.1)
<b>Season 1 + 2</b> Cumulative (median 18 months)	<b>67.2%</b> (48.2, 80.0)	<b>78.8%</b> (52.6, 92.0)

- Efficacy observed across age groups and in adults with underlying comorbidities
- Safety and reactogenicity data consistent with initial phase III results
- Optimal timing of revaccination still to be determined; trial will continue

### US CDC advisory panel recommended *Arexvy* for upcoming RSV season

- Recommended for in adults aged 60 and older with shared clinical decision making
- 77 million older adults in the US<sup>1</sup> could be eligible for RSV vaccination for the first time
- On track for making product available before the start of the 2023/2024 RSV season

### Next steps

- Data from two influenza co-administration trials (quadrivalent high dose and quadrivalent adjuvanted) to be filed H2 2023
- Phase III data for 50-59 year old high-risk adults expected H2 2023
- Regulatory decision in Japan anticipated H2 2023

# Influenza market poised for disruption using multivalent mRNA

## Significant unmet medical need due to the high burden of disease

Annual influenza illnesses

~1 billion<sup>1</sup>

Annual deaths

≤650k<sup>1</sup>

Market size by 2028

~£8 billion

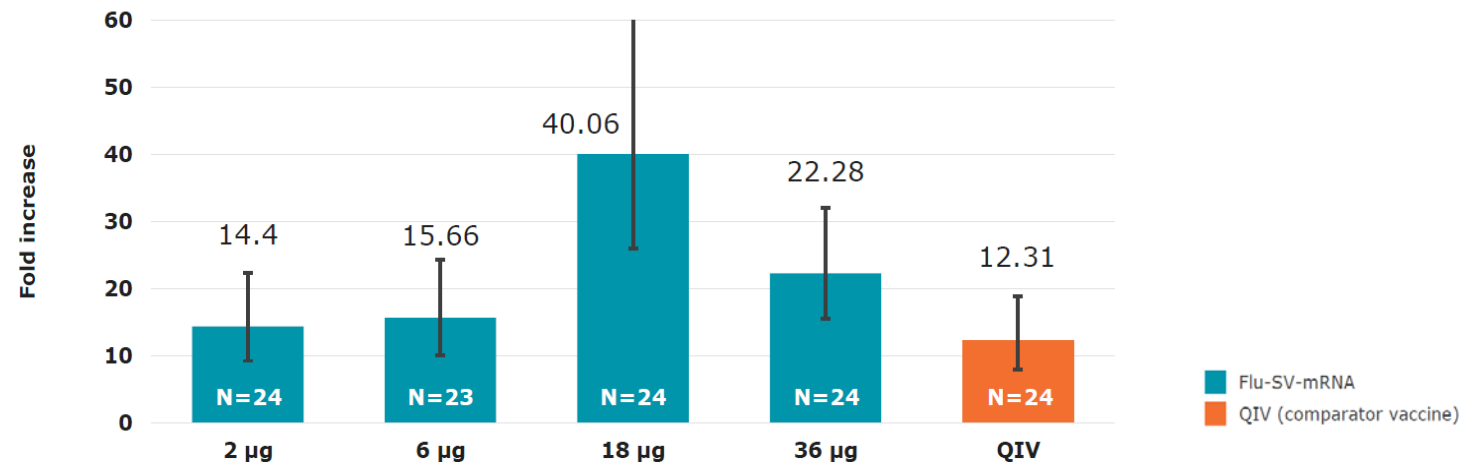
Influenza

Next-generation  
multivalent vaccine  
candidate

- Preliminary positive phase I data showed strong functional antibody increase at lowest dose of Flu-SV-mRNA (monovalent), in line with comparator vaccine
- Multivalent phase I/II trials underway; data expected end 2023/2024

Ratio post- to pre-boost titres:

Ratio of serum HI geometric mean titres induced by Flu-SV-mRNA in younger adults (18-45 years)



# mRNA offers potential for accelerated combination vaccines

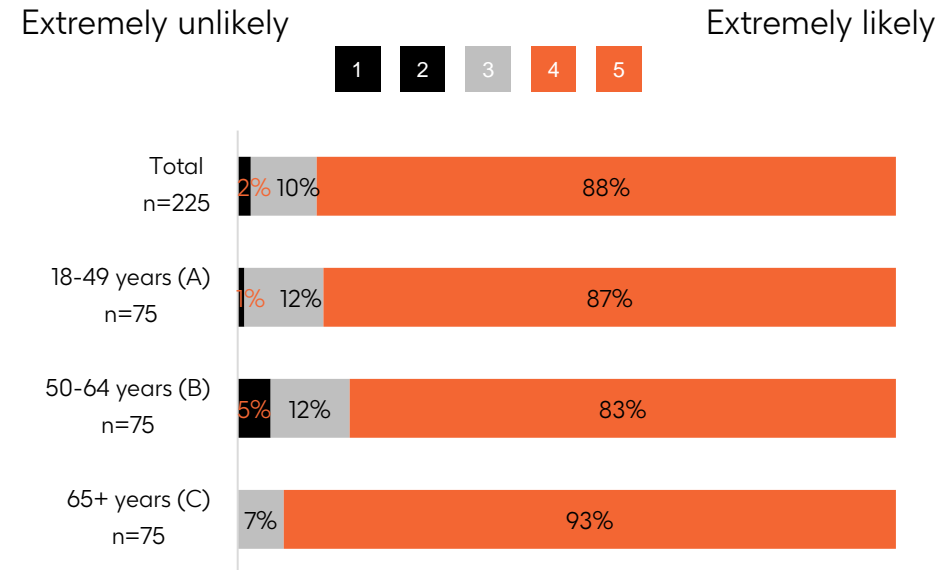
Efficacious and tolerable multivalent vaccines needed for consumer acceptance

- Regulatory environment supportive of seasonal respiratory combination options
- Healthcare providers and consumers willing to accept combinations
- Value proposition for combination vaccines is stronger than individual components due to added convenience and potential for higher immunisation rates

## Consumers likely to accept respiratory combination vaccines

95% consumer acceptance of flu-COVID combination<sup>1</sup>

Likelihood to receive flu + COVID-19 combination vaccine



Weighted intention to convert - calculated as (100% \*4-5 box, Extremely likely) and (50% \*3 box neither/nor)



# News flow in seasonal respiratory viruses and full ID pipeline

## Commitments to profitable growth

Respiratory syncytial virus<sup>1</sup>

>£3bn

in peak year sales

- **Status:** first US FDA and EMA approved vaccine for RSV
- **Next steps:** additional flu co-admin data, 50-59 high-risk adults phase III data and further regulatory decisions (JP) anticipated in H2 2023

Influenza<sup>2</sup>

>£3bn

in peak year sales

- **Status:** full-year 2022 sales of £714 (+5% AER, -4% CER). Positive phase I next-generation monovalent modified mRNA vaccine candidate data; successfully boosted antibody titres against matching flu strain
- **Next steps:** results for newly started phase I/II trial for multivalent vaccine candidate expected late 2023/2024

### Phase I - 22 assets

2904545 (adjuvanted recombinant protein*) <i>C. difficile</i>
4429016 (adjuvanted bioconjugated, recombinant protein*) <i>K. pneumoniae</i>
3993129 (adjuvanted recombinant subunit) cytomegalovirus <sup>1</sup>
4382276 (mRNA*) seasonal flu
4396687 (mRNA*) COVID-19
4077164 (bivalent GMMA*) invasive non-typhoidal salmonella**
3943104 (recombinant protein, adjuvanted*) therapeutic herpes simplex virus
3536867 (bivalent conjugate*) salmonella ( <i>typhoid + paratyphoid A</i> )
2556286 (Mtb cholesterol dependent inhibitor*) tuberculosis
3186899 (CRK-12 inhibitor** <sup>2</sup> ) visceral leishmaniasis
3494245 (proteasome inhibitor*) visceral leishmaniasis
3772701 ( <i>P. falciparum</i> whole cell inhibitor*) malaria
3882347 (FimH antagonist*) uncomplicated UTI
3923868 (PI4K beta inhibitor) viral COPD exacerbations
4182137 (anti-spike protein antibody*) COVID-19 <sup>1</sup>
3965193 (PAPD5/PAPD7 inhibitor) Hep B
5251738 (TLR8 agonist*) Hep B
cabotegravir (integrase inhibitor [400 mg/ml formulation]) HIV
3739937 (maturation inhibitor) HIV
4004280 (capsid protein inhibitor) HIV
4011499 (capsid protein inhibitor) HIV
4524184 (integrase inhibitor*) HIV

### Phase II - 14 assets

3437949 (adjuvanted recombinant protein*) malaria fractional dose
4406371 (live, attenuated) MMRV new strain
3536852 (GMMA*) Shigella
3528869 (viral vector with recombinant protein, adjuvanted*) therapeutic hepatitis B virus <sup>1**</sup>
4023393 (recombinant protein, OMV, conjugated vaccine) MenABCWY, 2nd Gen <sup>1</sup>
4178116 (live, attenuated) varicella, new strain
5101956 (MAPS*) adult pneumococcal disease, 24-valent
5101955 (MAPS*) paediatric pneumococcal disease, 24-valent
4106647 (adjuvanted recombinant protein*) human papillomavirus <sup>1</sup>
4348413 (GMMA) gonorrhoea <sup>1</sup>
3036656 (leucyl t-RNA synthetase inhibitor*) tuberculosis
sanfetrinem cilexetil (GV118819) tuberculosis
BVL-GSK098 (ethionamide booster*) tuberculosis
VIR-2482 (neutralising monoclonal antibody* <sup>3</sup> ) influenza
3810109 (broadly neutralising antibody*) HIV

### Phase III - 8 assets

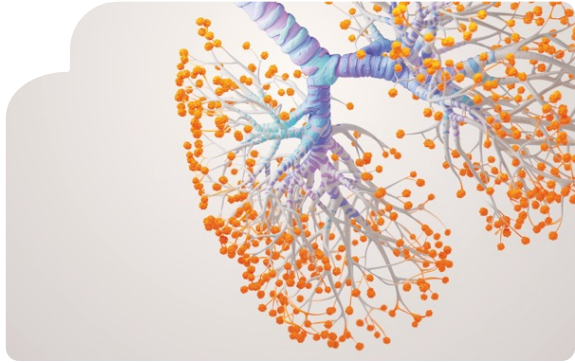
Arexvy (adjuvanted recombinant protein*) RSV older adults <sup>4</sup>
SKYCovione (recombinant protein nanoparticle, adjuvanted* <sup>5</sup> ) COVID-19 <sup>6</sup>
gepotidacin (BTI inhibitor*) uncomplicated UTI**
bepirovirsen (antisense oligonucleotide*) hepatitis B virus**
Bexsero (recombinant protein) MenB
MenABCWY (recombinant protein, OMV, conjugated vaccine) MenABCWY, 1st Gen
tebipenem pivoxil (antibacterial carbapenem*) complicated UTI <sup>5</sup>
Brefafemme (antifungal glucan synthase inhibitor*) invasive candidiasis

■ Infectious diseases  
■ HIV

# Q & A

# Getting ahead of infectious diseases with GSK management

Four Q&A-focused, virtual breakout sessions

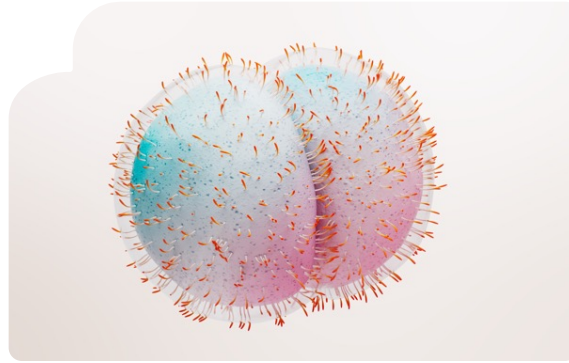


## Seasonal respiratory viruses

Session 1: 14:30-15:00 BST  
Session 2: 15:15-15:45 BST

Phil Dormitzer  
Christi Kelsey  
Luke Miels

IR: [jeffrey.r.mclaughlin@gsk.com](mailto:jeffrey.r.mclaughlin@gsk.com)



## Bacterial and fungal infections

Session 1: 14:30-15:00 BST  
Session 2: 15:15-15:45 BST

Kumaran Vadivelu  
Rob Bowers  
David Redfern

IR: [joshua.x.williams@gsk.com](mailto:joshua.x.williams@gsk.com)



## Chronic viral infections

Session 1: 14:30-15:00 BST  
Session 2: 15:15-15:45 BST

Chris Corsico  
Lizzie Champion  
James Greenhalgh  
Tony Wood

IR: [mick.j.readey@gsk.com](mailto:mick.j.readey@gsk.com)



## Delivering health impact at scale

Session 1: 14:30-15:00 BST  
Session 2: 15:15-15:45 BST

Deborah Waterhouse  
Thomas Breuer

IR: [frances.p.defranco@gsk.com](mailto:frances.p.defranco@gsk.com)