

## Breakout 2

### Bacterial and fungal infections

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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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Head of General  
Medicines, Commercial

# Bacterial and fungal infections

## Treating common infections with novel approaches

### Meningococcal disease

**~10-15%**  
of people infected die<sup>1</sup>

- Bacteria called *Neisseria meningitidis* cause meningococcal disease. Three serogroups (B, C, and Y) of *Neisseria meningitidis* cause most of the illness seen in the United States.<sup>2</sup>
- Acute bacterial meningitis is one of the deadliest and most disabling forms of this illness, leading to death of 1 in 6 people<sup>1</sup>

### Pneumococcal disease

**~1 million**  
global deaths annually<sup>3</sup>

- Bacteria called *Streptococcus pneumoniae*, or pneumococcus, can cause many types of infections, including the ears, lungs, blood, sinuses, and the lining of the brain and spinal cord. Some of these infections can be life-threatening<sup>4</sup>

### Uncomplicated urinary tract infections (uUTIs)

**>50%**  
of all women are affected<sup>5</sup>

- >25% of women suffer from recurrent disease, which can cause significant patient burden, including discomfort and restriction of daily activities<sup>6,7,8</sup>
- uUTIs caused by resistant bacteria is increasing, which can result in higher treatment failure rates<sup>9</sup>

### Complicated urinary tract infections (cUTIs)

**3 million**  
cases in the US per year<sup>10, 11</sup>

- New oral antibiotics for cUTIs urgently needed to reduce hospitalisation, facilitate early discharge, and avoid re-admissions and emergency dept. visits
- >620k US hospitalisations per year<sup>12</sup>

### Vulvovaginal candidiasis (VVC)

**>10 million**  
US patients suffering per year<sup>13</sup>

- Commonly known as “yeast infections” caused by a fungus called *Candida*
- 1/3 of patients considered to have complicated or challenged VVC with no treatment options

1. CDC. Accessed June 2023. Available at: <https://www.cdc.gov/meningococcal/about/diagnosis-treatment.html> 2. CDC. Accessed June 2023. Available at: <https://www.cdc.gov/meningococcal/about/causes-transmission.html> 3. WHO. Accessed June 2023: <https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/vaccine-standardization/pneumococcal> 4. Centers for Disease Control and Prevention. Pneumococcal Disease. Types of Infection. Accessed June 2023. Available at: <https://www.cdc.gov/pneumococcal/about/infection-types.html> 5. National Library of Medicine. An introduction to the epidemiology and burden of urinary tract infections. Accessed June 2023. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6502976> 6. Hooton TM. Uncomplicated Urinary Tract Infection. N Engl J Med. 2012;366:1028-37 7. Rich SN, Klann EM, Almond CR, Larkin EM, Nicolette G, Ball JD. Associations between antibiotic prescriptions and recurrent urinary tract infections in female college students. Epidemiology and Infection. 2019;147 8. Medina M, Castillo-Pino E. An introduction to the epidemiology and burden of urinary tract infections. Therapeutic Advances in Urology. 2019;11:175628721983217 9. Kaye KS, et al. Antimicrobial resistance trends in urine Escherichia coli isolates from adult and adolescent females in the United States from 2011 to 2019: rising ESBL strains and impact on patient management. Clin Infect Dis 2021;73:1992-1999. doi: 10.1093/cid/ciab560 10. Based on Carreno et al. Longitudinal, Nationwide, Cohort Study to Assess Incidence, Outcomes, & Costs Associated with Complicated Urinary Tract Infection. Open Forum Infectious Diseases, Volume 6, Issue 11, November 2019 & Trinity Claims 11. Spero TRINITY Claims Analysis (Komodo & CDM data) 12. National Library of Medicine. Complicated Urinary Tract Infections. Accessed June 2023. Available at: <https://www.ncbi.nlm.nih.gov/books/NBK436013/> 13. Benedict et al. 2022 DOI:10.1186/s12905-022-01741-x

# Positive preliminary phase III data for MenABCWY vaccine candidate

## Combination could improve vaccination rates among adolescents

MenABCWY vaccine candidate combines *Bexsero* and *Menveo*

# 5 in 1

MenB vaccination rates among US adolescents are low

# 31%<sup>1</sup>

“The potential for a simplified immunisation schedule could improve accessibility for the target population susceptible to meningococcal disease.”

Professor Terry Nolan, principal investigator for the phase III trial\*

MenABCWY pivotal phase III data demonstrated statistical non-inferiority compared to *Bexsero* and *Menveo*

- Only investigational candidate that showed immunological effectiveness against 110 diverse MenB invasive strains
- Generally well tolerated, with a safety profile consistent with *Bexsero* and *Menveo*
- US regulatory submission in 2024
- Ongoing lifecycle management work to expand coverage, age populations and pursue global licensures

Current US CDC recommendation includes four doses<sup>2</sup>

	11-12 years	16-18 years
MenACWY	1 dose	1 dose
MenB		2 doses

Potential immunization schedule could reduce to three doses

	11-12 years	16-18 years
MenACWY	1 dose	
MenABCWY		2 doses

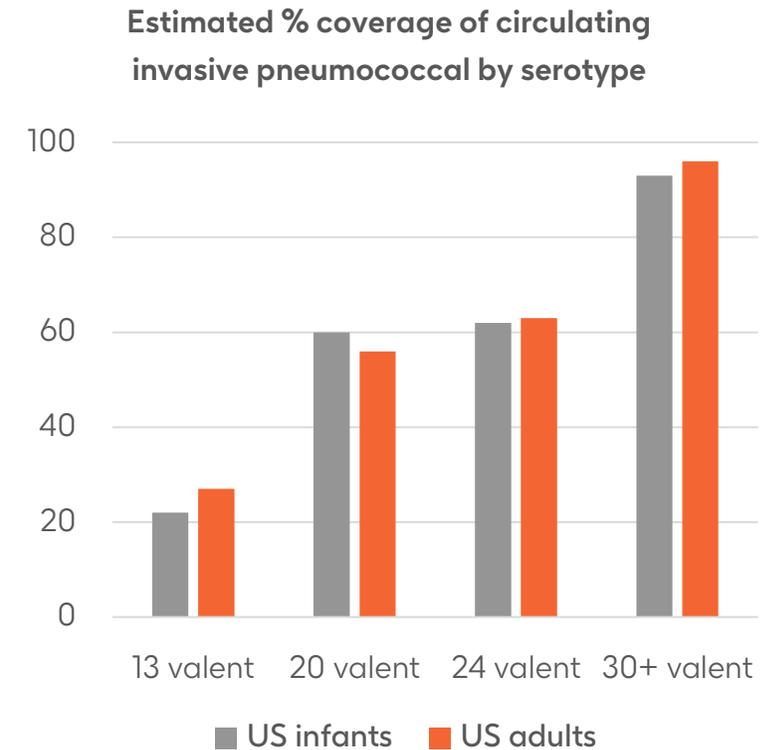
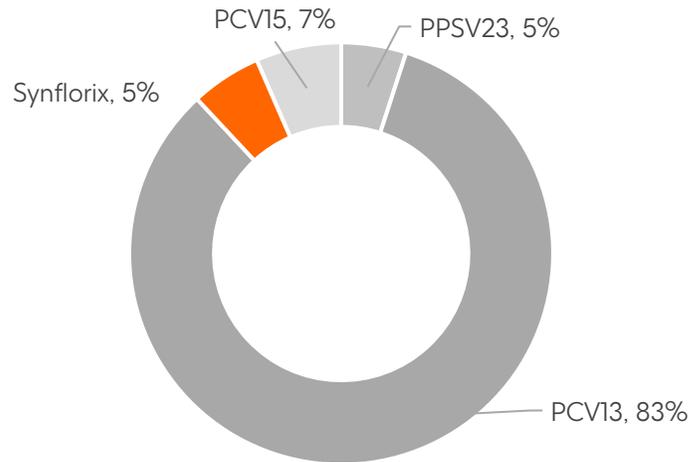
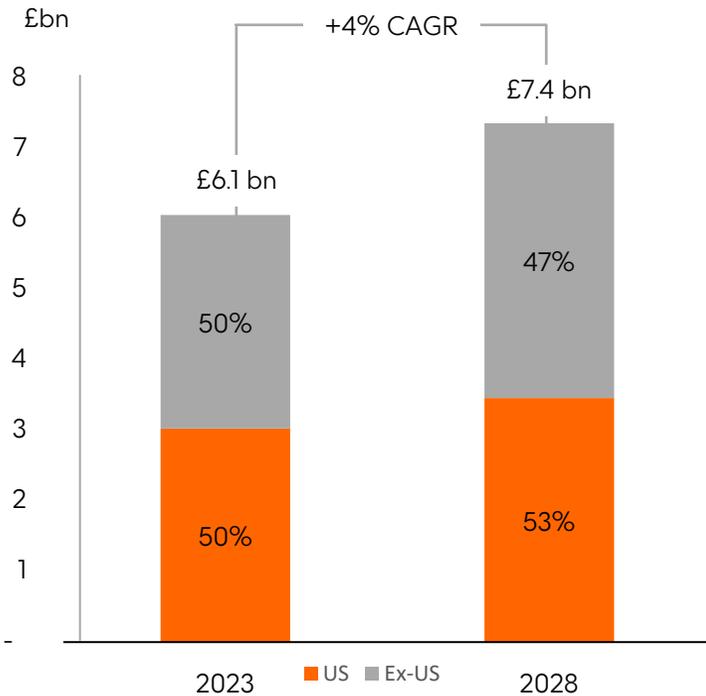
# Pneumococcal Vaccine Market

## Significant burden in adults and children despite successful PCV13 vaccination

High unmet medical need: global pneumococcal vaccine market +4% CAGR 2023-2028

Pneumococcal market ripe for disruption from a higher valent vaccine

Significant opportunities remain to address disease burden by expanding serotype coverage



# Multiple Antigen Presenting System (MAPS)<sup>1</sup>

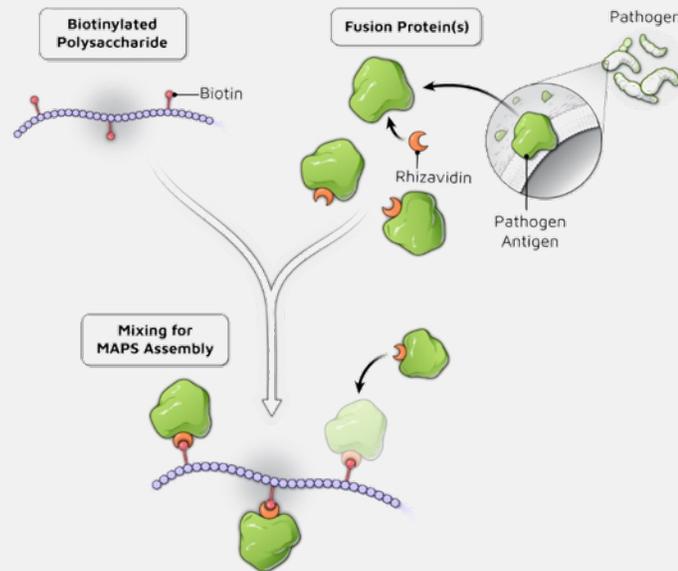
Highly-innovative approach allowing for higher valency and robust immune

MAPS offers a broad immune response: antibody-mediated immunity to the polysaccharides and B-cell and T-cell response to the proteins

“Beads on a string”

Immunogenic epitopes are not compromised, enabling the immune system to recognise and induce a protective response to pneumococcal protein carriers and polysaccharides

Distinctive plug-and-play technology allows for an efficient and scalable manufacturing process and the development of higher-valent vaccines

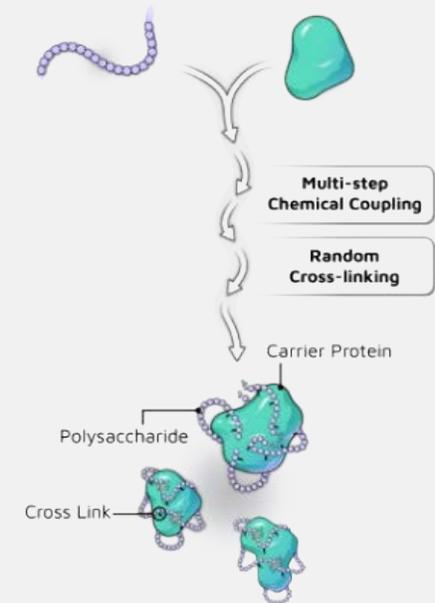


Conventional conjugate vaccine provides only antibody-mediated immunity

“Spaghetti and meatballs”

Carrier protein unrelated to the target pathogen (e.g. CRM197)

Carrier-induced immunological suppression might limit the possibility to go above 20-valent

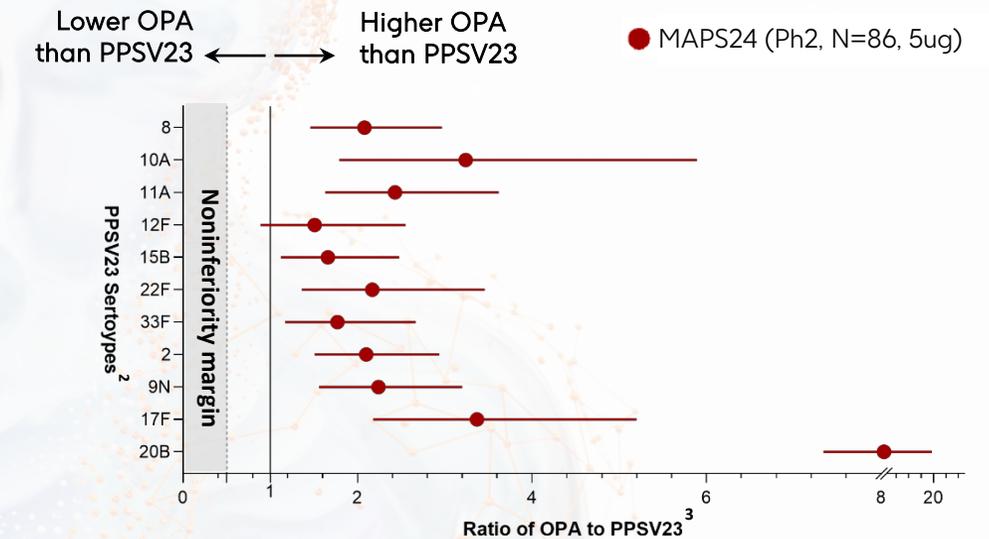
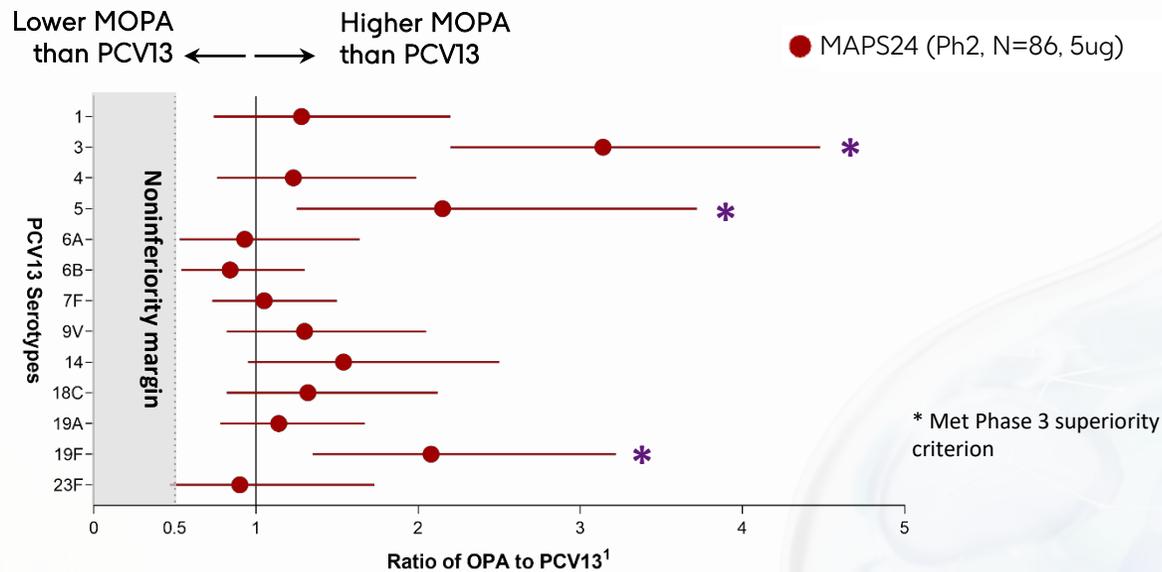


# MAPS-24 valent data showed immune responses across serotypes

## Phase 2: enhanced immune response for majority of serotypes

MAPS24 OPA Ratio to Prevnar 13 (PCV13)  
in Older Adults (aged 65 – 85)<sup>1</sup>

MAPS24 OPA Ratio to Pneumovax 23 (PPSV23) in Older Adults (Aged 65 – 85)<sup>1</sup>

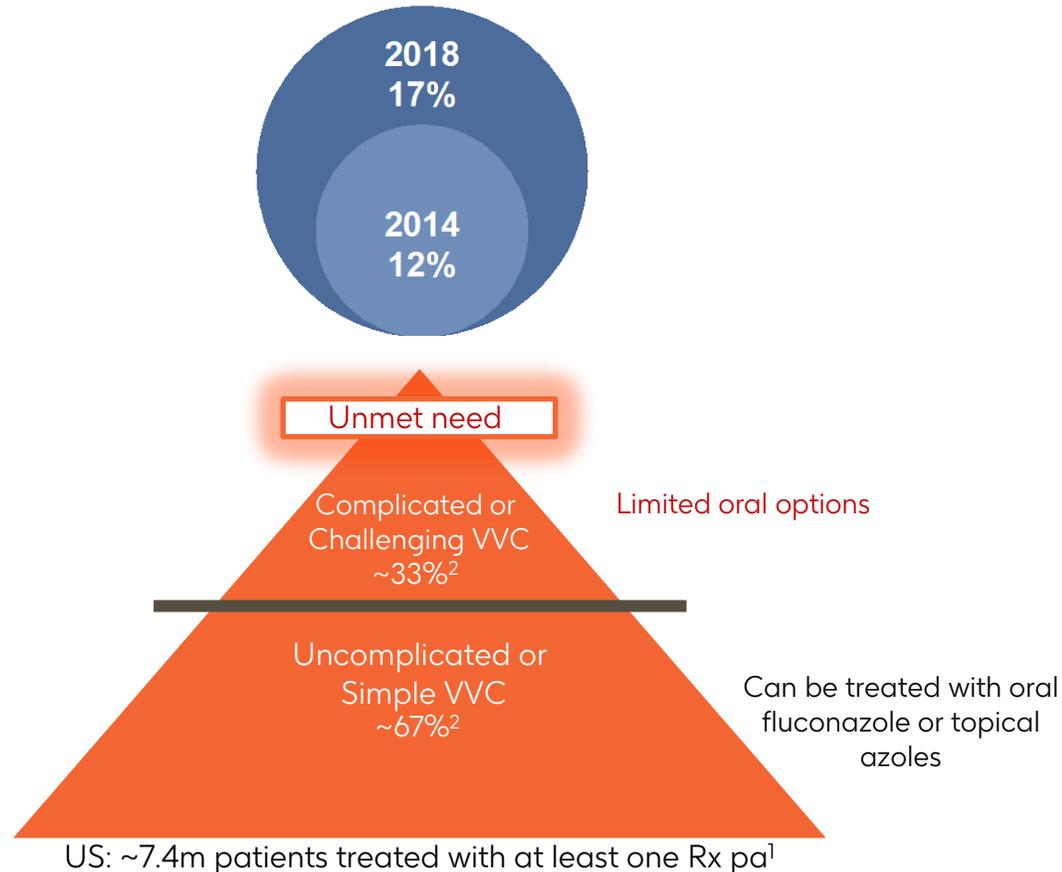


MAPS24 met Ph 3 superiority criterion for Serotypes 3, 5, and 19F, potentially addressing a significant unmet need in SoC  
The Phase 3 superiority criterion was met for most additional serotypes shared with PPSV23

# Need for novel bacterial and fungal treatment options

Significant morbidity burden heightened by AMR and little innovation for decades

% of UTI isolates that are ESBL+\* in US hospital setting is rising



## Reasons to believe in commercial success

- **Large populations:** focused on significant areas of unmet need
- **Novel assets only:** differentiated assets, avoiding “me too” products
- **WHO pathogens:** widely appreciated concern and need to act now
- **Oral, community treatment options:** oral medicines keeping patients out of hospital and reducing healthcare costs
- **Limited competition:** Legacy experience and highly-skilled salesforce in community setting

# A new chapter for novel or first-in-class oral anti-infectives

## Pipeline of oral, outpatient, community options

### Gepotidacin

Potential first in new class of oral antibiotics for uUTI in over 20 years

#### Stopped early for efficacy

- Both phase III studies met primary endpoint of non-inferiority to nitrofurantoin (a first-line antibiotic) and one study also demonstrated statistical superiority
- Showed consistent treatment effect in resistant, recurrent and patients >50 yrs
- Safety data indicated an acceptable tolerability profile

#### Next steps

- Preparing US and EU regulatory submissions
- 2024: US regulatory decision and Japanese regulatory submission

### Tebipenem

Potential first oral carbapenem for cUTIs in patients with limited options

#### Important subclass of antibiotics

- > 3.3m cases of cUTI in US each year<sup>1,2</sup>
- Limited oral treatment options for multi-drug resistant cUTIs – patients hospitalized and put on IV
- IV treatment costs US healthcare system >\$6bn per year<sup>1</sup>

#### Next steps

- Spero on track to start a new phase III clinical trial in 2023, following encouraging US FDA feedback on proposed clinical trial design

### *Brexafemme*

First-in-class oral with broad spectrum anti-fungal activity

#### Proven activity against priority pathogens

- Distinct mechanism of action similar to echinocandins, with fungicidal action against candida
- First and only oral antifungal approved for both the treatment of VVC and reduction of incidence of RVVC
- Also being studied in Invasive Candidiasis – a life threatening fungal infection
- Activity against WHO-designated pathogens including *Candida albicans* and *Candida auris*

#### Next steps

- Relaunch the VVC and rVVC indication in the US
- Phase III programme in invasive candidiasis underway

# News flow in bacterial and fungal infections and full ID pipeline

## Commitments to profitable growth

### Meningitis<sup>1</sup>

£1-2bn

in peak year sales

### *Streptococcus pneumoniae* (pneumococcal)<sup>2</sup>

>£4bn

in peak year sales

### Anti-infectives<sup>3</sup>

~£2bn

in peak year sales

- Status:** full-year 2022 sales of £1,116 (+16% AER, +11% CER). Phase III primary endpoints met; only 5-in-1 vaccine to demonstrate immunological effectiveness against 110 diverse MenB invasive strains
- Next steps:** US regulatory submission in 2024
- Status:** access to next generation pneumococcal vaccine candidate and highly innovative MAPS technology
- Next steps:** 24-valent adult phase III start in 2024. Phase III data 2025+. Paediatrics launch before the end of the decade. 30-plus valent adult to advance to the clinic in 2024
- Status:** Portfolio of novel or first-in-class, oral assets for community or outpatient infections with growing resistance.
- Next steps:** Preparing US and EU regulatory submissions for gepotidacin, start a new phase III clinical trial in 2023 for tebipenem, relaunch *Brexafemme* for VVC and rVVC in US

## 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*) 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

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

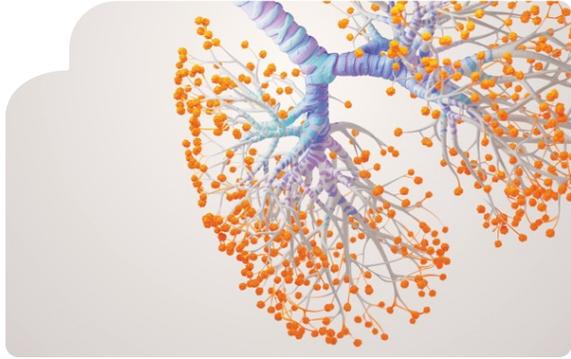
■ Infectious diseases  
■ HIV

# Q&A



# Getting ahead of infectious diseases with GSK management

Four Q&A-focused, virtual breakout sessions

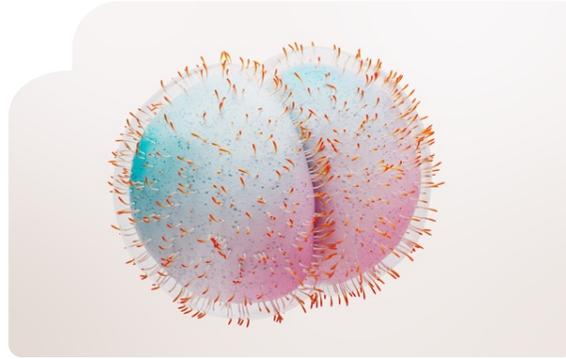


## Seasonal respiratory viruses

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)

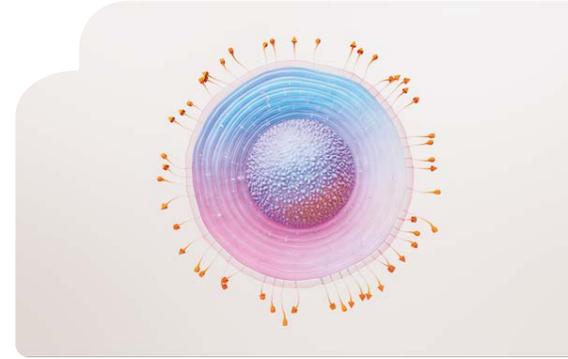


## Bacterial and fungal infections

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)