

Breakout 2

Bacterial and fungal infections

Dr Kumaran Vadivelu, Head of Vaccines Development

Rob Bowers, Head of General Medicines

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

Cautionary statement regarding forward-looking statements

This presentation may contain forward-looking statements. Forward-looking statements give the Group's current expectations or forecasts of future events. An investor can identify these statements by the fact that they do not relate strictly to historical or current facts. They use words such as 'anticipate', 'estimate', 'expect', 'intend', 'will', 'project', 'plan', 'believe', 'target' and other words and terms of similar meaning in connection with any discussion of future operating or financial performance. In particular, these include statements relating to future actions, prospective products or product approvals, future performance or results of current and anticipated products, sales efforts, expenses, the outcome of contingencies such as legal proceedings, dividend payments and financial results.

Other than in accordance with its legal or regulatory obligations (including under the Market Abuse Regulations, UK Listing Rules and the Disclosure Guidance and Transparency Rules of the Financial Conduct Authority), the Group undertakes no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise. Investors should, however, consult any additional disclosures that the Group may make in any documents which it publishes and/or files with the US Securities and Exchange Commission (SEC). All investors, wherever located, should take note of these disclosures. Accordingly, no assurance can be given that any particular expectation will be met and investors are cautioned not to place undue reliance on the forward-looking statements.

Forward-looking statements are subject to assumptions, inherent risks and uncertainties, many of which relate to factors that are beyond the Group's control or precise estimate. The Group cautions investors that a number of important factors, including those in this presentation, could cause actual results to differ materially from those expressed or implied in any forward-looking statement. Such factors include, but are not limited to, those discussed under Item 3.D 'Risk factors' in the Group's Annual Report on Form 20-F for the full year (FY) 2022 and any impacts of the COVID-19 pandemic. Any forward-looking statements made by or on behalf of the Group speak only as of the date they are made and are based upon the knowledge and information available to the Directors on the date of this presentation.

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



**Dr Kumaran
Vadivelu**
Head of Vaccines
Development, R&D



Rob Bowers
Head of General
Medicines, Commercial

Bacterial and fungal infections

Treating common infections with novel approaches

Meningococcal disease

~10-15%

of people infected die¹

- 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.²
- Acute bacterial meningitis is one of the deadliest and most disabling forms of this illness, leading to death of 1 in 6 people¹

Pneumococcal disease

~1 million

global deaths annually³

- 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-threatening⁴

Uncomplicated urinary tract infections (uUTIs)

>50%

of all women are affected⁵

- >25% of women suffer from recurrent disease, which can cause significant patient burden, including discomfort and restriction of daily activities^{6,7,8}
- uUTIs caused by resistant bacteria is increasing, which can result in higher treatment failure rates⁹

Complicated urinary tract infections (cUTIs)

3 million

cases in the US per year^{10, 11}

- 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 year¹²

Vulvovaginal candidiasis (VVC)

>10 million

US patients suffering per year¹³

- 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%¹

“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 doses²

	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

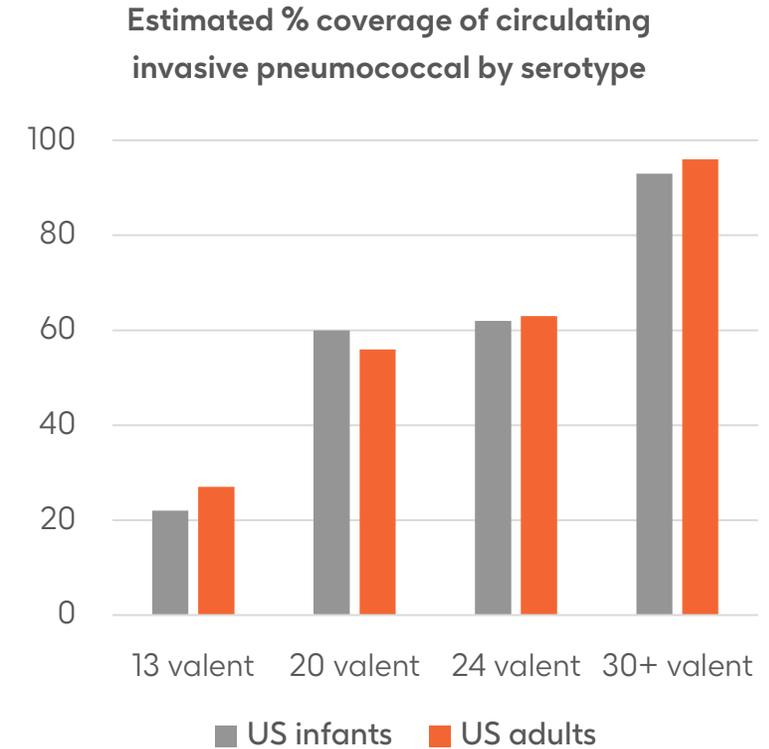
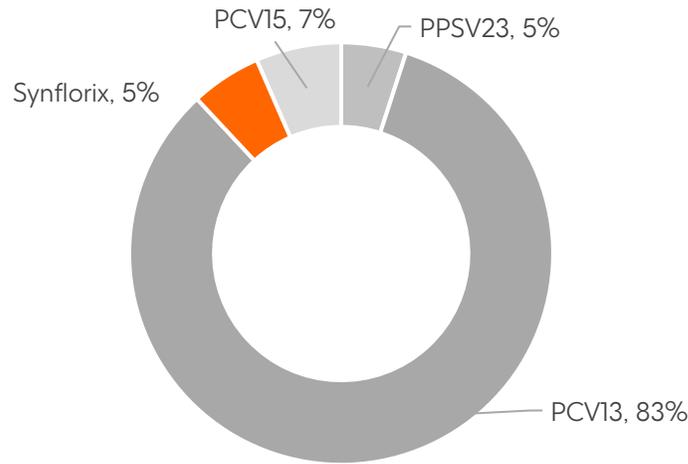
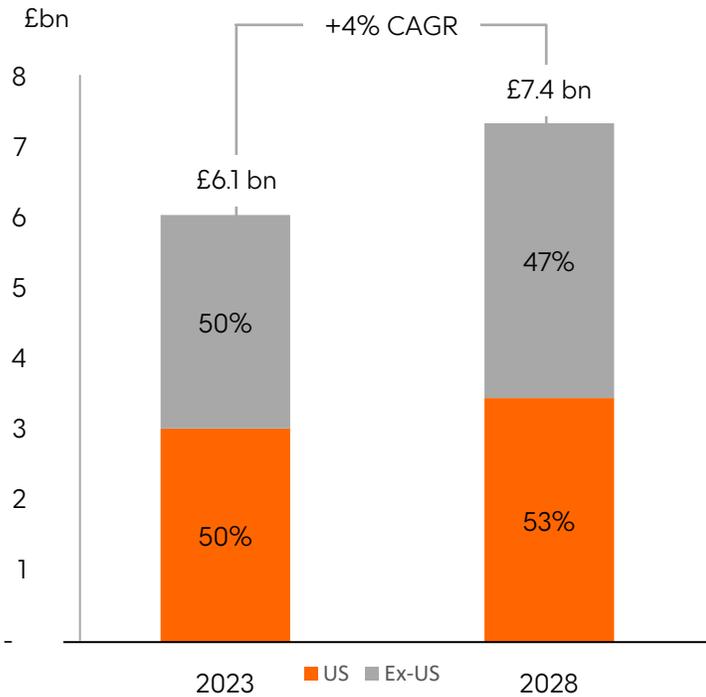
Pneumococcal Vaccine Market

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)¹

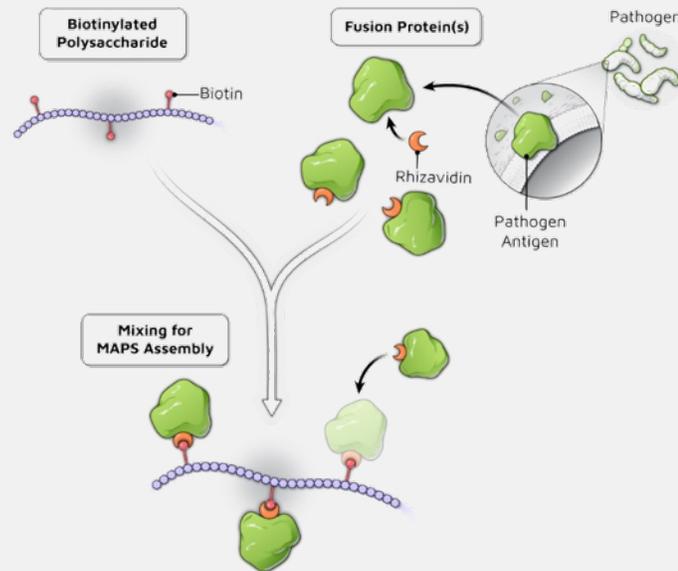
Highly-innovative approach allowing for higher valency and robust immune

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

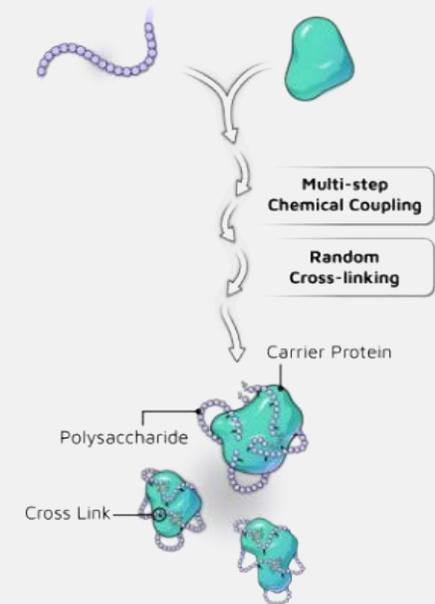


Conventional conjugate vaccine provides only antibody-mediated immunity

“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

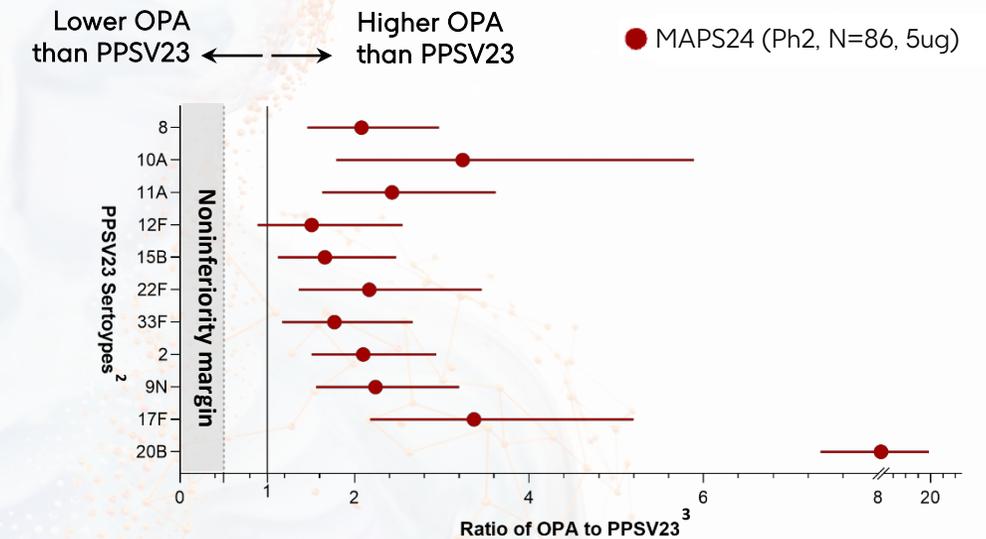
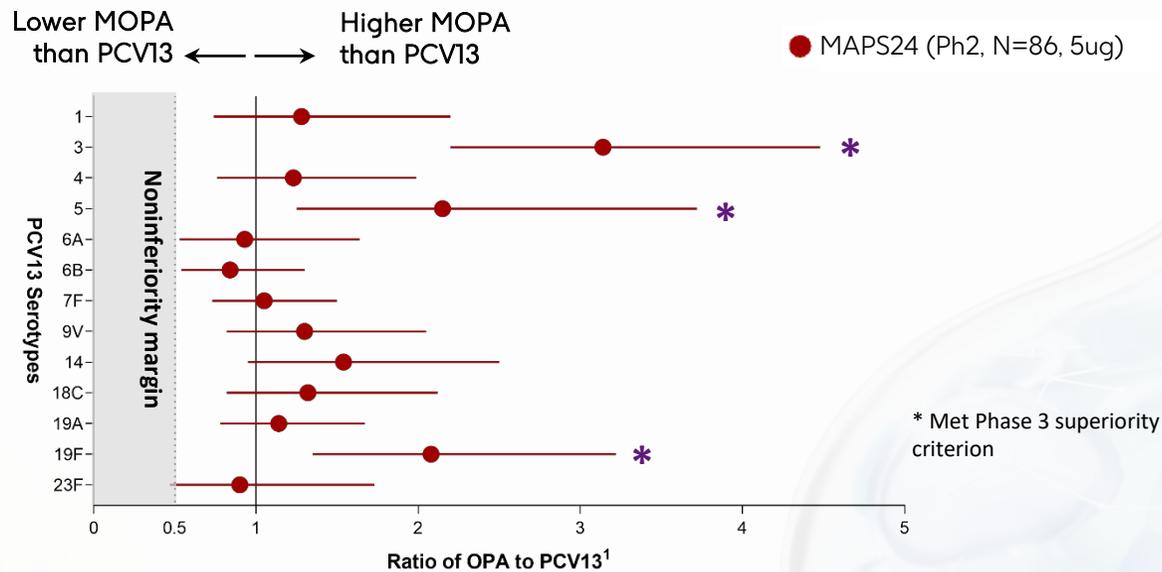


MAPS-24 valent data showed immune responses across serotypes

Phase 2: enhanced immune response for majority of serotypes

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

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

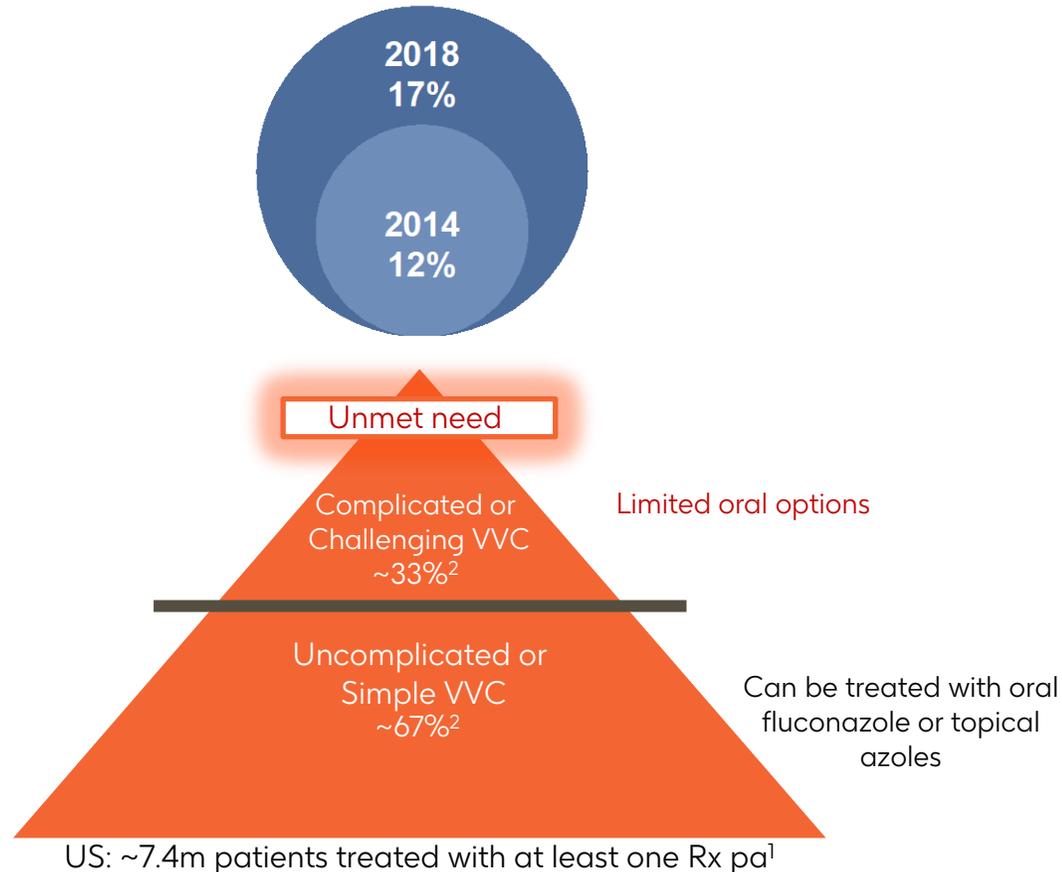


MAPS24 met Ph 3 superiority criterion for Serotypes 3, 5, and 19F, potentially addressing a significant unmet need in SoC
The Phase 3 superiority criterion was met for most additional serotypes shared with PPSV23

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^{1,2}
- Limited oral treatment options for multi-drug resistant cUTIs – patients hospitalized and put on IV
- IV treatment costs US healthcare system >\$6bn per year¹

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

Meningitis¹

£1-2bn

in peak year sales

Streptococcus pneumoniae (pneumococcal)²

>£4bn

in peak year sales

Anti-infectives³

~£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 ¹
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 ¹
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 ^{1**}
4023393 (recombinant protein, OMV, conjugated vaccine) MenABCWY, 2nd Gen ¹
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 ¹
4348413 (GMMA) gonorrhoea ¹
3036656 (leucyl t-RNA synthetase inhibitor*) tuberculosis
sanfetrinem cilexetil (GV118819) tuberculosis
BVL-GSK098 (ethionamide booster*) tuberculosis
VIR-2482 (neutralising monoclonal antibody*) ³ influenza
3810109 (broadly neutralising antibody*) HIV

Phase III - 8 assets

<i>Arexvy</i> (adjuvanted recombinant protein*) RSV older adults ⁴
<i>SKYCovione</i> (recombinant protein nanoparticle, adjuvanted*) COVID-19 ⁴
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 ⁵
<i>Brexafemme</i> (antifungal glucan synthase inhibitor*) invasive candidiasis

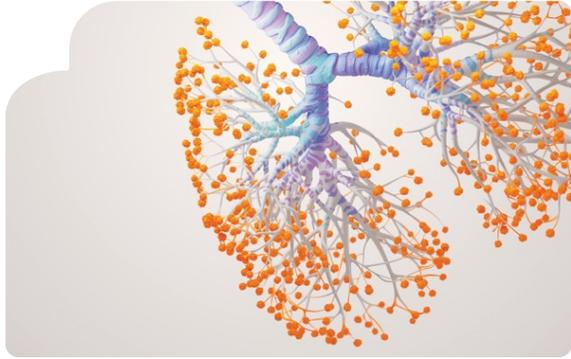
■ Infectious diseases
■ HIV

Q&A



Getting ahead of infectious diseases with GSK management

Four Q&A-focused, virtual breakout sessions

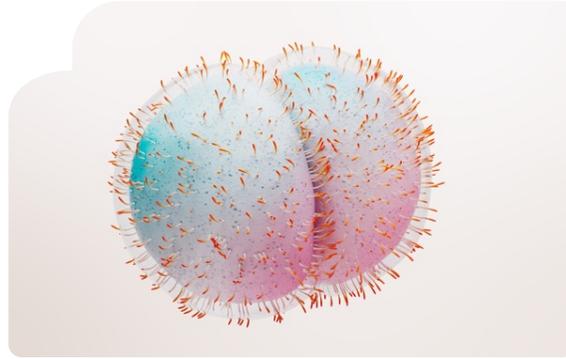


Seasonal respiratory viruses

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

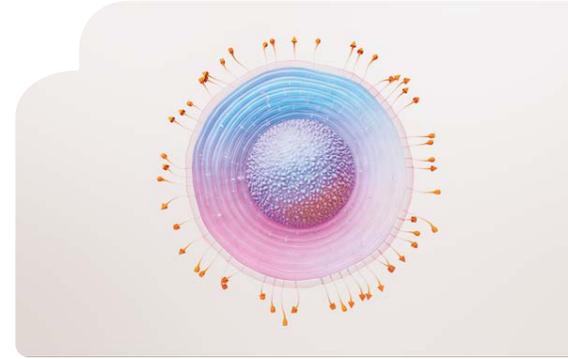


Bacterial and fungal infections

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



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



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