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.

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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
### Meningococcal disease

<table>
<thead>
<tr>
<th>~10-15% of people infected die(^1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacteria called <em>Neisseria meningitidis</em> cause meningococcal disease. Three serogroups (B, C, and Y) of <em>Neisseria meningitidis</em> cause most of the illness seen in the United States. (^2)</td>
</tr>
<tr>
<td>Acute bacterial meningitis is one of the deadliest and most disabling forms of this illness, leading to death of 1 in 6 people(^3)</td>
</tr>
</tbody>
</table>

### Pneumococcal disease

<table>
<thead>
<tr>
<th>~1 million global deaths annually(^3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacteria called <em>Streptococcus pneumoniae</em> 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(^4)</td>
</tr>
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### Uncomplicated urinary tract infections (uUTIs)

<table>
<thead>
<tr>
<th>&gt;50% of all women are affected(^5)</th>
</tr>
</thead>
</table>

### Complicated urinary tract infections (cUTIs)

<table>
<thead>
<tr>
<th>3 million cases in the US per year(^10,11)</th>
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</thead>
<tbody>
<tr>
<td>Vulvovaginal candidiasis (VVC)</td>
</tr>
<tr>
<td>&gt;10 million US patients suffering per year(^13)</td>
</tr>
</tbody>
</table>

\(^1\) 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
\(^7\) Rich SN, Kline EM, Larkin EM, Nicotella G, Blixt 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;11:6756282019382577
\(^10\) Based on Carreno et al. Longitudinal, Nationwide, Chort Study to Assess Incidence, Outcomes, & Costs Associated with Complicated Urinary Tract Infection. Open Forum Infectious Diseases. Volume 6, Issue 11, November 2019 & Trinity Claims
\(^12\) 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

<table>
<thead>
<tr>
<th></th>
<th>11-12 years</th>
<th>16-18 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>MenACWY</td>
<td>1 dose</td>
<td>1 dose</td>
</tr>
<tr>
<td>MenB</td>
<td>2 doses</td>
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</tbody>
</table>

Potential immunization schedule could reduce to three doses

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<tr>
<td>MenACWY</td>
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<tr>
<td>MenABCWY</td>
<td>2 doses</td>
<td></td>
</tr>
</tbody>
</table>

*Professor Terry Nolan is and Head of the Vaccine and Immunisation Research Group at the Peter Doherty Institute for Infection and Immunity at the University of Melbourne, and Murdoch Children’s Research Institute

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

Serotype distribution in CDC and ECDC pneumococcal datasets grouped by vaccine of interest, by age group, and by year of interest signed by Gael the 12th of May 2023, the reference number is VEO-000655 / PLWID: 61337
Multiple Antigen Presenting System (MAPS)\textsuperscript{1}

Highly-innovative approach allowing for higher valency and robust immune response

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

“\textit{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.

\textbf{Conventional conjugate vaccine provides only antibody-mediated immunity}

“\textit{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)

- Lower MOPA than PCV13
- Higher MOPA than PCV13

MAPS24 (Ph2, N=86, 5ug)

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

- Lower OPA than PPSV23
- Higher OPA than PPSV23

MAPS24 (Ph2, N=86, 5ug)

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

1The point estimate is the ratio of the geometric means. Whiskers extend to the 95% confidence interval of the ratio. Dotted line indicates ratio of 0.5. 2Randomized controlled trials assessing the clinical efficacy of MAPS24 compared to PCV13 have not been conducted.

Source: Chichili et al., Vaccine, 2022.
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

2018 17%

2014 12%

Unmet need

Complicated or Challenging VVC
~33%

Uncomplicated or Simple VVC
~67%

Can be treated with oral fluconazole or topical azoles

US: ~7.4m patients treated with at least one Rx pa¹

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

¹ Truven claims data ² Proprietary HCP market research. cVVC includes patients who are severe, non albicans candida, recurrent or patients with co-morbidities
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 year\(^1\)

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

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1. Based on Carreno et al. Longitudinal, Nationwide, Cohort Study to Assess Incidence, Outcomes, and Costs Associated With Complicated Urinary Tract Infection. Open Forum Infectious Diseases, Volume 6, Issue 11, November 2019 and Trinity Claims analysis
2. Spero TRINITY Claims Analysis (Kamodo and CDM data)
## News flow in bacterial and fungal infections and full ID pipeline

### Commitments to profitable growth

#### Meningitis

- **£1-2bn 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 10 diverse MenB invasive strains
  - **Next steps:** US regulatory submission in 2024

#### Streptococcus pneumoniae (pneumococcal)

- **>£4bn in peak year sales**
  - **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

#### Anti-infectives

- **~£2bn in peak year sales**
  - **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

<table>
<thead>
<tr>
<th>ID</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004645</td>
<td>(adjuvanted recombinant protein*) C difficile</td>
</tr>
<tr>
<td>4420076</td>
<td>(adjuvanted biocogulation, recombinant protein*)</td>
</tr>
<tr>
<td>3993231</td>
<td>(adjuvanted recombinant subunit) cytomegalovirus</td>
</tr>
<tr>
<td>4382727</td>
<td>(mRNA*) seasonal flu</td>
</tr>
<tr>
<td>4396667</td>
<td>(mRNA*) COVID-19</td>
</tr>
<tr>
<td>4077664</td>
<td>(dovant GMMA*) invasive non-typhoidal salmonella**</td>
</tr>
<tr>
<td>3943004</td>
<td>(recombinant protein, adjuvanted*) therapeutic herpes simplex virus</td>
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### Phase II - 14 assets

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<tr>
<th>ID</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>3187687</td>
<td>(dovant uptake receptor) meningitis (glymph &amp; paraphosphat A)</td>
</tr>
<tr>
<td>2652841</td>
<td>(MBP cholesteryl dependent inhibitor*) tuberculosis</td>
</tr>
<tr>
<td>386889</td>
<td>(CRK-12 inhibitor*) visceral leishmaniasis</td>
</tr>
<tr>
<td>3492426</td>
<td>(proteasome inhibitor*) visceral leishmaniasis</td>
</tr>
<tr>
<td>3777070</td>
<td>(P. aeruginosa whole cell inhibitor*) malaria</td>
</tr>
<tr>
<td>3882347</td>
<td>(FimH centraporin*) uncomplorated U/T</td>
</tr>
<tr>
<td>3929868</td>
<td>(FimH beta inhibitor) viral COPD exacerbations</td>
</tr>
<tr>
<td>4152127</td>
<td>(oral spike protein antibody) COVID-19*</td>
</tr>
<tr>
<td>3966972</td>
<td>(PAOS/PF07) inhibitor) Hep B</td>
</tr>
<tr>
<td>525073</td>
<td>(TURB apopain*) Hep B</td>
</tr>
<tr>
<td>519232</td>
<td>(intraperitoneal vaccine) 400 mg/ml formulation* HIV</td>
</tr>
<tr>
<td>3730927</td>
<td>(maturant inhibitor) HIV</td>
</tr>
<tr>
<td>4004230</td>
<td>(capped protein inhibitor) HIV</td>
</tr>
<tr>
<td>401499</td>
<td>(capped protein inhibitor) HIV</td>
</tr>
<tr>
<td>4524184</td>
<td>(intraperitoneal inhibitor*) HIV</td>
</tr>
</tbody>
</table>

### Phase III - 8 assets

<table>
<thead>
<tr>
<th>ID</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>3036656</td>
<td>(bucill t-RNA synthetase inhibitor*) tuberculosis</td>
</tr>
<tr>
<td>3136666</td>
<td>(sulfamethoxan/UV1818) tuberculosis</td>
</tr>
<tr>
<td>4100447</td>
<td>(adjuvanted recombinant protein*) human papillomavirus*</td>
</tr>
<tr>
<td>4384413</td>
<td>(GMMA) gonorrhea</td>
</tr>
<tr>
<td>3247557</td>
<td>(dovant receptor) RSV older adults^4</td>
</tr>
<tr>
<td>5275517</td>
<td>(adjuvanted receptor) RSV older adults^4</td>
</tr>
<tr>
<td>3104807</td>
<td>(mitrochondrial translator) 400 mg/ml formulation* HIV</td>
</tr>
<tr>
<td>3965193</td>
<td>(PAPD5/PAPD7 inhibitor) Hep B</td>
</tr>
<tr>
<td>4106647</td>
<td>(adjuvanted recombinant protein*) human papillomavirus*</td>
</tr>
</tbody>
</table>

**Infectious diseases**

**HIV**

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**Status as of 26 April 2023**

1. Additional sales from MenABCWY
2. Affinavax (incl. 24 and 30-plus valent in paediatrics and adults)
3. gepotidacin, tebipenem HBr and Brexafemme

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**Phase III**

- Arexvy (adjuvanted recombinant protein*) RSV older adults^4
- SKYCovione (recombinant protein nanoparticle, adjuvanted*) COVID-19^5
- gepotidacin (BTI inhivitor*) uncomplorated U/T**
- bepapertin (biptase, dinucleotider*) hepatitis B virus**
- Beepers (recombinant protein) Pf Beep
- MenABCWY (recombinant protein, OMV, conjugated vaccine)
- MenABCWY 1st Gen
- tebipenem pivoxil (antibacterial carbapenem*) complicated UTI**
- Brexafemme (adjuvanted glucan synthase inhibitor*) invasive candidates
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