Full year and Q4 2022 results
Conference call and webcast for investors and analysts

Wednesday, 1 February 2023

Introduction | Nick Stone, Head, Investor Relations

Hello, everyone and welcome to our full year and Q4 2022 conference call and webcast for investors and analysts. The presentation was sent to our distribution list by email earlier today and you can also find details at GSK.com.

Cautionary statement regarding forward-looking statements

This is the usual safe harbour statements. We will comment on our performance using constant exchange rates or CER unless stated otherwise. As a reminder, the Consumer Healthcare business was demerged on 18 July, 2022 to form Haleon.

For today we are presenting continuing operations for GSK.

Agenda

Today's management presentation will last approximately 30 minutes with the remaining 30 minutes for your questions, and this is to ensure that we get you to your next call given it's such a busy day for those on the street.

For those on the phone, please join the queue by pressing *1 and we request that you ask one to two questions so that everyone has a chance to participate.

Our speakers are Emma Walmsley, Tony Wood, Luke Miels, Deborah Waterhouse and Iain Mackay, with David Redfern joining the rest of the team at Q&A.

I will now hand the call over to Emma..

Strategic summary | Emma Walmsley, Chief Executive Officer

Thanks, Nick, and welcome to everyone.

A focused global biopharma company with bold ambitions

2022 was a landmark year for GSK. We successfully delivered the most significant corporate change in 20 years and began a new chapter of competitive and profitable growth. GSK is a focused global biopharma company with the ambition and purpose to unite science, technology and talent to get ahead of disease together.

We are a world leader in the prevention and treatment of infectious diseases with an industry-leading Vaccines franchise that continues to strengthen and expertise in HIV that is pioneering in innovation, and we have an exciting emerging pipeline based on the science of the immune system.

Through ongoing focus on R&D productivity and operating performance we are unlocking the potential of this company. We are realising our bold ambitions reflected in our commitments to attractive growth and a significant step-change in delivery, and through the demerger of Haleon, a world leading consumer healthcare business in its own right, we have strengthened our balance sheet creating additional flexibility to invest in continuing growth and innovation.

Full year 2022 Delivered a landmark year

I am delighted with today's results which demonstrate that our strategy is driving the step-change in financial performance we committed to with continued strong momentum as we enter 2023.
In 2022 we delivered:

- double-digit sales growth of 13%, 10% if you exclude COVID solutions including the more than £2 billion sales of *Xevudy*
- adjusted operating profit growth of 14%, 17% excluding COVID solutions
- adjusted EPS growth of 15%
- and strong free cash flow of £3.3 billion, further strengthening our financial flexibility.

This outstanding performance was driven by strong sales growth across both Specialty Medicines and Vaccines alongside continued pipeline progress and underpins our guidance today.

In 2023, excluding COVID solutions, we expect sales to increase between 6% and 8%, adjusted operating profits to increase between 10% and 12% and adjusted EPS growth between 12% and 15%.

Delivering committed improvements in performance

Excluding COVID-19 solutions

This strong delivery in 2022 and commitment to do so again this year supports our increased confidence in all dimensions of the 2026 outlook and demonstrate the continuing successful momentum in our transformation of GSK.

Our portfolio mix has meaningfully shifted to Vaccines and Specialty Medicines, now approaching two-thirds of our sales in 2022 compared to 46% in 2017. This evolving portfolio shape and our prioritised investment in innovation and product launches with good cost discipline are reflected in our continuing margin expansion.

2022 pipeline progress and momentum

World leader in infectious disease based on science of the immune system

Before handing over to Tony for more detail, I would like to share a couple of headlines on our progress in reshaping and advancing our pipeline, our number one priority.

We have built a pipeline of 69 vaccines and medicines, many with the potential to be first or best-in-class. We have also had over 20 new approvals in the last five years, now representing nearly a third of our 2022 sales, excluding COVID solutions, and we anticipate more regulatory decisions this year.

Our 2022 achievements include the launch of *Apretude*, the first and only long-acting injectable for HIV prevention alongside *Cabenuva*, the first and only long-acting HIV treatment regimen. We intend to continue to lead in changing the landscape for people living with HIV around the world over the coming years.

In Vaccines, the key highlight was our exceptional RSV older adults data that led to a prompt regulatory submission and priority review acceptance by the US FDA. Our vaccine candidate has a potential best-in-class profile and represents a significant commercial opportunity with multi-billion *Shingrix*-like potential.

We also made some important advances in the clinical development of two late-stage assets, gepotidacin, a new novel antibiotic for uncomplicated UTIs, and bepirovirsin, which has the potential to provide a first-in-class functional cure for chronic Hep B.

Strategic business development also played an important role in reshaping our pipeline. The acquisitions of Sierra Oncology and Affinivax complement our portfolio and, in the case of Affinivax, it gives us access to not only a Phase II next gen 24-valent pneumococcal vaccine but also the novel MAPS platform technology to target complex pathogens that have multiple serotypes.

We have a world-leading profile in infectious diseases and an exciting portfolio in the pipeline based on the science of the immune system which we are confident will sustain growth through this decade and beyond. I will now hand over to Tony for more details.

Innovation | Tony Wood, Chief Scientific Officer

Thank you, Emma.

Innovation: four focused therapeutic areas

Today, I will talk about recent R&D developments and preview important events that will shape our pipeline.

In 2022, nearly a third of our sales came from assets launched in the prior five years and we are confident that our early-stage pipeline is well positioned to provide continued strong commercial execution to deliver our 2031 ambitions.

This slide illustrates our focus in four key therapeutic areas, shaped by our world-leading capabilities in infectious diseases, our understanding of the science of the immune system, and human genetics.

In 2022, we progressed 16 novel candidates into the clinic, added nine to Phase II and started five Phase III programmes, which reflected our core therapeutic focus, including the initiation of Phase III lifecycle innovation trials for depemokimab in eosinophilic disease, and cobolimab for the treatment of second-line non-small cell lung cancers.

Today, our pipeline comprises 22 vaccines and 47 medicines, many of which are potential first or best in class. These novel programmes will form the basis for our next wave of pipeline innovation and growth.

I am pleased with our continued progress and the next slide shows some highlights from last year.

Innovation: 2022 in review

In 2022, our highest profile result was the publication of the Phase III data for our RSV older adult vaccine candidate. This demonstrated 94% protection against severe disease, with consistent and sustained high efficacy against both RSV A and B strains, in people in their 70s and in those with comorbidities.

Our global regulatory submissions include data showing that the vaccine can be safely co-administered with a flu vaccine, without diminishing the effect of either. Following regulatory submission, we received a priority review from the US FDA and we anticipate a regulatory decision in early May.

Our ongoing Phase III trial continues to collect data and will determine if protection extends beyond one season. We anticipate generating second season data in time for the June ACIP meeting. Additionally, we are also recruiting a Phase III trial examining the effectiveness in protecting adults aged 50 and above who are at higher risk of developing severe disease.

It is important that I mention the ongoing development of *Shingrix.* We presented data last year showing the *Shingrix* provides overall efficacy greater than 80% over a follow-up period of six to 10 years after the initial vaccination.

These 10-year data were generated as part of our ongoing lifecycle innovation and we regularly review *Shingrix*'s duration of protection and the potential need for a booster. These data will inform the next steps in clinical development and I will keep you updated with progress.

In HIV, we are committed to improving the existing treatment options for people living with HIV. We have an exciting pipeline, including options for self-administration and ultra-long-acting medicines. We are also investigating new approaches to HIV treatment. Last year we presented proof of concept data from the Phase II BANNER trial for N6-LS, our broadly neutralising antibody. This is one of several exciting opportunities within our HIV portfolio and we remain on track to move these into Phase III development in 2024.

Oncology is an emerging therapeutic area. We reported positive high-level results of the *Jemperli* Phase III RUBY trial, which met its primary endpoint – the first trial to show a PFS benefit for an IO agent in the treatment of women with primary advanced or recurrent endometrial cancers. These data may support the use of *Jemperli* in the first-line setting.

We also decided to progress all arms of the COSTAR lung trial into Phase III. This compares cobolimab and dostarlimab combinations in treating patients with advanced non-small cell lung cancers – a large patient population with significant unmet medical need. We expect to see data from this trial in 2024.

In 2022, we progressed several Phase I programmes and reported positive proof of concept data. Read-outs last year included data from our randomised Phase Ib trial of CCL17 in osteo-arthritis, demonstrating evidence of efficacy at the end of the eight-week dosing period. We plan to progress development and will share more later this year.

Our partner, CureVac, also announced interim Phase I data for flu and COVID mRNA vaccines. These preliminary data provide promising evidence of activity, which included a monovalent flu vaccine that successfully boosted antibody titers against a matching flu strain – even at the lowest dose. Based on these promising data, we believe there is a significant opportunity to accelerate the development of this based on this technology. We are excited about the potential of doublet vaccines and we are pleased with the progress we are making on both the COVID and influenza projects.

As Emma mentioned, we also completed several business development deals in 2022, enhancing our portfolio and platform technology. These deals supplement our late stage pipeline, support further growth and deliver our R&D strategy. BD and capital allocation will be a strong focus in 2023 and beyond.

We also announced a collaboration with Wave Life Sciences to enhance our discovery and development capabilities using novel oligonucleotides.

Now I would like to provide a brief summary of the progress of our most advanced oligonucleotide bepirovirsen.

Innovation: bepirovirsen - a potential new era in the management of hep B

I am particularly excited to disclose that the first patient has been recruited into the B-WELL Phase III programme for bepirovirsen in the treatment of hepatitis B patients with low baseline surface antigen.

Remember that in our Phase II trial B-CLEAR, we observed that an unprecedented number of patients treated with low baseline surface antigen experienced sustained hep B surface antigen and DNA loss at the end of the 48-week study period.

Hepatitis B infection is a significant unmet medical need with over 300 million people having this chronic disease and around 900,000 who die from liver disease-related consequences. The current standard of care achieves functional cure in fewer than 5% of patients, and managing the disease places a significant burden on global healthcare systems.

Our aim is for bepirovirsen to become the backbone of future therapy. Around mid-year, I also look forward to sharing data from B-TOGETHER, a Phase II trial that administers bepirovirsen followed by interferon therapy with the goal of improving functional cure rates still further.

Innovation: gepotidacin - a potential novel antibiotic to treat uUTI[1]

In November, we reported that two Phase III gepotidacin trials for the treatment of uncomplicated urinary tract infections were stopped early for efficacy after successful interim analysis. Data collection and analysis are on-going and we anticipate making a regulatory submission later this year.

The world needs new classes of antibiotics. Treatment failure, increasing community resistance rates and increasing safety warnings for existing medicines, including fluoroquinolones, are reducing the available oral options for uncomplicated UTIs.

If approved, gepotidacin will become the first new oral antibiotic for the treatment of uncomplicated UTI for over 20 years. Unmet medical need is significant with around 15 million episodes of uncomplicated infection in the US alone, a quarter of which recur or have some level of resistance. Gepotidacin would be positioned as an oral option for patients at risk of treatment failure.

In September last year, to complement the development of our antimicrobial franchise, we announced a licence agreement with Spero Therapeutics to commercialise tebipenem, a novel antibiotic in Phase III development for the treatment of complicated UTIs. There are around three billion complicated UTIs in the US each year and 14% of these infections are resistant to broad spectrum oral antibiotics. Tebipenem could be the first oral carbapenem approved for the treatment of complicated UTI reaching the market by 2026.

Our goal is to develop two novel oral antibiotics that cover the spectrum of urinary tract infections and address increasing recurrence and community antimicrobial resistance.

Innovation: 2022-2024 key news flow

This slide illustrates some of the pipeline news we anticipate over the next year or so. We expect 2023 to be a busy year across the portfolio and we look forward to presenting our RSV older adult vaccine at the forthcoming US FDA VRBAC meeting in March, followed by a US FDA regulatory decision in early May.

We also anticipate Phase III data from our pentavalent meningococcal vaccine in the first half. There are around 1.2 million cases of invasive meningococcal disease each year and, if successful, this vaccine would target the five most common serotypes in one product.

As I mentioned earlier, we expect to present data from the gepotidacin Phase III programme and data from the bepirovirsen Phase II trial, B-TOGETHER, around mid-year.

In Oncology, momelotinib has been submitted with regulatory authorities and we expect to hear from the US FDA during the first half. We shall also present the *Jemperli* RUBY data at a medical conference later this year.

Finally, we are also anticipating a regulatory decision from the US FDA on daprodustat for the treatment of anaemia of chronic kidney disease, with a decision from European regulators around mid-year. I'll now hand over to Luke.

Performance | Luke Miels, Chief Commercial Officer

Thanks, Tony.

Performance: full year 2022 sales £29.3 billion, +13%

In 2022, we delivered 13% sales growth, or 10% excluding COVID solutions, and we are proud to report that 10 products exceeded £1 billion in sales for the year, including *Shingrix*, *Trelegy*, *Nucala*, *Benlysta* and *Dovato*. This is a great example of strong commercial execution.

Benlysta remains the market leader with 85% of new patient starts in Q4 and we continue to see a strong growth globally in both SLE and lupus nephritis with only 25% biopenetration in the US. *Nucala* continues to lead the IL5 class across all major markets and *Nucala* remains the first and only biologic approved for four eosinophilic diseases, with new indications driving growth and differentiation.

Xevudy delivered £2.3 billion in sales, although based on the trajectory of the pandemic, we expect limited sales in 2023. Deborah will comment on HIV shortly.

In oncology, sales were up 17% for the year. With label changes to *Blenrep* and *Zejula* in the US we expect to see a short-term decline before oncology returns to growth in 2024.

In general medicines, *Trelegy* had an excellent year, up 32% versus last year, retaining leadership in key markets. This was also bolstered by the post-pandemic rebound of the antibiotic market globally, and increased demand for *Augmentin*.

Performance: Vaccines +17%

Turning to our vaccines performance, in 2022 vaccines had a strong year, up 17%, excluding pandemic adjuvant sales. This reflects strong commercial execution across the portfolio, including a record year for *Shingrix*, and increased contributions from *Bexsero* in the US, with higher CDC demand and increased market share.

Shingrix sales grew significantly across all regions, reflecting post-pandemic rebound, and new market launches through geographic expansion. The US saw higher demand in both the retail and non-retail setting and favourable channel inventory movements, while ex-US delivered around one billion in sales for the year.

Shingrix has launched now in nine markets in 2022, and is now available in 26 countries, and we expect to continue to expand our geographic footprint in line with our goal to be in 35 countries by 2024.

Performance: ongoing evolution to Specialty Medicines and Vaccines

Here you can see that prioritisation of R&D and commercial investment in Specialty Medicines and Vaccines, plus optimisation of the General Medicine portfolio, is delivering strong growth driver progress. Our '22 results demonstrate that our strategy is working, we are delivering on the commitments we made at the Business Investor Update in 2021, and the data on the right hand chart show this shift up from 7% to 42% to date.

Looking ahead to 2023, for the Specialty portfolio, including the short-term impact of oncology, we expect sales in 2023 to increase mid to high single-digit per cent, excluding *Xevudy*.

In General Medicines we expect 2023 sales to decrease slightly and remain on track with our broadly stable sales outlook between 2021 and 2026.

In Vaccines, overall we expect to increase mid-teens per cent, excluding pandemic adjuvant sales, and expect to see *Shingrix* momentum continue, with double-digit growth with another record year of sales.

With that, let me now hand over to Deborah.

Performance | Deborah Waterhouse, CEO, ViiV Healthcare and President, Global Health

Thank you, Luke.

Performance: 12% HIV growth in 2022 driven by innovation portfolio

Our HIV business delivered sales of £5.7 billion in 2022, growing 21% in Q4 and 12% for the year, with our US and European businesses both reporting significant growth. We achieved a notable acceleration in our innovation sales, delivering £2.5 billion, representing 43% of our portfolio for the year, and 48% in the quarter, up from 29% in the full year 2021.

Our performance benefited from strong patient demand for our innovation HIV medicines, *Dovato*, *Cabenuva*, *Juluca*, *Rukobia* and *Apretude,* contributing 9 percentage points of growth. US pricing favourability and year end inventory build together contributed 4 percentage points of growth, which was partially offset by international tender decline.

Sales of *Dovato* delivered £438 million in the quarter, and £1.4 billion for the full year, and this medicine is now firmly on track to become our biggest-selling HIV product. We see the opportunity for *Dovato* as being balanced globally, with around 50% of the potential sales in the US and the remainder split between Europe and the rest of the world.

Turning to our injectable portfolio, *Cabenuva* is our first in class long-acting treatment regimen for HIV. Sales for the quarter were £129 million, and £340 million for the full year, reflecting strong patient demand with high levels of market access and reimbursement across the US and Europe.

Moving on to prevention: *Apretude* is the world's first long-acting injectable for the prevention of HIV, dosed every two months. Launched in the US in January 2022, *Apretude* delivered £21 million of sales in the quarter, and £41 million in the full year. HIV prevention is an area of significant unmet need, as current options are associated with stigma and adherence issues. *Apretude* addresses these challenges and has demonstrated superior efficacy over daily oral tablets.

Looking ahead to 2023, we expect to see continued strong patient demand for our new HIV medicines. We expect the year end inventory build to burn through the first half of 2023; we are confident of delivering mid single-digit growth this year.

We're excited by our pipeline, focused on innovative, long-acting regimens which we believe illustrates our ability to maintain our leadership beyond *Dolutegravir*. By the second half of the decade we expect *Cabotegravir* to increasingly replace *Dolutegravir* as the foundational integrase inhibitor in our portfolio.

We have three clear target medicine profiles: to provide the world's first self-administered long-acting regimen for treatment, and to provide ultra long-acting regimens for treatment and prevention, with dosing intervals of three months and longer. We are looking forward to presenting further data on our pipeline, including the SOLAR study, a head-to-head trial between *Cabenuva* and *Biktarvy*, and data on N6LS, our broadly neutralising antibody, at CROI in Seattle later this month.

Our Q4 results demonstrate continued progress against our ambition to achieve a five-year mid-single-digit sales CAGR to 2026. By 2026, we estimate that long-acting regimens will be generating around £2 billion which equates to around a third of HIV sales. The changing mix of our portfolio towards long-acting and the success of our pipeline offers the potential to significantly replace the revenue from dolutegravir post loss of exclusivity.

And with that, I will hand you over to Iain.

Performance | Iain Mackay, Chief Financial Officer

Thank you, Deborah. I will cover the financials and references to growth are at constant exchange rates unless stated otherwise.

As Luke and Deborah covered the main revenue drivers I will focus my comments on the income statement, including the main cost drivers, margins, cash flow and guidance for 2023.

Performance: 2022 results and total to adjusted reconciliation

This slide shows the bridge from total to adjusted results and includes the effect of the successful Consumer Healthcare demerger in 2022.

Total earnings per share were 371.4p, profit earnings per share from discontinued operations were 260.6p. This primarily reflected the gain of the demerger and the gain on the retained stake in Haleon.

Continuing operations for 2022, turnover was £29.3 billion, up 13% and adjusted operating profit was £8.2 billion, up 14%.

Total earnings per share were 110.8p, up 18% while adjusted earnings per share were 139.7p, up 15%.

The main adjusted items of note on adjusted results were continuing operations in the year were transaction-related which primarily reflected ViiV contingent consideration liability movements, the majority of which related for foreign exchange and in divestments, significant legal and other which reflected the upfront income received from Gilead in the first quarter as well as a fair value mark to market gain on the retained stake in Haleon.

Pandemic solutions reduced growth of adjusted operating profit by approximately three percentage points and growth of adjusted earnings per share by around three points.

The full-year currency impact was a favourable 6% on sales and 12% on adjusted earnings per share.

Performance: 2022 adj. Operating margin

Improvement to 27.8%

The 2022 adjusted operating margin of 27.8% reflected an improvement versus last year. The positive margin dynamics reflected the sales growth with a favourable mix excluding *Xevudy*, high royalty income and favourable currency movements which were a 1.2 percentage point benefit in the full year. These factors were offset by the impact of lower margin sales of *Xevudy* and commercial investment behind launches and key products.

Overall adjusted operating profit grew 14%. COVID solutions reduced adjusted operating profit growth by approximately three percentage points and the adjusted operating margin, excluding COVID solutions was approximately 1.3 percentage points higher at constant exchange rates.

Turning to key dynamics of the year, within cost of goods sold, the increase primarily related to sales of lower margin *Xevudy* which increased the cost of sales margin by around 2.5 percentage points mainly reflecting the profit share payaway to-be-advised technology.

Excluding *Xevudy*, cost of goods sold benefited from a favourable business mix with Specialty Medicines and Vaccines comprising 62% of commercial operation sales ex-pandemic. This mixed benefit was partly offset by increased supply chain costs including the commodity prices and in freight.

SG&A increased at a rate slightly above sales which primarily reflected launch investment in Specialty Medicines and Vaccines which was particularly focused on HIV and *Shingrix* to drive post-pandemic demand recovery and support market expansion.

The SG&A growth also reflected an unfavourable comparison for beneficial legal settlement in 2021.

These factors were partly offset by continued delivery of restructuring benefits with around £900 million of annualised savings to date from the separation preparation programme and tight control of ongoing costs.

R&D spend grew 6% with increased investment across several programmes, particularly in Vaccines clinical development including our mRNA technology platforms, and MAPS following the Affinivax acquisition, along with investment in early discovery programmes.

In Specialty Medicines with assets like depemokinab and bepirovirsin, and within Oncology there was an increased investment in our early-stage immuno-oncology asset, momelotinib following the Sierra Oncology acquisition. These increases were partly offset by the lapping of now completed late-stage clinical programmes and reduced investment in COVID-19 assets relative to 2021.

Royalties benefited from the *Biktarvy* contribution and higher sales of *Gardasil.* Again it should be noted the *Gardasil* royalty stream will cease at the end of 2023.

Performance: 2022 adj. operating profit to adj. profit attributable to shareholders

Moving to the bottom half of the P&L, I would highlight that net finance expense was higher reflecting the net cost associated with the November Sterling Notes repurchase, higher interest on tax, partly offset by increased interest income due to higher interest rates and larger cash balances as a result of the Consumer Healthcare demerger and the effective tax rate of 15.5% reflected the timing of settlements with various tax authorities which were favourable versus the expectations set out at Q3.

In the next slide I will cover cash flow.

Performance: 2022 free cash flow of £3.3bn

In 2022 we generated £3.3 billion of free cash flow from continuing operations. Within free cash flow, cash generated from operations increased around £700 million, up 10% to £7.9 billion with higher operating profit being the key driver, partly offset by other factors which you can see on this slide.

Below cash generated from operations, there were higher tax payments and lower pre-receipts from disposals along with higher capex, partly offset by reduced purchases of intangibles. In 2023, we expect cash generated from operations to be slightly lower, primarily due to the positive impact of the Gilead settlement in February 2022, partly offset by improved operating profit growth. We remain firmly on track with a medium-term outlook, driven by higher adjusted operating profit and working capital improvements.

Performance: 2023 guidance builds on 2022's step change in delivery

Turning now to slide 25 and guidance for 2023. We expect to build upon the step-change in performance we delivered in 2022. As a reminder, all our guidance excludes the contribution from pandemic COVID-related solutions and references to growth are at constant exchange rates.

We expect sales to increase between 6% and 8% and expect adjusted operating profit to increase between 10% and 12%. This is influenced by expected cost dynamics, where we expect cost of goods sold to have a respectable increase slightly below sales; SG&A to grow broadly aligned to sales, and for royalties to grow versus 2022.

Below operating profit, net interest payable is expected to be between £750-£800 million and the effective tax rate is expected to be around 15%. In light of these dynamics, we expected adjusted earnings per share to increase between 12% and 15%. We do not expect any significant pandemic-related sales in 2023.

With regards to the phasing of the year, due to phasing in 2022 and resulting comparators, we would expect operating profit growth to be lower in the first half of the year and higher in the second half, relative to full-year expectations. This reflects strong comparisons in the first half, including stock build in ViiV and *Shingrix* US channel inventory build in the first half of 2022.

We would also expect SG&A to grow at a higher rate than sales, reflecting investment to support recent and anticipated launches. Q1 is expected to be a more challenging quarter, following the ViiV stock-building at the end of 2022. In the second half, we would expect the growth to be higher, due to expected launches of new products including RSV, as well as momentum across existing product drivers.

Regarding dividends to shareholders, we anticipate a 56.5 pence dividend per share, aligned to our dividend policy and prior disclosures.

We start 2023 with excellent momentum from a highly successful 2022 and remain firmly on track to deliver our medium-term financial commitments.

With that, I will hand it back to Emma.

Trust | Emma Walmsley, Chief Executive Officer

Trust: delivering health impact sustainably

Thanks, Iain.

Purpose: to get ahead of disease together

Turning to Slide 27, we continue to be guided in all of this by our purpose to unite science, technology and to get ahead of disease together. Integral to this is running a responsible business, one which builds trust and reduces risk, to deliver sustainable health impact at scale, shareholder returns, and to support our people to thrive. To do so, we prioritise our resources to focus on the six material areas depicted here.

This quarter, our leadership and progress in access were recognised once again, as we topped the Access to Medicines Index for the eighth consecutive time, and we continue to lead in innovation to address antimicrobial resistance. Also, we announced an investment of £100 million to help strengthen health systems in lower income countries, along with our commitment to invest £1 billion in global health innovation where it's needed – as evidenced by our progress with the new first-in-class candidate medicine for patients with tuberculosis.

A focused global biopharma company with bold ambitions

In closing I do want to thank our people for delivering this tremendous performance – a landmark year for GSK as a newly focused global biopharma company with big ambitions. We are delivering a step-change in performance and we enter 2023 confident that we will keep delivering again this year for our medium-term outlooks and with the momentum to sustain growth through the decades beyond.

With that, operator, the team is ready to go to the Q&A.

Question & Answer Session

Kerry Holford (Berenberg): Thank you for taking my question. My focus is the RSV vaccine specifically the patient cohort. If you could discuss the commercial opportunity you see within that 50 to 59-year old group? If we assume the Phase III data that you are going to publish later this year is positive, and the vaccine is ultimately approved in that age group, do you think that an ACIP recommendation for the population is a realistic scenario? I would be interested to know whether your existing target for that asset of more than £3 billion excludes any potential sales in that younger cohort. Thank you.

Emma Walmsley: Thank you, Kerry. We will go straight to Luke on that one. This is obviously an asset that we are very excited about, with a lot of opportunity here. Luke?

Luke Miels: Thanks, Kerry. Yes, it is in that immunocompromised population. It is a sizeable population but the primary benefit is from a contract negotiation point of view for the 2024 season, because we will be the only one with that profile and the evidence in that group which, along with older individuals, obviously bears a significant burden from RSV infection.

The previous guidance we have given includes that study as the full life-cycle programme.

Peter Welford (Jefferies): My question is on the outlook for Vaccines, the mid-teens. I wonder if Luke could give us some idea of the usual update regarding the *Shingrix* doses and where we are with regard to inventory as far as burning through that. Presumably, we are back to a more normal seasonality of *Shingrix* with the 'flu season towards the end of the year. What have you assumed in that mid-teens for RSV in the outlook as well? Are you assuming a fairly modest contribution or how should we think about mid-teens in the context of this being the first potential year of RSV sales in the US? Thank you.

Emma Walmsley: As Luke said, another record year of *Shingrix* is expected with double digit growth and obviously the first season for RSV but for a major contributor to growth for the years ahead. Luke, do you want to give a bit more shape on *Shingrix*?

Luke Miels: Thanks, Peter. I will give an overarching view on the first and give you more detail on the US dynamics around stock levels and so on with *Shingrix*. I shall also incorporate RSV into that answer.

Our strategy remains the same. We try to decouple *Shingrix* from the 'flu season and, yes, there is still volume associated with that with people coming into the pharmacy. The Inflation Reduction Act in the US taking away the copay in that 65+ group will be helpful and we know from our data that around 8% of patients reject a *Shingrix* shot based on copay concerns. That is probably understated because pharmacists may self-select in terms of proposing that to patients but we will see that in time.

In Europe and Japan, things are really starting to move. We just had a record month in Germany in January, things are moving in Italy and other European markets, and if you look at the rest of the world as China starts to normalise, the potential for that over the next couple of years remains very sizeable. Ultimately, we have the opportunity to go back and re-challenge these populations with a booster in the second half of this decade.

As far as short-term now in the US, the retail/non-retail split has stabilised: it is about 53% retail and 47% non-retail in Q4 but the growth is evenly balanced between retail and non-retail. Stock levels came down in Q4, they are very much within the normal range of 1.1-0.9 so we ended the year at 0.9 levels in the US.

Regarding RSV, I don't want to give too much colour but Pfizer has made statements around penetration similar to 'flu and we agree with that. I believe that this product will build over multiple years in the US and, as we follow a similar strategy as we have done with *Shingrix*, it is maintaining price discipline, expanding into Europe and rest of world over the next few years.

Emma Walmsley: Thanks, Luke. I believe you said we are 15% more likely to get shingles post-COVID as well.

Luke Miels: Yes, it is certainly observable.

Dominic Lunn (Credit Suisse): My question is on pricing. If we look at the January list price rises for GSK and, indeed, for the industry as a whole, these have been in line with historic price rises, so one could have expected price taking to be a bit stronger given the high levels of inflation. It looks like there is still room to take further price throughout the year before you hit the limits imposed by the inflation price caps in Medicare as well. How should we think about pricing through the rest of the year: could we get maybe smaller, more frequent, incremental price rises throughout the year?

Emma Walmsley: GSK has a long track record of being very responsible around its pricing and, as you know, on a net basis over the last few years, we have even been very slightly down and really thoughtful about how we take this forward. Luke and perhaps Deborah, a comment from both of you?

Luke Miels: I completely agree, Emma, we are playing the long game here. Past patterns over the last two years are probably a good indicator of our behaviour going forward.

Deborah Waterhouse: I would agree with what Luke said. The other thing to which people should give some thought is what is happening outside the US. If you look at our HIV business, for example, and many others will be experiencing the same thing, we are seeing significant additional net price pressure from clawbacks and price cuts. Therefore, from a pricing perspective, I believe we have priced fairly and appropriately and are playing the long game in the US. We need to be aware and very vigilant about what is happening outside the US in terms of economic challenges leading countries to put pressure on pricing.

James Quigley (Morgan Stanley): I have a question on HIV. Could you give us an idea of the amount of stocking that you saw in the fourth quarter and which key products were impacted? Clearly, for the full year, *Tivicay* and *Triumeq* seemed to fare better in the US than in ex-US. With those two products as well, what are you assuming for next year in the guidance? Then can you also give us a bit more colour on the dynamics for *Cabenuva* and *Apretude* in terms of take-up, patient attitudes, physician attitudes and how that is changing with greater experience, and how you expect the growth curve to look for the two long-acting drugs next year? Thank you.

Deborah Waterhouse: Let's talk about stocking. We entered last year with about three days of stock, which was low, normally we exit each year with about six or seven days of stock, so we entered 2023 with three days

of stock, we exited with thirteen days of stock, so as you can see there's been a material shift between where we started '22 and where we exited. If we assume that we're just going to have a normal 2023 and that there will be seven days of stock in the channel at the end of the year, you can see that we have six days to burn, and we believe that's going to burn in the first half of the year, so that's the details on the stock evolution.

In terms of *Tivicay* and *Triumeq*, we're seeing *Tivicay* and *Triumeq* at a relatively steady evolution: *Triumeq* is declining quite significantly as it's cannibalised by *Dovato*, but also competitors, but *Tivicay* is pretty stable, actually – it's declining, but obviously it's the only second generation integrase inhibitor that you can have as a standalone and not as part of as a triple or a doublet, so we continue to see a strong and sustained business for *Tivicay*. *Triumeq.* We think that business will decline as better opportunities are now there for people living with HIV.

In terms of *Cabenuva*, we've seen really strong patient demand, we're seeing excellent execution from our commercial teams which is broadening the prescriber base and deepening the number of prescriptions each position is writing. We're doing a lot of work in the environment to overcome some of the barriers you see when you introduce an injectable into a new therapy area for the first time, and we're really happy about the progress we're making. The level of access is significant, and as I've said before, the quality is also probably really, really positive as well, so I think *Cabenuva* is doing really well.

Apretude was slower last year, as we said. In the first year of any new medicine, and particularly an injectable, it takes a while to secure access and get all the big accounts signed up, specialty pharmacy signed up, on the product. That is now in a very, very positive place, and we have very strong ambitions for *Apretude* in 2023. Again, all the research we do in terms of physician and patient, we know that the demand is very strong for this product, as it offers something very different to the oral, and obviously we have superiority data, so I hope you take away from that a lot of ambition and optimism for our long-acting injectable portfolio.

Emma Walmsley: I think also, as Deborah referred to in her comments, the overall momentum on 2DRs across the board I think is up to 40% between *Dovato* and with long-acting other business, that's where we've done what we said we'd do, in the shift of the portfolio, and we completely expect to do so again through long-acting, as Deb said, with the profile of the business by '26, but also to continue to shift beyond that, ahead of the patent challenge on *Dolutegravir*, and that's what's so exciting about what's coming through in the next generation pipeline, which Deborah and team will give you more insight on over the 18 months ahead. Next question please.

Andrew Baum (Citi): Staying with *Cabenuva*, given the profitability of this product, even with the profit share, it's obviously hugely important for GSK going forward. Could you just give us a little bit more information on the source of the switching to date, and by that I mean, just in the US market, how much from Medicare, how much from 340B, how much is there from inventory? I know it may not represent long term what things look like, and it's dynamic, but I would be interested.

Second, in relation to the new generation of *Cabotegravir* line extensions, including the subcut, we're going to get data in '24. How long will it take, do you believe, to secure approval, assuming that you do PKPD bioequivalence trials starting in '24 – should I be assuming '26, '27 by the time these hit the market? Thank you.

Emma Walmsley: Thank you Andrew. So, straight back to Deb. Just as a reminder for everyone, part of our portfolio shift strategy, which is evidenced as working when you see that shift from 46 in the portfolio up to two-thirds and our confidence by '26 of getting to three-quarters toward Vaccine and Specialty Medicines, is so that we're continuing to drive leverage in the P&L and affording our ability to keep investing at the same time in R&D and in our launches, too. So as well as within HIV through the innovation Deb talked to but also on the broader GSK agenda we're seeing an important area of focus there.

Deborah Waterhouse: Just to quickly cover your points, Andrew, in terms of the source of business, there are two ways we look at this. First of all, where are we getting the business from, and I can confirm about 60% of our *Cabenuva* business is from our competitors and about 40% from our own portfolio. The second point, which is around what segments of the market are we getting *Cabenuva* from, actually we have really good coverage across all the payers and all the key accounts, so actually the split that we see for *Cabenuva* is broadly in line with the split of the overall market, which as you know is 40% commercial payer in HIV and 60% government, so there's no unique attribute to *Cabenuva* versus how the market normally plays out.

In terms of the pipeline, there are three timelines that we've laid out in our business investor update. We've talked about a self-administered treatment, and a longer acting prevention between '25 and '27. Then we have talked about a longer acting treatment, so three months-plus after 2027 probably in the '27, '28 period, and then we've got, which we are very excited about, our third generation integrase inhibitor which will either be teamed with our capsid or with our bNAb and that is where you've got the potential for six month- plus in terms of gap between administration and that's towards the end of the decade. That is what we set out in the update that we gave and we are still absolutely on track for that, very excited about the future.

And just to reiterate our shorter-term goal, we are very confident in our ability to deliver that £2 billion of revenue in 2026 which is a third of our overall business in HIV at that point.

Tim Anderson (Wolfe Research): Thank you. I have a question on COVID-flu co-formulated vaccine. Pfizer yesterday suggested launch of a combo product 2025, talk about it as a compelling durable offering. Does Glaxo see an opportunity here for itself and what is the timeline of launch for a similar product from Glaxo?

And then if I can just sneak in one quick housekeeping question: *Zejula*, when do you expect mature overall survival data from the PRIMA trial in front-line ovarian? Thank you.

Emma Walmsley: Right, both of those to come to Tony, and as he did refer to in his remarks, obviously we are pleased to see the data that has come through from our partners at CureVac and the potential for doublet here is definitely interesting and we will update more on our actual specific plans I think later in the year, but Tony, I am sure you will want to add to that as well as the *Zejula* question.

Tony Wood: Yes, let me just build on the question about doublet. I think I would start with just giving you a sense of the exciting data that we are generating with our partners, particularly CureVac, in the context of establishing the opportunity for a therapeutic window between immunogenicity and reactogenicity. In a doublet vaccine, particularly with regards to flu, for example, you can think about this as the majority loading of the doublet vaccine coming from components that are addressing flu. We very much see the opportunity in

the second half of the decade associated with the high dose flu market where an eight-valent vaccine covering both hemagglutinin and neuraminidase antigens is really the opportunity at hand.

Let me just quickly address what we are seeing in these early data that gives us the opportunity for excitement, and that is, in the flu vaccinations, you will have noted that in a comparator, a monovalent comparator, we see immunogenicity at the lowest dose which is consistent or better than that comparator and seroconversion which is also better than the comparator.

In our COVID studies which have a slightly different comparator basis, we see reactogenicity which is at the low end in terms of distribution of grades and severity at the highest doses involved. What that is doing for us on the back of monovalent constructs is creating an opportunity for a window in therapeutic index which makes an eight-valent flu plus COVID doublet a practical possibility.

We are now accelerating studies from mono-valency into multi-valency, with the aim of targeting a multi-valent seasonal vaccine focused on eight-valent flu in the second half of the decade.

As far as PRIMA is concerned, obviously this is an event-driven outcome study so it's something I am reluctant to give data on. We are not expecting OS data before 2024.

Graham Parry (Bank of America): Great, thanks for taking my question. Going back to the RSV vaccine, I think you referred to this requiring a lot of education and obviously having more than one player in the market can help there.

You have also referred to probably a launch trajectory below *Shingrix.* I am just wondering if there is a lower bound analogue for launch that you could point to that you would think is appropriate, whether it's pneumococcal vaccines or perhaps one of the older paediatric vaccines. Any thoughts you have on the recent Moderna interim data and the level of competition that you see from having three vaccines in the market just from a contracting and pricing point of view more than anything else? Thank you.

Emma Walmsley: Right, Luke.

Luke Miels: Yes, Graham, I think a lot about pneumococcal, again it's not a perfect comparator but I think that's a fair one. I think you will get more information with pricing being presented at the February ACIP by ourselves and Pfizer on 23 and 24 February.

Look, I think having three companies there you are definitely going to drive awareness and a more rapid uptake so the pie will be larger but obviously shared three ways. Our expectation is that it will be only be Pfizer and ourselves at the June ACIP, and that remains the same. From a strategy point of view, as always you need to anchor in your own evidence base and the 94% efficacy that we have in adults with comorbidities is impressive, and the similar range that we have in the 70-79 year old group who obviously bear the brunt of RSV infections.

I mentioned earlier from Kerry's question, for the 50-59 year old population we will also have evidence for that in the 2024 cycle. All of these things help contracting and there are two big variables that remain unknown. One is the final label that we will ultimately get. Again, we have only seen headline data at this point. Secondly,

our sales at Pfizer are likely to have that second year of exposure data just before the June ACIP, and that is a variable that remains unfactored at this point. Net-net it is still a very exciting opportunity and what is striking is the level of awareness and the depth of the RSV infections we have seen this year post-COVID.

Emma Walmsley: Exactly and our co-admin on 'flu is another thing that is relevant to there retail and where so much of the distribution will be here.

James Gordon (JP Morgan): I have two questions please, both on vaccines. One is on RSV and, in terms of multi-year protection, based on what you have seen so far, have you seen things that are encouraging as far as the efficacy that you have seen through the year that suggest you are likely to get multi-year protection? If you do, is that something that will be upside to the share assumptions you already have, or was multi-year protection somewhat baked into the projections you have already given for this vaccine? That is my first question.

The second one is on *Shingrix*. There is the potential need for a booster mentioned. What data would you need for that and do you have some data that already tells you when you might need revaccination, and would you have to do a study that shows a statistically significant benefit on symptoms from revaccination, or would it be more just about antibody titers? Is there a quicker route to get such a recommendation?

Emma Walmsley: I shall give both of those to Tony, but just as a reminder on *Shingrix*, we launched it in 2018 or 2017 and we have good data for 10 years, so the cohorts coming through for boosting are more for later in the decade, as Luke alluded to, but definitely something we will look at. Tony, do you want to respond on RSV durability and *Shingrix*?

Tony Wood: First of all, as far as duration for RSV, obviously we have solid coverage across single season vaccine efficacy with our existing data package. James, you may remember that we also have titers that are elevated above baseline as measured at the end of first year. As Luke indicated, we are planning - and indeed the study was designed with this purpose in mind - to bring second season data to ACIP in June and that obviously depends on the dynamics of the second season. Therefore, we shall be able to report more out on that when we get to the June date. Second season data were not incorporated into the baseline model so it would be an upside.

To your second question on *Shingrix*, we have 10-year data from Study 049 that show outstanding duration of protection, that is a cumulative vaccine efficacy of greater than 82% over the six to 10-year period of follow-up, 89% vaccine efficacy over the 10-year period. Study 049 was designed to continue to generate data in order to answer the booster question. Remember, that the vaccine was launched in 2018, so we are reaching a point now where 10 years subsequent to that, we will be looking to later in the decade. It is reasonable to expect that we shall see some waning in vaccine efficacy associated with an aging population. However, to your point, James, we are also engaging in ongoing conversations with the regulators to understand what the design of the study required to show the need for a booster would look like and for whom but I don't want to go into any greater detail about that at this stage.

Emma Walmsley: Great, thank you. Maybe one or two more questions and we'll try to speed through those.

Emily Field (Barclays): The level of detail provided on the ongoing *Zantac* litigation in the release was very helpful, particularly following the MDL update in December, and the timelines on California are also helpful. I wonder whether you can put into context how you are thinking about the rest of the state cases? On our side, it has been tough to follow what follows a doublet standard and what doesn't. Outside of California, are there any states that could be moving to trial in the near future that we should be mindful of?

Emma Walmsley: Obviously, we were delighted with the outcome in December and we have some things to navigate through this year. Iain, perhaps you could update on the situation with different states?

Iain Mackay: Emily, MDL was incredibly impactful and it took out of the equation 46,000 claims within the suits filed at the federal level, so we are delighted with that decision as Emma said.

You reflect on the bulk of claims in the State court, they sit in Delaware, with more than 70,000, and although it's clearly for the courts in Delaware to decide, there is a pattern of behaviour where they've tended to follow Federal precedent in that regard, so that is probably an encouraging indicator.

Then across the other states, we have a little bit less than 6,000 claims out there, of which about 3,000 are in California and the rest are spread across half a dozen other states. We have four bellwethers that we expect to take place in California this year, the first of which will kick off a little bit later this month or early March. The Sargon hearing for that trial has actually been pushed back another week to 16 February, as the judge reflects on input from both plaintiff and defense attorney.

Again, the really important thing here, the MDL decision, the Daubert decision, was incredibly helpful. It was informed by the strength of the epidemiological independent studies, of which there are now 13, the consensus of which is there is no causality between consumption of ranitidine and any form of cancer, and it's clear from Judge Rosenberg's decision that was the significant factor informing her decision, so we will continue to defend vigorously, and first up are a couple of trials in California. We'll keep you posted.

Simon Baker (Redburn): Thanks very much for squeezing me in, and I promise I'll be quick. A question on *Blenrep*: Tony, back in November on the Q3 call you mentioned that there was ongoing analysis involving soluble BCMA as a prognostic indicator, I just wonder if you could give you any update on the findings from that? And related to *Blenrep*, I see DREAMM7 and 8 have moved from H1 into H2, is that because of event-driven studies or is there anything else we should be aware of? Thank you very much.

Emma Walmsley: You cut out just for the second part of that question, but I think it was what are the implications for the first half second half on 7 and 8. Over to you, Tony.

Tony Wood: Simon, the analysis that we discussed in terms of soluble BCMA and other markers that might explain the crossover that we see in DREAMM3 is still ongoing. As far as DREAMM7 and DREAMM8 outcomes are concerned, we're now targeting a more complete picture of those, and if I remind you, these are two studies that are looking at *Blenrep* in combination versus standard of care, in contrast to DREAMM3, which was *Blenrep* in monotherapy. We're expecting to be able to provide a deeper update on those at the end of the year, and not much more to say at this stage, Simon. The analysis is ongoing, we'll give an update at the end of the year when I have a clearer picture.

Emma Walmsley: Thanks, great. Well, thank you everyone, I hope this has been an efficient call for you. We're delighted with momentum and progress in the business, we look into 2023 with confidence, and do so also for our medium-term outlook and beyond. We look forward to staying connected and keeping you updated in coming quarters and along the way.

Thanks very much, bye.

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