

# **GSK**

## **Year-to-Date and Q3 2022 Results**

**Wednesday, 2 November 2022**

### **Conference Call and Webcast for Investors and Analysts**

**Nick Stone (Head of Investor Relations):** Welcome to our year-to-date and Q3 2022 conference call and webcast for investors and analysts.

Earlier today, the presentation was posted to GSK.com and it was also sent by email to our distribution list. Please turn to slide 2.

#### **Cautionary statement regarding forward-looking statements**

This is the usual safe harbour statement. We will be making comments on our performance using constant exchange rates or CER, unless stated otherwise.

As a reminder, the Consumer Healthcare Business was demerged on 18 July to form Haleon and, as a result, we are today presenting continuing operations for GSK.

Turn now to slide 3.

#### **Agenda**

This is today's agenda, where we plan to cover all aspects of our year-to-date and Q3 2022 results. The presentation will last approximately 35 minutes with around 40 minutes for questions. For those on the phone, please join the queue by pressing \*1, and we request that you ask one question so that everyone has a chance to participate. We can always come back for a second round.

Today, our speakers are Emma Walmsley, Tony Wood on the phone, Luke Miels, Deborah Waterhouse and Iain Mackay. In the Q&A portion of the call we will also be joined by David Redfern.

Turning to slide 4, I will now hand the call over to Emma.

#### **Year-to-date and Q3 2022 – delivering a landmark year**

**Emma Walmsley (CEO):** Thanks, Nick, and hello to everyone joining our Q3 conference call today. Please turn to the next slide.

## Year-to-date 2022 – delivering a landmark year

I am very pleased with today's results, which demonstrate that our strategy is driving the step-change in performance and landmark year that we committed to. Year-to-date, we have delivered double-digit sales growth of 19%; adjusted operating profit growth of 16%; adjusted EPS growth of 20%, and strong free cash flow of £2.5 billion. This broad-based momentum and our continued pipeline progress support my strong confidence, heading into 2023, and in our medium-term outlook and growth through the decade.

Based on these encouraging results and our excellent momentum, we are again increasing our full-year guidance, which excludes COVID solutions. We now expect sales to increase by between 8% to 10%, with improving outlooks in all three product areas, with adjusted operating profit growth between 15% to 17% and adjusted EPS growth around 1% below adjusted operating profit.

Please turn to slide 6.

### Q3 2022 - Sales growth +9%<sup>1</sup> (+7%<sup>2</sup>)

In Q3 we delivered another quarter of growth, with sales increasing 9% to £7.8 billion; adjusted operating profits growing 4% to £2.6 billion – an increase of 2% excluding COVID solutions, and adjusted EPS growth of 11%, to 46.9 pence. This performance was driven by consistently strong commercial execution all across our business, as we build our broad portfolio of scale medicines and vaccines, with Specialty Medicines growing 24% to £2.7 billion and by 11%, excluding *Xevudy*. Here, we continue to benefit from strong demand for our HIV medicines, particularly *Dovato* and *Cabenuva*, as well as *Nucala* in Respiratory and *Benlysta* in immunology. Vaccine sales grew by 5% to £2.5 billion and by 9% excluding pandemic vaccines. This strong performance reflected another record quarter for *Shingrix*, with sales exceeding £750 million. Lastly, General Medicines sales grew 1% to £2.6 billion, driven by the strong growth of *Trelegy* in Respiratory.

We continue to invest in commercial growth and our R&D pipeline.

In SG&A, we continued our disciplined cost control, while prioritising effective investment behind launches – particularly *Shingrix* – as we accelerated international expansion and in HIV, to drive the growth of our innovation during the year.

In R&D, we continued to increase investment in Vaccines clinical development, including in mRNA technology and the newly acquired Affinivax MAPS platform, as well as in late-stage

Specialty Meds – particularly the Phase 3 programme for depemokimab in severe asthma. We also continued our investment behind several earlier stage research projects.

Please turn to slide 7 and our pipeline headlines.

### **Year-to-date 2022: late-stage R&D pipeline momentum**

This quarter we took significant steps to progress our pipeline and platform capabilities and, of course, we are now delighted to have Tony as Chief Scientific Officer – and you will hear more from him in a moment.

It was great to present at IDWeek the Phase 3 results of our RSV older adults vaccine, which demonstrated more than 90% efficacy against severe disease. It is wonderful to have received US priority review as well as regulatory submission acceptances in Europe and Japan, all over the last couple of weeks. Overall, we believe our RSV vaccine has the potential best-in-class profile and we are very excited about the potential benefits it can bring to older adults. Of course, it is a tremendous commercial opportunity for GSK.

During the quarter, we also received several important regulatory approvals in our Vaccines business and as we close out this landmark year we look forward to further newsflow across the portfolio.

I want to reiterate that there are no changes in our capital allocation priorities. As a company, we continue to focus on making significant improvements in R&D and productivity, and performing competitively in the field with our pipeline remaining our top priority. We will continue to focus investment across four therapeutic areas while adding complementary and strategic business development to bring additional optionality.

This quarter we completed the important acquisition of Affinivax, and gained access to a Phase 2 next generation 24-valent vaccine. We also signed an exclusive licence agreement with Spero Therapeutics for tebipenem, a novel oral antibiotic in late-stage development, for UTIs.

Importantly, we are consistently driving pipeline momentum. This remains our priority, and alongside our strong commercial performance makes us stronger and better-positioned to achieve our ambitions than we were even a year ago.

Now, Tony, to you on Slide 8.

## **Innovation**

**Tony Wood:** Thank you, Emma.

### **A focused biopharma company**

Our shared purpose within GSK is to unite science, technology and talent, to get ahead of disease together. I want to spend the next few minutes explaining how R&D will support this objective, and how I expect the organisation to evolve under my leadership.

First, it's essential to recognise that GSK has changed: we have developed a unique operating model based on the science of the immune system, human genetics and advanced technologies. With this we have delivered a much more competitive performance in new drug approvals. This is encouraging, and something our organisation can be proud of, but there's more to be done. I'm confident we can further strengthen our pipeline of innovative and practice-changing new vaccines and medicines, to deliver long-term competitive growth.

To achieve this, we will rigorously prioritise R&D capital allocation in our four therapeutic areas. To achieve these objectives I have three key priorities for R&D. My first priority is to execute flawlessly on our pipeline, today consisting of 23 vaccines and 42 medicines. Flawless execution means prosecuting the development of our late-stage pipeline, bringing new vaccines and medicines to patients as quickly as possible, organically and through business development. It also means acceleration of development of our most promising pre-clinical and early-stage research projects. Our guiding question will be, can this meaningfully improve patient outcomes, and deliver a new standard of care?

My second key priority is exploiting new and existing platform and data technology to identify and accelerate clinical development opportunities. We already have a broad set of platform technologies, including an unrivalled suite within vaccines. We will continue to add to this, augmenting our capabilities. To illustrate this, we leverage our world-leading adjuvant capabilities to deliver a best in class RSV vaccine candidate for older adults. Likewise, through complementary strategic development we acquired Affinivax, and the disruptive MAPS technology mentioned by Emma. This allows us to develop multi-valent vaccines for complex bacterial infections.

In data technology we have access to the richest and largest data set, thanks to our data-focused collaborations, including our recent agreement with Tempest, which provides access to one of the world's largest sources of de-identified patient data, to accelerate drug discovery.

My third priority relates to R&D culture: a key element of my job is to create an environment in which we are ambitious for patients, and where our people are empowered to take smart risks and make the right decision at the right time; but taking smart risks is not solely a scientific endeavour. Luke and I chair a Portfolio Review Board, with cross-functional teams providing input into all key R&D decisions. My partnership with Luke and Deborah is key, and has never been more important, as we allocate capital towards those new vaccines and medicines that have the greatest potential to raise the bar for patients.

### **Innovation: four focused therapeutic areas**

We will continue focusing on developing innovative vaccines and specialty medicines. Infectious diseases and HIV now represent about two-thirds of our pipeline and are the primary focus for R&D. We have an opportunity to build on our leading position in vaccines, and complement the extraordinary success with *Shingrix* with new vaccine candidates for RSV in older adults, meningitis and pneumococcal disease. In HIV we are true innovation pioneers: we have led the way with two-drug regimens and long-acting injectible medicines. We will strengthen our leading position with longer-acting and more convenient treatments for people living with HIV, and alternative options in pre-exposure prophylaxis.

At the intersection of infectious disease and immunology we are developing bepirovirsen, a potentially transformative treatment for people living with chronic hepatitis B, which is responsible for around 900,000 deaths annually. Bepi also represents a foundational asset for the new oligonucleotide platform, that will increase our scope to prosecute promising new research targets from our leading position in genetics. We will prioritise immunology, respiratory and oncology programmes, using human genetics, functional genomics and AI/ML to support smart risk-taking.

Within Oncology, our primary focus is *Jemperli* and the CD2-26 axis and outside of IO we will take a pragmatic approach within synthetic lethality and tumour cell targeting.

In business development we will remain agile and ambitious, looking for opportunities that address high unmet medical need and complements our R&D strategy.

We will also target opportunities with genetic evidence that suggests a higher probability of success.

Let me now review some of the recent highlights within our pipeline. Please turn to Slide 11.

## **Innovation: potential best-in-class RSV vaccine in the most vulnerable adults**

This quarter's highlight was the exceptional Phase 3 data for our novel RSV vaccine in older adults presented at IDWeek. RSV is a common contagious respiratory virus responsible for around 420,000 hospitalisations and 29,000 deaths annually in developed countries. RSV disease is a significant burden on the elderly with almost half of all US cases observed in the over-65s.

Our data demonstrated unprecedented efficacy in older adults with 94% protection against severe RSV disease. The vaccine showed consistent and sustained high efficacy against RSV A and B strains in people in their 70s and those with comorbidities. The latter group is significant with over 90% of adults hospitalised with RSV disease having underlying medical conditions. These patients suffer the most and have the greatest impact on healthcare costs. We submitted these data as part of a comprehensive package which includes data demonstrating that the RSV vaccine can be co-administered with an influenza vaccine safely and without diminishing the immune response against either vaccine, an important consideration for the target population.

To date we have received regulatory acceptance of our submissions by the European Medicines Agency and in Japan and yesterday we received US regulatory acceptance and priority review with a goal date of 3 May, 2023 putting us firmly on track for June ACIP.

Now, moving to significant pipeline events which occurred in 3Q, please turn to Slide 12.

## **Innovation: scientific momentum**

Earlier this quarter we presented ten-year data for *Shingrix* also at IDWeek. This demonstrated a persistent immune response and illustrated that the duration of protection against shingles extends to ten years after vaccination. These data underscore the advantages of our proprietary adjuvant technology and set a new gold standard that will be very difficult to beat.

In HIV we presented data from the Phase 2a proof-of-concept BANNER study for N6LS, our broadly neutralising antibody. These early data show that a single infusion demonstrates strong antiviral activity. The decline in viral load, duration of response and good tolerability observed at two doses suggests a potential best-in-class antibody treatment.

Next week at the American Association for the Study of Liver Diseases Conference we will present the B-CLEAR end of study data for bepirovirsen, a potential new treatment for people living with Hepatitis B. This is an important trial because it demonstrates for the first time that

bepi alone or in combination with antiviral nucleotides or nucleosides can deliver a sustained reduction in both viral DNA and HBV surface antigen which together are key measures of efficacy.

B-CLEAR also identified a clear predictor of response that will guide future development. We are currently in discussion with the regulators about the design of Phase 3 studies and I will look forward to providing an update at our full-year results in February.

In Oncology we announced positive headline results for the PERLA Phase 2 trial, the largest head-to-head trial of PD-1 inhibitors in non-squamous non-small-cell lung cancer. PERLA evaluated *Jemperli* versus pembrolizumab in combination with chemotherapy but was not designed to demonstrate superiority. These data will be used to support future clinical development of novel combinations.

We also announced that both arms of the COSTAR Lung trial will progress into Phase III. This three-arm trial compared cobolimab, dostarlimab and chemotherapy in patients with advanced non-small-cell lung cancer who have progressed on prior PD-L1 therapy and chemotherapy. Last week the US FDA Cardio-Renal and Renal Drugs Advisory Committee reviewed our application for daprodustat. We are pleased the committee recognised the potential for daprodustat to help certain patients living with a new or a chronic kidney disease given their limited treatment options.

We look forward to working with the FDA as they complete their review of our new drug application. A PDUFA action date has been set for 1 February, 2023.

Finally, we decided we will not progress otilimab. Although the pivotal ContRAst trials met their primary endpoint, the efficacy demonstrated is unlikely to transform care for this difficult to treat population.

Please turn to Slide 13.

### **Innovation: 2022-2023 key news flow**

Looking ahead, we anticipate several significant late-stage readouts and regulatory decisions over the next 12 months. I won't attempt to go through everything on this slide but I want to highlight a few key events. In particular, before year end, we expect to report data from our pentavalent meningococcal vaccine, MenABCWY, as well as data from the RUBY trial in first-line endometrial cancer for *Jemperli*.

For *Blenrep*, we are on track to provide an update for DREAMM 3 before the end of the year, and we anticipate data from DREAMM 7 and DREAMM 8 in the second-line setting in 2023.

We also expect FDA regulatory decisions for daprodustat and momelotinib in the first half of 2023.

With that, I'll now turn the call over to Luke.

### **Performance: growth drivers**

**Luke Miels:** Thanks, Tony. Please turn to slide 15.

### **Performance: Q3 2022 turnover £7.8bn, + 9%**

In Q3 we saw strong execution across commercial operations and total sales growth of 9% in the quarter and increasing demand from all product groups. Two percentage points of growth came from *Xevudy* so that ex-pandemic overall sales growth of 7%.

Based on this good performance and our ongoing momentum, we have increased our full year sales growth guidance for Specialty Medicines to low double digits, excluding *Xevudy*. As usual, Deborah will comment on HIV while I highlight a few key dynamics.

In Immunology, *Benlysta* continues to be the leader in lupus, with sustained growth across major markets, including the US, where we are getting 80% of new starts. We are also making good progress with the lupus nephritis indication, now reaching around 15% of patients in the US with plenty of room to grow.

For *Nucala* we continue to be the first and only biologic approved for four EOS-driven diseases and our leading IL-5 class across major markets. In the US, we now have more than 50% market share for all our approved indications and we are on track to potentially add a fifth with our Phase 3 COPD trial due to complete in the first half of 2024.

In Oncology, our in-line and launch brands delivered double-digit growth, achieving £164 million in the quarter, including *Zejula* which was up 11% and *Blenrep* up 32%.

In General Medicines, we continue to lead the single inhaler therapy class with *Trelegy* and saw an increasing demand for *Augmentin* due to the post-pandemic rebound of the antibiotic market. As a result of this performance, in the quarter and year-to-date, we now expect full year sales for GenMeds to be broadly flat, which compares to the slight decrease that was previously signalled.

### **Performance: Vaccines +9%; Shingrix delivers record performance**

Turning to our Vaccines performance on slide 16.

Our Vaccines performance was very strong with sales growth of 9%, excluding the impact of prior year pandemic vaccine sales. This growth is driven by the continued recovery of *Shingrix* where we delivered another record quarter of turnover. In the US, *Shingrix* sales benefited from higher demand in both retail and non-retail channels, which was partly offset by expected unfavourable wholesaler inventory movements.

Outside the US, we are seeing the growing impact of new launches and strong commercial execution in Europe and International, with nearly 40% *Shingrix* Q3 sales now coming from markets outside of the US. *Shingrix* is now available in 25 countries with two new launches during Q3, and we remain on track to expand our geographic footprint.

In 2024, we plan to be in 35 countries representing nearly 90% of the global vaccines market, and we continue to expect *Shingrix* to deliver record year performance with strong double-digit sales growth this year. We now expect fourth quarter growth to be lower than in the previous quarter due to expected inventory burn in the US, reflecting the draw down of inventory channel fields from earlier this year.

So, Vaccines overall, excluding pandemic solutions, we expect sales growth for the full year in the mid-to-high teens up from our low-to-mid-teens expectation in Q2. This reflects strong commercial execution across the portfolio and increased contributions from *Bexsero* in the US due to higher CDC purchases, and increased market share versus Pfizer.

Let me now hand over to Deborah on slide 17.

### **Performance: HIV momentum driven by innovation sales**

**Deborah Waterhouse:** Thanks, Luke.

We delivered another good quarter with HIV sales, with £1.5 billion at 7%, taking year-to-date growth to 9%. Performance benefited from strong patient demand for our innovation portfolio which comprises *Dovato*, *Cabenuva*, *Juluca*, *Rukobia* and *Apretude*, and now accounts for 44% of our sales.

Strong growth of 11% in each of these in Europe was the result of excellent commercial execution behind our two drug regimens, and *Dovato* in particular. For the first time in a quarter, *Dovato* sales exceeded those of *Tivicay* with *Dovato* accounting for almost 25% of our total HIV business.

Turning to our injectable portfolio, *Cabenuva*, also known as *Vokabria+Rekombys* in Europe, is our first-in-class long-acting treatment regimen for HIV. Sales for the quarter were

£101 million, reflecting strong patient demand. At AIDS 2022, we were pleased to present new data from the CAROUSEL study, demonstrating successful implementation of *Vokabria+Rekambys* across a range of European health care settings.

More than 80% of studies supported that the complete long-acting regimen was less stigmatising than daily oral treatments. The outlook for this innovative medicine is compelling with strong brand recognition and high levels of market access and reimbursement across the US and Europe.

Moving on to prevention, *Apretude* is the world's first long-acting injectible for the prevention of HIV, dosed every two months. Launched in the US in January, *Apretude* delivered £10 million of sales in the quarter.

HIV prevention is an area of huge unmet need, as current medical options are associated with stigma and adherence issues. *Apretude* addresses these issues and has demonstrated superior efficacy over daily oral tablets. In the last week, we announced that the European Medicines Agency has accepted our application to make *Apretude* available to people who would benefit from PrEP in Europe. This is an important step forward in offering expanded options in HIV prevention.

Finally, we were pleased to present more than 50 abstracts across the recent scientific congresses, IDWeek and HIV Glasgow. The highlight, as Tony mentioned earlier, was the positive proof of concept data from the BANNER study of N6LS, our investigational, broadly neutralising antibody.

In conclusion, our Q3 results demonstrate continued positive momentum towards delivering our 2026 outlook and successfully evolving our product mix to the end of the decade.

I will now hand over to Iain, with the next slide.

## **Performance: financial results**

**Iain Mackay:** Thanks, Deborah. As I cover the financials, references to growth are at conference exchange rates, unless stated otherwise.

As Luke has covered the main revenue drivers, I will focus my comments on the income statement, including margins, cash flow, capital allocation and guidance. Please turn to slide 19.

### **Performance: Q3 2022 results and total to adjusted reconciliation**

Whilst my comments will focus on continuing operations, I will start by covering the effects of the demerger on total results.

Total earnings per share were 255.9 pence, of which earnings per share from discontinued operations were 237.1 pence in the quarter. This reflected £9.6 billion profit after taxation for the gain arising in the demerger of Consumer Healthcare. This was comprised of a £7.2 billion gain on demerger and a £2.4 billion gain on the retained stake in Haleon.

Turning now to continuing operations, for the third quarter of 2022 Commercial Operations turnover was £7.8 billion, up 9%, and adjusted operating profit was £2.6 billion, up 4%. Total earnings per share were 18.8 pence, down 35%, while adjusted earnings per share were 46.9 pence, up 11%. The main adjusting items of note between total and adjusted results for continuing operations in Q3 were transaction-related, which primarily reflected the ViiV contingent consideration liability movements, the majority of which related to foreign exchange; and in divestments, significant legal and other, which reflected a fair value mark-to-market loss on the retained stake in Haleon.

Pandemic solutions increased growth of adjusted operating profit by approximately two percentage points and growth adjusted earnings per share by around three points. The Q3 currency impact was a favourable 9% on sales and 14% on adjusted earnings per share.

Please turn to the next slide.

### **Performance: Q3 2022 adjusted operating margin**

The Q3 margin of 33.3% was stable and aligned with 2021's delivery. The positive margin dynamics reflected the sales growth with a favourable mix, excluding *Xevudy*, higher relative income, and favourable currency movements which were a 1.6 percentage point benefit in the third quarter. These factors were offset by the impact of lower margin sales of *Xevudy* and continued commercial investment behind launches and key products.

COVID solutions increased adjusted operating profit growth by approximately two percentage points and the adjusted operating margin, excluding COVID solutions, was approximately 1.3 percentage points lower at constant exchange rates.

Within cost of goods sold, increase primarily related to sales of lower margin *Xevudy*, which increased the cost of sales margin by around two percentage points, mainly reflecting the profit share pay-away to Vir Biotechnology.

Excluding *Xevudy*, cost of goods sold benefitted from a favourable business mix, with Specialty Medicines and Vaccines comprising 65% of commercial operation sales ex-pandemic. This mix benefit was offset by increased supply chain costs, including commodity prices and freight, which we continue to manage closely.

SG&A increased at a higher rate than sales in the quarter, which reflected launch investments in Specialty Medicines and Vaccines, but this was particularly focused on HIV and *Shingrix*, to drive post-pandemic demand recovery and support market expansion. Freight and distribution costs also contributed to the increase. These factors were partly offset by continued delivery of restructuring benefits and the gains on the Vir Biotechnology collaboration profit share.

R&D spend grew 8% in the quarter, with increases in investment across several programmes, particularly in Vaccines clinical development, including in our mRNA technology platforms, and MAPS following the Affinivax acquisition; in Specialty Medicines, with assets like depemokimab and momelotinib, and in early stage research programmes. These increases were partly offset by the lapping of now completed late-stage clinical programmes and ongoing efficiencies.

Royalties benefitted from Biktarvy contribution and higher sales of Gardasil. In the year-to-date, adjusted operating profit grew 16% to £6.6 billion with an operating margin of 29.9%, reflecting the strong business performance. The commercial contribution of COVID solutions on adjusted operating profit growth was neutral.

Please turn to slide 21.

### **Performance: Q3 2022 adj operating profit to net income**

Moving to the bottom half of the P&L, I'd highlight that net finance expense was slightly lower, reflecting increased interest income due to higher interest rates and larger cash balances following the demerger, and the effective tax rate of 16.6% reflected the timing of settlements with various tax authorities.

On the next slide, I will cover cash flow.

**Performance: Year-to-date 2022 free cash flow of £2.5bn**

In the year-to-date, we generated £2.5 billion of free cash flow from continuing operations. The main driver of higher free cash flow this year has been higher cash generated from operations, which has grown 49%, to £5.8 billion. This has primarily benefitted from increased operating profit, including the upfront income from the Gilead settlement in February, a favourable foreign exchange impact, and favourable timing of collections. These factors were partly offset by unfavourable timing of profit-share payments for sales of *Xevudy*, increased contingent consideration payments reflecting the Gilead settlement and increased cash contributions to pensions in the third quarter.

Below cash generated from operations there were higher tax payments and reduced purchases of intangibles, partly offset by lower proceeds from disposals and increased capital investments. We continue to have a keen focus on cash generation, and were pleased with our progress this year.

I'll take the opportunity to reiterate our capital allocation framework, which supports continuing investment in the business for future growth. Through R&D, both organic and inorganic, as evidenced by the Sierra Oncology and Affinivax deals, through commercial excellence, new product launches and effective capital projects, as well as delivering growing and sustainable shareholder return

, including through our dividend policy. Our strengthened balance sheet provides the basis from which we can execute this policy, with net debt standing at around £18 billion after the recent acquisitions. This provides greater flexibility and supports our maintenance of a strong investment-grade rating.

**Performance: increasing guidance for sales and adj. operating profit**

Moving on to guidance, Q3 performance was again slightly better than our expectations, and our year-to-date delivery has been strong. Taking that momentum and the positive fundamentals into account, we are again raising our guidance for full year 2022. We now expect sales, excluding COVID solutions, to increase between 8 and 10% at constant exchange rates, and for adjusted operating profit to increase between 15 and 17%.

We expect the year-on-year impact from COVID solutions to reduce adjusted operating profit growth by around 4% for the full year. In the fourth quarter we anticipate a relatively high

rate of R&D spend, reflecting prior year comparisons and in-year failing as well as continued targeted investment. In the round, for the full year, we also expect adjusted earnings per share to be 1% lower than adjusted operating profit growth, reflecting the balance of adjustments to be expected to effective tax and interest expense charges. For the third quarter we have declared a dividend of 13.75 pence per share, in line with expectations.

Before closing, let me touch on *Zantac*, given the impact it has had on the stock price over recent months. We set out the facts in the press releases on 11 and 16 August, and today's results release provides the latest information on the US cases. GSK's position on the scientific validity of these cases has not changed, and we will continue to defend all claims vigorously. As you will have seen, we await the outcomes of the Daubert hearings over the coming weeks, and we will of course continue to update the market as things evolve.

We continue to be highly confident in the performance of the business, and we are optimistic that the step change in delivery that we've seen in 2022 to date will continue in Q4, and will set up GSK for another year of success in 2023.

With that, I will hand it back to Emma.

### **Trust: delivering health impact sustainably**

**Emma Walmsley:** Thanks, Iain.

### **Purpose: to get ahead of disease together**

We continue to be guided by our purpose, to unite science, technology and talent to get ahead of disease together. Integral to this is running a responsible business, which builds trust and reduces risk for sustainable health impact, shareholder returns and supporting our people to thrive. This quarter we advanced our environmental leadership by launching our Sustainable Procurement Programme at Climate Week in New York, the recently-announced S&P Corporate Sustainability Assessment also recognised our sustainability leadership, and we were also delighted to gain World Health Organization pre-qualification for our malaria vaccine, a key step in making this ground-breaking vaccine available to more children.

In closing, I want to thank our people for delivering this tremendous performance momentum. I am deeply committed to GSK being a company that helps our talented people thrive, and we recognise the significant pressures many are experiencing due to the unprecedented context and the practicalities of the rising cost of living in many parts of the world, and this quarter,

we invested in supporting those most affected, as well as in company-wide enhanced benefits and wellbeing support.

Together, we are delivering our landmark year, also with another quarter of strong performance, upgraded guidance and excellent momentum. As we look to the years ahead as a focused global biopharma company we are well on track to meet our bold ambitions for patients and our commitment to competitive growth for the decade ahead.

With that, we will move to Q&A.

### Question & Answer Session

**James Gordon (JP Morgan):** Thank you for taking the questions. The first question was on older adult RSV vaccine. We now have the GSK and the Pfizer data in the public domain. What can you say about the comparative efficacy and tolerability? Are you still seeing GSK taking the dominant market share, or could there be similar products with the same ACIP recommendation, so maybe you have better efficacy but not so good on tolerability? What might the ramp look like, is *Shingrix* a proxy?

If I could just squeeze in a follow-up question which is a more general one on the pipelines – a question for Tony. How are you thinking about peak sales potential for the pipeline? It seems like oncology is a bit less of a focus than before, and there are some quite punchy targets set before, *Blenrep*, *Zejula*, *Jemperli*, being multi-billion dollar products. Are you re-affirming those forecasts or might those be under review, and are there other areas maybe outside Oncology where you see higher peak sales potential?

**Emma Walmsley:** Thanks, James. Two quite chunky questions there. I'll come to Tony first and let's deal with the RSV question. Tony, I think you can talk about the data both on efficacy and tolerability, and Luke, perhaps you can pick up on the ramp. Then we'll come back on your question of overall pipeline strength and prospects.

I just want to reiterate, James, what I said in my comments which is, compared to where we were just a year ago when we presented both our outlooks for growth and the five-year horizon, and a snapshot in that moment of time of the risk-adjusted pipeline, we are in a better and stronger position when we look across those three periods on a net basis. Obviously some things go away, other things have matured and as you know we have added business

development and maturing early pipeline in a fairly material way as well, so we would always expect that to keep adjusting.

But first of all let's deal with RSV in the round and then we'll come back, Tony, if you want to comment on building on your presentation on the pipeline assets, but RSV first, please.

**Tony Wood:** Yes, thank you, Emma, and James, thank you for the question. The first thing I would stress is that we are confident that our vaccine has a best-in-class profile and that really is anchored on the consistent high vaccine efficacy, particularly against RSV lower respiratory tract disease in the 70 to 79 population and in those with comorbidities. We know from the CDC that 94% of adults hospitalised with RSV disease are in those comorbid populations. Just to remind you, there we have consistent 94% vaccine efficacy across the board.

I would also highlight the data that we have with 'flu co-admin which serves to show no impact on efficacy of either vaccine, again important in that population and the fact that we have high vaccine efficacy against both A and B strains with an overall vaccine efficacy of 82.6%, so we are confident in our best-in-class efficacy profile.

As far as tolerability is concerned, the data we have shows that reactogenicity is mild to moderate, it resolves within two days and it is entirely consistent with the level of reactogenicity that is seen for a majority of adult vaccines.

Emma, I will leave it there in terms of the RSV answer.

**Luke Miels:** Sure, and just to build on Tony's points, I would expect at this point that ACIP would take a relatively conservative position but we have until June of next year, and as they get more evidence and more reflection benefit from obviously the exchange that occurred with both companies, let's see how that position evolves.

We have done early market research on data presented by both companies so that has actually enabled us to do some depth in terms of tracking. What is interesting is in terms of ACP, they only see one in four of their 60-plus patients who are actually healthy, so I guess three-quarters are perceived to be unhealthy and it's in that population that you actually see the difference start to emerge in terms of the perception of these two products for the reasons that Tony has said when you look at the efficacy, but I think also critically, again, these are scientifically fluid individuals, they are practising doctors, they understand confidence intervals, they understand consistency, and they understand and see which of their patients go to hospital each year. I think that's something we can build on and we are certainly looking forward to that scientific debate.

In terms of the ramp, again there's low levels of awareness amongst potential subjects to be vaccinated, but that will change with two companies obviously vigorously explaining that. Some of the press coverage around the results is a good indication of that. Physicians are obviously aware that there has been no solution beyond antibodies in kids, so we expect that this understanding will grow but the ramp will be more consistent and steady over time. I think the Inflation Reduction Act will also help in terms of co-pay reduction, in terms of a single-digit effect, and in terms of willingness to get vaccinated.

There is a build over time but I think it's exciting and I can imagine this is a class of vaccine that is going to grow over the next 15 years consistently year-on-year globally.

**Emma Walmsley:** Great, thanks, Luke. I don't know Tony whether you just want to give a very quick view to James' second part of the question on the shift in the portfolio and your priorities there and then we will move on because we have a long queue of questions.

**Tony Wood:** Yes, this is really for me about a focus on allocation of capital where we see data driving the potential for meaningfully different contributions to standard of care and I would point to the RSV results we have just been discussing, the emerging profile we have for bepi and of course the exciting opportunity we have within the pneumococcal vaccine opportunity based on the Affinivax acquisition. I expect momentum to continue in that part of the portfolio and that's why you see that two-thirds of our development portfolio is now coming from infectious diseases and vaccines.

**Simon Baker (Redburn):** Thank you for taking my question. On COVID in two parts if I may, please, firstly one for Deborah and for Luke, if you could just give us an update on where we are in terms of treatment diagnosis rates across the key therapeutic areas at this stage in the endemic phase.

Then on *Xevudy*, it was a very strong performance in the third quarter in contrast to a number of other antibodies in the space, so I just wonder, Tony, if you could update us on the data on efficacy that you have for the latest circulating variants of the Omicron variant and set against that you appear to be indicating Q4 sales for *Xevudy* as close to nothing. I just wondered if you could explain what that was, whether there were orders for Q4 that essentially came in to Q3, just a little bit of colour on that would be very helpful. Thank you very much.

**Emma Walmsley:** I'll come to Luke first to give you a shape of the *Xevudy* business, what's happened and what we don't expect ahead and I think you were asking for

commentary from Deborah also, and maybe Luke you can add to that, what's happening in the overall market in the context of COVID, and we know that's hit a few areas. Deborah, you might give a sentence on HIV and then if there is anything further to add, Tony, on variant switches as this becomes more endemic then we can add that at the end. Luke, first to you.

**Luke Miels:** Tony will cover the debate about *in vitro* versus *in vivo* activity but our feedback from physicians actually using the infusion is they still see activity, and so we are still seeing volumes employed and in some markets it's actually higher than anticipated.

Now in terms of extra orders, we are not expecting any in Q4 because governments have stockpiles. The shelf life is two years, we are working to extend it to four years, so we see it essentially as a saturated market at this point unless there's evolution of the variant.

In terms of impact on other areas, the primary area of suppression remains the ovarian cancer diagnosis, surgery and treatment. It's still down by about 9% and there are some signs of recovery but still suppressed. The rest of the markets with the exception of China are essentially starting to revert to the mean which is encouraging and gives us confidence in terms of the outlook.

**Emma Walmsley:** Thanks, Luke. Deborah, any comments?

**Deborah Waterhouse:** Yes, so in terms of the HIV market the overall TRx market in both Europe and the US has returned to pre-pandemic levels and is growing between 1% and 2% overall.

If we look at the dynamic part of the market, in Europe you can see that the dynamic part of the market is pretty much back to where it was pre-COVID. In the US, the NBRx's weekly were around 5,500 to 6,000 pre-pandemic. They seem to have settled now at about 4,500 per week so suppressed versus where we were before the COVID pandemic but I do think this is probably where they've settled so a slightly less dynamic market and obviously we work very hard to create that dynamism with our new portfolio of medicines which as you can see are being very well accepted and have a rapid uptake, both in Europe and in the US.

**Emma Walmsley:** Great, thanks. Tony, anything to add just on variants?

**Tony Wood:** Yes, just a quick one. The latest real-world evidence from an independent group demonstrates clinical effectiveness for *Xevudy* through the BA.2 wave which we believe can be extrapolated to BA.5 which is the currently dominant global sub-variant. That's all I have to add.

**Emma Walmsley:** Okay, just to remind everybody, I think everyone knows, that COVID solutions is completely excluded from our guidance in this year and in our five-year outlook. We have been very proud to contribute billions but mainly the impact for healthcare primarily through *Xevudy* through the pandemic. We are still watching to see what happens endemically. We have our platform in mRNA including potentially there but the world has plenty of COVID vaccines, so this is not at the core of our development plans going forward.

Right, the next question please.

**Richard Parkes (BNP Paribas Exane):** Hi, thanks for taking my question. I have a question for Tony. I just wondered if he could discuss his thoughts on R&D capital allocation in Oncology R&D going forward. There has been quite a lot of focus on rebuilding Glaxo, GSK as it is presently over recent years but it sounds like investment is going to be a bit more selective going forward. I don't know whether I am interpreting that correctly but maybe you could just discuss what you think GSK needs in order to compete effectively in Oncology, whether it be in terms of technology or capabilities and how you would achieve that over time rather than just fully de-investing. Thank you.

**Emma Walmsley:** Great, thanks, and just as a reminder, and we will come to Tony and then maybe Luke, you might want to add something commercially but our priority has consistently been to grow GSK through innovation in vaccines and specialty medicines. As Tony did say, two-thirds of the pipeline are in infectious diseases and in HIV but we see Oncology as part of what will drive growth at the end of the decade, but I will let him comment more specifically within Oncology. Then, Luke, you might want to add on that in terms of commercial as I know we are excited about what momelotinib might bring next year.

Tony, first to you.

**Tony Wood:** Thanks, Emma. We are committed to Oncology because of persisting medical need and scientific opportunity, and for us really Oncology is an emerging therapeutic area, so you can expect in terms of capital allocation our approach to be a pragmatic one through careful business development such as is exemplified by the Sierra Oncology deal, and as I mentioned earlier, a focus on assets in the portfolio where we see an opportunity for meaningful contribution to standard of care, for example our focus on immuno-oncology in the case of dostarlimab, where we have a number of interesting data sets starting to emerge, and in the CD226 axis, where access to CD96, PVRIG, TIGIT and other members gives us an

opportunity for full blockade of that axis. We will continue then to deploy our capital into oncology driven by data, which suggest that we can expect to see meaningfully different clinical contributions.

As far as the later stage pipeline is concerned, we're continuing to evaluate *Blenrep's* potential to make a difference in the treatment of patients with multiple myeloma, and as I mentioned, we expect to be able to report data from D-3 before the end of the year, and in DREAMM-7 and DREAMM-8 in second line in 2023.

Perhaps I'll pause there and pass over to Luke to make any additional comments.

**Luke Miels:** Thanks, Tony. I think this theme of discipline, in terms of competitive profile, is something that we spend a lot of time on. I think to build on Tony's point, I would direct you all to the ESMO IO PERLA publication for dostarlimab at the end of this year. I think it has a very intriguing read across for the COSTAR study, where there is a chemo/dostarlimab arm.

In momelotenib, if you look at the awareness and early market research that we have, it's very high, there is clearly a lot of enthusiasm around this product, so we're excited about the filing involved with that product, and the potential uptake.

**Steve Scala (Cowen):** Thank you. This is a big picture question for Tony, since I believe this is your first quarterly call: over the past 25 years GSK has tried many different R&D structures and programmes to infuse energy, accountability, creativity, but other than in vaccines and HIV, none have been particularly successful when compared to leading competitors. Hal made some positive steps, but still outcomes such as otilimab have been far too frequent. Why do you think this has been the case at GSK? Without identifying the root cause it would seem very difficult to fix. Thank you.

**Emma Walmsley:** Thanks, Steve. Perhaps, Tony, we go straight to you on that. I just would remind everybody again that on a net basis, when we look at our outlook for growth we're in a much better position than we were five years ago. Overall, in terms of number of approvals, I think we get to 13, we've doubled our number of late-stage assets and our current momentum as well as our prospects of growth haven't looked stronger. Obviously we have failures, because that is the nature of the industry, and I'm really pleased that we call when we don't think we can bring meaningful differentiation.

In terms of your core big picture questions on operating model, Tony, it would be great to have your reflections at this stage on that, and I'm sure the conversation will continue in the quarters ahead.

**Tony Wood:** Thank you, Emma. Let me start by just reiterating that together with Hal I was co-architect of the strategy that focuses on science and technology and culture in terms of transforming our business performance. As Emma has mentioned we have substantial momentum in that context, particularly our performance with regard to our late-stage portfolio, our performance of the past year is better than our past, and it's in line with our peers.

So what you can expect to see from me, and the priorities that I have delineated, is a continuing of that focus. I might take in particular on an aspect of culture associated with decision-making, in particular improving late-stage governance, and there the focus that you will see on investing capital into assets which have a meaningful opportunity to change standard of care, and that is going to continue to shape our late-stage development portfolio in the way that you can see it evolving today with this greater than 60% of our assets now focused on vaccines and infectious disease.

We will continue to focus there. My priorities again, in terms of technology then, building in additional capabilities in platform technologies – I would remind you that we already have a substantial suite of powerful platform technologies in vaccines, our adjuvant technology, recently-added technology for MAPS, and in our medicines portfolio the growth and effectiveness of building our capability in biologics, underscored, for example, by the performance that we demonstrated for *Xevudy* in bringing that monoclonal quickly to the market. *Nucala* is an example of a monoclonal leading in the IL-5 class, and a growing focus now on oligonucleotides exemplified through bepirovirsen and other cases in our portfolio.

I'm confident that, based on our focus on science, technology and culture, and a build-out in technologies both in platform technology and data technology, you should continue to see the momentum that was built under Hal continue and accelerate.

**Emma Walmsley:** Thanks, Tony. We're going to move to the next question, and we'll try and speed through as many as we can.

**Graham Parry (Bank of America):** Thanks for taking my question. You gave some interesting details on the *Zantac* litigation and the number of cases. I just wanted to clarify something as there might be some confusion out there, that you essentially have over 110,000

claimants now, and so the 33,000 in the MDL are the unfiled claims, and the 77,000 are filed claims. Could you give us a feel for exactly what the proportion of those are the five cancers outside the MDL?

Secondly, on daprodustat, post- the data, is that something which you would consider worth launching in dialysis-dependent only? Or is that an out-licensing candidate, given that GSK doesn't really have a cardio-renal franchise? Is that something on which you would be able to make an economic return on the R&D that was invested in it through an out-licensing deal? Thank you.

**Emma Walmsley:** Thanks, Graham. I will ask Iain who, alongside our General Counsel, both from a governance and a disclosure point of view, is on point for the *Zantac* work. Just to reiterate, we always prioritise patient safety. The scientific consensus on this is clear: we are vigorously defending our point and we are focusing very much on delivering the fundamentals of keeping you updated. Iain will comment on that, and then I will ask Luke, and then we go to the latest feedback and the outcome on Luke's comments on plans for dapro.

**Iain Mackay:** Graham, thank you for the question. Overall, if you look at where we are at present, we have just over 4,000 cases filed across State and Federal. The Federal cases are consolidated within that multi-district litigation in the Southern District of Florida. At a state level, what we have seen develop over the last few weeks is about 70,000 claims filed in the state of Delaware. Based on the data available, there are a couple of points. One is that the vast majority of those claims have not been vetted at this point in time and so we do not really know much about the claimants' circumstances, whether it is Rx, OTC or anything else. What seems to be quite clear, however, is that a significant amount, if not the majority of those, are transfers from the MDL case on the actions of the plaintiffs' lawyers to pursue five as opposed to 10 cancers.

Clearly, what is quite important in terms of the MDL case are the Daubert hearings which took place at the end of September and the beginning of October. We are hopeful of hearing Judge Rosenberg's decision either later this month or into the month of December and that is quite important in terms of informing how this case then proceeds, certainly in multi-district litigation at Federal level, but it would also to some degree inform what might happen at a state level, most notably within the state of Delaware, which is where the majority of the state cases are now filed.

In terms of the 33,000 cases sitting within the MDL, those address multiple defendants, including GSK – because there are other co-defendants within that case. Again, in terms of the numbers of claimants within that class, again that will be informed by Judge Rosenberg’s decision in the Daubert hearings, which we will hopefully hear about a little bit later.

The underpinning on this, Graham, is that we still have not had a single trial on this. The first trial we expect will be in California, kicking off in the middle of February. That addresses a single claimant’s case. Then we would expect MDL to kick off around the middle of the year but exactly how that plays out will, to a significant degree, be informed by Judge Rosenberg’s decision, which we will hopefully hear reasonably shortly.

Where we are is that there is absolutely no change in the consensus of scientific opinion in terms of no clear evidence and consistency around the causality of ranitidine in any form of cancer. Grounded in that, in the strength and confidence that gives us, we will continue to defend each case vigorously.

All I would add here is that, as matters evolve in this case, we will continue to provide timely and transparent disclosure, both in terms of the numbers and other developments. Certainly, keep your eyes peeled for any RNSs that we might issue, and obviously our quarterly disclosures and Annual Report and Accounts. I hope that is helpful.

**Luke Miels:** Graham, the short answer is yes, and yes. If we do it ourselves, it is financially attractive. We can also do it with a partner and make that work. I think our preference is to do it ourselves because of the synergies with *Benlysta and various other reasons*.

In the US, if we get dialysis, and assuming that we don’t have an onerous REMS programme, I think you will see the product evolve in three phases. The first phase, which is about nine months, based on CMS cycles, is pre- TDAPA, but I do not think you will see much volume at point because you are competing with EPOs which are embedded the bundle.

Then, the TDAPA period, which will run for about two years – that is essentially where the cost of the medicine is removed from the bundle and so there is a strong incentive, deliberately created by CMS, for the large dialysis organisations which dominate about 80% of the market in the US to utilise this drug, because of course the allowance that they have for EPO would be removed from the bundle. The amount they receive for the bundle will not change, so there is a heavy volume incentive for them. That period will run, based on our timelines, from 1 October 2023 through to 31 September 2025. After that when it goes back into the bundle, it’s very much

going to become a volume contracting game in direct competition with EPO, biosimilar EPO, so a tougher game.

Now all these elements with dialysis don't require a large field force. This is going to be a very concentrated group of people that I could probably count on two hands and maybe take one of my shoes off, so a very small infrastructure involved there for what is, net/net, from a P&L point of view quite an attractive asset.

For Europe, we expect to get the broader label and of course that's more of a classical non-dialysis build profile, but again we can embed that with the Benlysta Team and I just direct you towards the performance of dapro in Japan with its five HIFs. It was not first to launch but it has captured 60% and growing market share, so we think we have a very competitive profile versus roxadustat in Europe.

**Emma Walmsley:** Great, thanks, Luke. The next question, please.

**Andrew Baum (Citi):** Thank you. The first question to Iain. Iain, you and I have spoken previously about the potential for the MDL to exclude multiple expert witnesses leading to up and to including the MDL being shut down in its entirety if all the experts are excluded. Could you tell us from the background knowledge, which I am sure your Chief Legal Counsel is aware of, any significant prior cases in drug liability litigation where the MDL has been closed that have resulted in significant settlements, including to address the plaintiffs in the State courts. That's the first question.

And the second question for Tony. You have taken your TIM-3, cobolimab, into Phase 3 development on the basis of prespecified hurdles for the expansion criteria per protocol. Could you just tell us what those expansion criteria were and when you referenced the per protocol analysis is this in relation to tox or is this just patients advancing and therefore not being able to take their drugs? Many thanks.

**Iain Mackay:** Yes, thanks, Andrew. Look, as we have talked recently on this topic, there is a range of possible outcomes that Judge Rosenberg will inform in her decision but the likelihood of all evidence being excluded and the MDL effectively stopped we think is probably very, very low to zero probability, and frankly it's probably unwise of us to try and guess, rather much more wise to sit and actually await Judge Rosenberg's opinion.

In terms of precedent, there are clearly instances in other product liability cases where Daubert hearings and other forms of hearings like the Sargon hearings in California narrow the scope of the possible prosecution and evidence that can be submitted both, interestingly, by plaintiffs and defendants' lawyers, so there is a range of practice in this.

I don't think we have any expectation that all evidence will be excluded and the MDL suppressed, that would be unlikely, but we are going to save our counsel and wait to hear from Judge Rosenberg, that's the best approach here.

**Emma Walmsley:** Thanks, Iain. Tony on TIM-3.

**Tony Wood:** Yes, thank you, Andrew. First of all I would say I am happy with the progression of COSTAR into Phase 3 on the basis of the IDMC recommendation. I don't want to disclose the details of our clinic trial and I am looking forward to waiting to see what the data is.

**Keyur Parekh (Goldman Sachs):** Hi, thank you for taking my questions. Two if I may, please. The first one; just on the ramp for the RSV vaccine and how you anticipate launching it in the US and ex-US. With *Shingrix* we saw kind of a staggered launch due to supply constraints, but just wondering how you see the trajectory of launch and what should we be anticipating as regards to the length of time it takes before you get to your peak sales outlook for the molecule.

And then separately, Tony, kind of big picture for you again coming back to R&D and culture and organisation, what are some of the things we should expect from you that might be different to what prior GSK management have done from an R&D perspective, and what is your broader picture for how you would define success for GSK R&D over the next 12 to 24 months? Thank you.

**Emma Walmsley:** Great, so Luke, for the competitive situation, over to you first on RSV ramp.

**Luke Miels:** Sure, thanks, Keyur. We have no supply constraints within reason, so unlike *Shingrix* where a deliberate decision was made to impair launches to direct supply to the US in early launch markets. We will go for a full global launch. There is some gating of course just from a resource point of view. The ramp I would expect to be quite steady. The peak for the US is after five years, globally it's going to be closer to ten years just because of building/filling in

the market, but as I said I would expect that this product grows throughout its lifecycle. It should just continue building and building as we see penetration in markets across the globe.

**Emma Walmsley:** Yes, and the last point on this one is of course we will still see the data prove out how long the duration of efficacy is and the frequency of re-protection. Tony.

**Tony Wood:** Thank you. Two points on that one: first of all, I would point again to portfolio decisiveness and decision-making. In particular, you should expect to continue to see a focus on those assets whose profile is consistent with a material contribution to standard of care, an acceleration of early-stage assets based on data, and a continued focus on business development.

As far as impact on the broader R&D culture is concerned then, it's doubling down on technology, and in particular, to drive performance within R&D, and you should expect the examples of how that technology deployment, be it against platform or data, is improving the overall characteristics of the portfolio.

**Emma Walmsley:** Thanks, Tony, and the measures of success, let's be clear, are the strength of the pipeline and the prospects for growth, profitable growth, it generates.

By the way, our proposal is, for anyone who's worried about not getting through all the questions, that we will extend the call by an extra ten minutes so we can get to everybody.

**Jo Walton (Credit Suisse):** Thank you. I will respect the one question rule here, and ask a little bit more on *Shingrix*: could you give us an idea of the level of inventory at the end of the third quarter in the US? I believe it was 1.9 million doses in the second quarter. And if you can tell us a little bit about the penetration in other markets – you've talked in the past about Germany and Canada as being the main two markets, but you're in more than 30, so can you talk about where you have good penetration, what sort of level of annual cohort you might expect to be able to get to in some of these other non-US markets?

**Luke Miels:** 1.8 in Q3, which compares to 1 in Q3 last year, but you would have seen the latest TRX as we just hit 200,000 last week, so good in-market demand in Q3 in actual doses about 6.3 million sold, so consistent demand, which is very deliberate, we wanted to smooth the process over the year and not have it aggressively concentrated around the flu season. I think we're proving to do that, because if you look Q1 was 6.6, Q2 was 6.5, Q3 was 6.3.

In terms of outside, you saw on the slide that I presented you have this growing European and international presence, and a critical point to make here is that if you look at price variance globally, it's around 5% from the US on average, so we've been able to preserve this pricing power so far at this point in the life cycle. German demand remains very strong, we're starting now in Spain, Italy, we're about to announce a major contract in one of the key European markets for full reimbursement, so yes, we continue to see very positive signs, and the aim, of course, is to have this market completely treated with a ten-year plus and evolving efficacy before anyone else gets close to launching.

Now, I spent time in emerging markets in August, it's quite encouraging what we see: early days with Brazil. Obviously we don't expect to see levels of penetration that we may reach in the US over the next couple of years, but we also have the flexibility to adjust that price down in the back end of the life cycle, to catch those patients who may not be seeking vaccination at this point in the out of pocket market in emerging markets as well.

So there's plenty of flexibility in terms of the structure and how we're positioning this vaccine for multiple-year growth.

**Emma Walmsley:** Fantastic, thanks Luke.

**Tim Anderson (Wolfe Research):** Thank you. My question is cash flows and business development: one of the challenges Glaxo has faced in years past is weak cash flow, limited business development activity, that improved after spinning out Consumer and cutting the dividend, but I'm wondering if business development in the form of acquisitions specifically could get put on hold again, given uncertainty around *Zantac*, because it's not inconceivable that at some point you have to take financial reserves seeing as the drug was pulled off the market. So, if the answer to my question is, there's no change, it's business as usual, maybe you can bracket the upper end of deal sizes you'll continue to look at.

**Emma Walmsley:** First of all, I want to be absolutely categorically clear, we will, as always planned, continue to pursue business development with agility, ambition and appropriate aggression, and due discipline from a financial point of view. There is absolutely no change to our intentions there, as articulated also by Tony, and from a capital allocation point of view from Iain. This is, as you rightly acknowledge, exactly why we went through significant structural reset of the balance sheet of GSK, but I'd also point us to the improving operating

performance generation of cash flow as well as continually competitive distributions, but also some of the pay down of debt (and of course we are helped by currencies).

It's really important that this is understood, that we are absolutely focused, with full support, to keep prioritising BD as part of our pipeline development, mainly for continued profitable growth in the end of the decade. We're very confident in our outlook, so we will stay disciplined on it, but that is the very clear intent and plan forward.

Iain, I don't know if there's anything to add?

**Iain Mackay:** I am not sure that there is much to add, Emma. We have a stronger balance sheet and we have strong cash flow. We did a reset on the dividend with good cover of that from '23 onwards. There is a strong focus on cash generation, cash management, across the business. To Emma's point around business development and M&A, there is a continued focus around those bolt-on acquisitions that we have done over the course of last few years. So, absolutely no change. There is not a *Zantac* overlay at this stage, for the obvious reason that we believe that there is a very strong consensus of scientific evidence supporting our position and we will defend the claims very vigorously on that front. There is absolutely no change in capital allocation priorities – none.

**Emma Walmsley:** Thanks, Iain. Next question, please.

**Peter Balfour (Jefferies):** Thanks for taking my question. This is a point of clarification on *Zantac*. Given the commentary you made with regard to the MDL and how the Daubert decision will inform how it proceeds, I am curious to know whether that is an event which the auditors, or I guess, Iain, consider then the time to consider a provision? Or will that likely wait for the bell-weather?

Then could I just ask on RSV? Coming back to what Luke was saying with regard to competitive positioning, we have obviously now also seen data from Pfizer on their maternal vaccine. I am curious about any view on that, and particularly how that potentially could impact your positioning of the product in the retail segment in the US, which I think you said is very important on the prior call – given that is obviously now two populations, potentially, that could be addressed in the US with that vaccine. Thank you.

**Emma Walmsley:** I suspect that we have covered what we can beyond the press release on *Zantac*, but Iain may want to add to that.

Then, on other people's vaccines, Luke may want to talk about the commercial prospects there.

**Iain Mackay:** On Daubert, Peter, it informs what testimony can be submitted in evidence, both by plaintiffs' and defendant's counsel, and possibly the scope of the MDL that will take place in the middle of next year. It doesn't inform anything else and therefore viewing that as definitive or if it is absolutely is not definitive that we have to go to court to try the case and we will defend ourselves vigorously in that matter and, depending on the outcome of it, then we will consider whether or not any provisioning may be appropriate at that time. But no, I don't think Daubert is an inflection point in that regard at all.

**Luke Miels:** I think these two populations will be separated. Again, it will come back to the efficacy in the groups most at risk and I think the numbers are quite illustrative: there are about 80 million people aged 60-plus who are either comorbid, or 65-plus, versus a birth cohort of about four million on the US each year. I think it is quite manageable, and that is assuming that it is approved, of course.

**Kerry Holford (Berenberg):** My question is on your meningitis vaccine franchise. Your competitor, Pfizer, has announced positive safety headlines for its 5-valent vaccine and they aim to file before the end of the year. You are confirming today that your Phase 3 data is due by year-end. If that is positive, how quickly can you move to file? Arguably, you have more to lose in this market and Pfizer has more to gain, so how comfortable are you that you can protect and indeed grow your position beyond *Bexsero* and *Menveo*?

A slightly different but related question: perhaps you could remind me of the difference between your generation 1 and 2 pipeline candidates in this area. Thank you.

**Emma Walmsley:** Thank you. Tony, perhaps you could comment on timing to file and gen 1 and 2, and then Luke we will come to you for what are, I know, your very strong ambitions and prospects there.

**Tony Wood:** Thank you. As I mentioned earlier, we are confident that the programme is on track as regards data and we are preparing to move to file post that, as quickly as possible.

**Luke Miels:** Yes. I just feel, in terms of the first generation assets, the important component – and we have published on this - is the 110 strain coverage, which we believe

strongly means it provides better protection. The generation 1 is really a US targeted vaccine, because in Europe it is largely an infant population where we see *Bexsero* being preserved and used in a mono setting. The pentavalent is very much targeting US adolescents, college-aged kids, and the penetration of *Bexsero* in there is still relatively early days. We think that the shift to the pentavalent and the beta (B) being embedded there will be a very competitive opportunity. It is not cannibalistic, but it is an opportunity to grow the aggregate business there in the US.

Then the generation 2 has the potential to be utilised more broadly.

The final thing I would direct you to – and we need to build the evidence for this and ultimately find a pathway for a label – is the activity around gonorrhoea. I think there is an excellent analogue with Merck's excellent work with *Cervarix* around HPV and genital warts. Again, when you look at gonorrhoea, about 83 million new cases in the US every year. College-aged kids of course by nature of their lifestyle point of age are at high risk, so we think these elements combined are very compelling and that last activity around gonorrhoea we don't believe it's accessible to the Pfizer meningococcal vaccine.

**Emma Walmsley:** Great, thanks, Luke. The next question, please.

**Michael Leuchten (UBS):** Thank you. Just a quick follow-up just going back to *Shingrix* and the stocking levels. In Q2, you were pointing out that inventory levels were running quite high. It sounds like they still are, but are you comfortable with that going forward or should we expect there to be a work-down as we go into the 'flu season? Thank you.

**Luke Miels:** Yes, Michael, comfortable. They kept ordering – I have said this in the past and it remains true – they order it because they are confident in using it and the scrip trend is certainly pointing that way, and actually we have seen a strong jump in non-retail utilisation which is not as visible to you guys, so the volume growths are very encouraging, so not concerned with Q3 inventory levels. Thank you.

**Emma Walmsley:** Right, we have two more questions, so the next one please.

**Emmanuel Papadakis (Deutsche Bank):** Thank you for taking the question. Perhaps a question on mRNA. You highlighted several times in the Q3 release the priority invested in mRNA, I assume that would be principally into the 'flu partnership and COVID partnership with CureVac but perhaps you could tell us if that's otherwise. Are we still expecting

Phase I data for both modified and unmodified 'flu assets by the end of this year, and what is your degree of confidence both in us seeing an improved risk-benefit profile relative to competitive datasets that we have seen over the last 12 to 18 months, particularly as regards reactogenicity and are you confident that you have the right external technology partner for that platform?

And then a very quick follow-up on royalties, if I may, a very big step up, and apologies if I missed it earlier. You didn't seem to call out any one-offs, is that the kind of run rate we should be thinking about going forward? Thank you.

**Emma Walmsley:** Right, Iain can you just pick up the royalties one and then, Tony, we will come to you on mRNA?

**Iain Mackay:** The royalties is the principal combination of the *Gardasil* and *Biktarvy* settlement. Those are the two key elements and obviously the *Biktarvy* settlement took effect in February of this year so we are probably hitting an appropriate run rate but it's informed by sales of *Biktarvy*.

**Tony Wood:** Thank you. In 'flu, our studies remain on track. I would remind you that we have a suite of clinical studies aimed at assessing optimisation of sequence and incorporation of modified bases in both the context of COVID and in the context of 'flu as well as an internal build which is continuing at pace, so I am confident that when you put all three of those together we are well placed to be able to solve the equation associated with getting to an appropriate reactogenicity versus efficacy proposition for a multivalent 'flu vaccine. We will know clearer how that stands certainly by the end of the first half of next year.

**Emma Walmsley:** Thanks, Tony. Okay, the last question, please.

**Emily Field (Barclays):** Hi, thank you for taking my questions and fitting me in. Hopefully first is a very quick clarification on *Zantac* and the impact of Daubert. You mentioned that a number of these cases in Delaware where plaintiffs are moving jurisdiction from the MDL to Delaware. I was just wondering whatever comes out of Daubert, will that have any impact on any other jurisdiction such as the State courts, i.e. a cancer is reduced in the MDL via Daubert, would that then have any impact on State cases?

And then I actually just wanted to ask a question on what looks like a recent decision to move the anti-TIGIT asset into Phase 2. If you could just comment on the thinking behind that as we are all awaiting the tiragolumab updated ELECT data, and it does look like an interesting trial

design given that you also have a pembro arm in there in the context of the PERLA study, so just any colour or commentary on that would be helpful. Thank you.

**Emma Walmsley:** Great, thanks. Iain swiftly on Daubert again and then Tony to finish up, please.

**Iain Mackay:** Sure. Emily, thanks for the question. At a State level they are not bound by decisions at the Federal court level and Daubert is informing the scope and testimony in the multi-district litigation in the Southern District of Florida, so the States can take a different view. What is interesting based on history is that Delaware has tended to follow precedent set by Federal courts, so it is possible that the Daubert hearings would have an impact specifically related to multi-district litigation in the Southern District of Florida in Federal court.

It is possible that the output of Daubert could also have a read-across to State cases and at State level probably notably in Delaware where we currently have about 70,000 claims filed of which the vast majority are as yet unvetted, so we know little about them other than the fact that they probably relate to five cancers that the plaintiffs' lawyers and the MDL have decided not to pursue. That is probably all I can add on that point at the moment, Emily. Hopefully that's helpful.

**Emma Walmsley:** Tony, TIGIT.

**Tony Wood:** Yes, thanks, Emily. Obviously TIGIT is an incredibly competitive class with more than 20 assets in development, and for that reason it's going to be important for us to move at pace, hence the change that you see. It's likely that certain assets are going to have dominant positions in certain indications, given combination partners and others. I don't really want to disclose where we may compete, but the movement that you see is consistent with that, and also building out a phase 2 platform capability, to be able to evaluate not only doublets in the PD1 TIGIT access, but other alternatives in combination, as I mentioned earlier, like CD96 and PVRIG.

**Emma Walmsley:** Thank you, Tony. A big thank you to everybody. I hope we got to most people's questions, and we'll certainly be following up in coming days. We are delivering our landmark year with another quarter of strong performance, upgraded guidance and great momentum, including on the pipeline, so we're very much on track to meet our bold ambitions for this year, for our five-year outlook and indeed for the decade ahead. Thank you very much everyone.

[Ends]