Q3 2024 results
Wednesday, 30 October 2024 at 12 noon GMT / 8am EDT

Introduction | Jeff McLaughlin

Hello everyone. Welcome to today's call and webcast. The presentation was sent to our distribution list by email, and you can also find it on gsk.com.

Please turn to slide 2.

Slide 2 | Cautionary statement regarding forward-looking statements

This is the usual safe-harbour statement - we will comment on our performance using constant exchange rates or CER unless stated otherwise.

Please turn to slide 3.

Slide 3 | Agenda

Today's call will last approximately one hour, with the presentation taking around 30 minutes and the remaining time for your questions.

Our speakers today are Emma Walmsley, Luke Miels, Deborah Waterhouse and Julie Brown, with Tony Wood and David Redfern joining for Q&A.

Please ask only 1-2 questions so that everyone has a chance to participate.

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

Q3 2024 continued momentum and R&D progress | Emma Walmsley

Slide 4 | Q3 2024 continued momentum and R&D progress

Welcome to everyone joining us today.

Please turn to the next slide.

Slide 5 | YTD & Q3 2024 performance

I am pleased to report that despite some challenges, this has been a positive quarter for GSK and we are delivering 9% sales growth and 19% core operating profit growth YTD. This growth reflects the accelerating momentum we have in Specialty Medicines and the overall resilience we have built in our portfolio, which underpins continued high confidence in our outlooks to 2026 and beyond.

Importantly, we have made considerable progress in our pipeline this quarter. And, with no admitted fault or failure, I'm delighted we have also drawn a line under the vast majority of Zantac litigation, removing a clear perceived risk for the company and allowing us to focus on the future.

Overall, excluding COVID, sales for the quarter grew 2% — 9% year to date — with Speciality Medicines up 19% and double-digit growth reported in HIV, Respiratory/Immunology and Oncology. We were particularly pleased to see the momentum now being established in our oncology business and I'm delighted that we filed Blenrep in Europe, Japan and the US in the quarter. We also continued to see strong progress in the transition of our HIV portfolio to long-acting medicines – now 18% of HIV sales and where we plan to continue to lead the way.

General Medicines also performed strongly this quarter with growth up 7%, led by another outstanding performance from *Trelegy*.

Total Vaccine sales were down due to lower sales of Arexvy and Shingrix. Recent guideline changes, and prioritisation of COVID vaccines in the US were key factors. But market shares for both these vaccines remain very strong.

Although both vaccines face market circumstances that will limit their growth potential in the near-term, over the medium and longer-term, the fundamental benefits these two best-in-class vaccines offer to protect people from disease and to take pressure off healthcare systems remain. And, with appropriate recommendations from public health authorities, we fully expect them and our vaccines pipeline, to deliver significant future sales growth to GSK.

Back to this quarter, we continued to deliver strong operating performance and leverage. Excluding COVID, core operating profit and core EPS growth were both up 5% - reflecting the positive margin benefit of Specialty Medicines and sustained focus on cost management. Year-to-date operating profit was up 19%, supporting double digit profit growth for the year.

Lastly, we are reporting further improvements in cashflow – with cash generated from operations of £5.3 billion year to date. This is providing increased funds for pipeline investment and returns to shareholders. Our dividend for the quarter is 15p up 7%.

Next slide, please.

Slide 6 | Pipeline delivering momentum across therapy areas

Pipeline progress was strongly evident in the quarter, with a series of filings and data readouts supporting future product momentum.

So far this year, we have had 11 positive phase III readouts. And we are currently planning launches for 5 major new product approval opportunities next year, with Blenrep, Depemokimab, Nucala for COPD, Gepotidacin, and our new meningitis vaccine (MenABCWY).

In the quarter, pivotal data from our ultra-long-acting biologic, depemokimab in severe asthma, was front and centre at the European Respiratory Society congress, and simultaneously published in the *New England Journal of Medicine*.

Additionally, we announced positive results from our phase III trial of Nucala in COPD.

In Oncology, we were delighted that Jemperli received an expanded approval by the FDA for all adult patients with primary advanced or recurrent endometrial cancer. And, Blenrep is now filed with multiple regulators, including the US.

I was also delighted to see the positive headline data from our mRNA influenza vaccine candidate, demonstrating positive A and B strain immune responses relative to standard of care, enabling us to progress to phase III clinical trials next year and build another key vaccine platform.

And we received a number of break-through regulatory designations, recognising the importance of our innovation for unmet medical needs. This included bepirovirsen, our antisense oligonucleotide for chronic hepatitis B; and B7-H3 our antibody drug conjugate for extensive-stage small-cell lung cancer.

B7-H3 is one of two promising ADCs we have in clinical development and part of the 'next wave' portfolio now emerging in R&D, which Tony will update you on at our next meet the management event in December.

Next slide, please.

Slide 7 | Trust: delivering health impact sustainably

Building trust by delivering sustainable heath impact remains a clear priority for all of us at GSK.

We continue to make progress across our six key areas and I would particularly like to recognise our HIV business for its commitment to make at least two million doses of Cabotegravir long acting for prevention available in low-and middle-income countries during 2025-2026. This further commitment builds on long-standing action to deliver sustainable access and triples supply compared to 2024.

Please turn to the next slide.

Slide 8 | Strong momentum underpins confidence in future profitable growth

GSK is delivering consistent financial performance**.** Looking to the end of this year and beyond, we are even more confident that the progress we are making in portfolio development, and in R&D, supports the delivery of our growth outlooks.

For 2024, we continue to anticipate sales growth of 7-9%, with double digit profit growth.

We also remain very confident in our outlooks to 2026 and 2031 and our investment choices to drive competitive growth in Specialty and Vaccines. It's also worth remembering that these outlooks do not yet include *Blenrep*, or progress in our early-stage pipeline. And we will continue to pursue bolt-on business development to further enhance our pipeline and our technology platforms with a focus on our core therapeutic areas.

With that, I will now hand over to Luke and Deborah to talk you through our commercial performance.

Performance | Luke Miels

Slide 9 | Performance: growth drivers

Thanks, Emma. Please turn to the next slide.

Slide 10 | Specialty Medicines growth led performance as our largest product area

Third quarter sales were up 2% to £8 billion and year-to-date sales were up 9%.

As you can see from the chart here, Q3 sales growth reflected a tough comparison, with strong growth from Specialty and General Medicines offsetting lower sales of Vaccines.

Specialty Medicines – the largest part of our business – grew 19%, reflecting strong performance of new products and the investment we have put into recent launches particularly in oncology and HIV. We expect this momentum to continue, with growth from these assets, and several material launch opportunities in respiratory, oncology and other disease areas coming later next year.

General Medicines sales were up 7% driven by strong performance of respiratory.

And, as has already been mentioned, lower demand for Shingrix and Arexvy this quarter led to an overall sales decline of 15% for Vaccines. I will cover this in more detail in a moment.

All of these dynamics were broadly reflected in the performance of our regions, with good growth internationally. And the US, unsurprisingly was more impacted by the lower vaccine demand we saw this quarter.

Please turn to slide 11 to look at Vaccines in more detail.

Slide 11 | Vaccines: -15% in Q3, broadly stable YTD[1] with strong market shares maintained

I'll focus commentary on Arexvy and Shingrix.

Arexvy performance was impacted by three factors: firstly by changes in ACIP guidelines that restricted the recommended populations of older adults receiving RSV vaccinations, secondly, by the prioritisation of COVID vaccinations in the US and thirdly, by lower seasonal RSV infections. In addition, it was a tough comparator given two-thirds of sales in Q3 last year were related to stocking. Despite these dynamics, we retained our strong leadership market share.

We are still in the foothills of this vaccine's availability and usage. In the US, we continue to make data available to ACIP and to support them as they move towards making longer-term recommendations on the use of RSV vaccines, including requirements for revaccination and cohort expansion.

Beyond the US, Arexvy has now launched in 35 markets, 16 with national recommendations and 6 with national reimbursement programmes. More rollouts, across Europe and International, will come in 2025.

For Shingrix, YTD growth was driven outside the US, now 58% of the business. The average immunisation rate across the top 10 markets ex US is around 6% so there is still a very large opportunity here. Growth outside the US was 9% this quarter.

US penetration was 39% at the end of the second quarter. Adding to US penetration remains a key focus, but *the pace* is slowing from around 6-7pts per year to 3-5pts making incremental growth more challenging. The visual on this slide also shows how US sales moderate as the immunisation rate slows.

Next slide, please.

Slide 12 | Vaccines: looking ahead

So, looking ahead on Vaccines...

This year we now expect vaccine sales to decline low-single-digits.

In 2025 we expect limited growth, reflecting the assumption that there will be no Arexvy re-vaccination or expansion of age cohorts next year.

Beyond 2025, for Arexvy, we expect further successful rollout and that public health recommendations for cohort expansion and revaccination will be confirmed, alongside international penetration given the patient need and the protection this vaccine can offer against RSV. And so, on this basis, we continue to expect Arexvy to make a significant contribution to future sales and we continue to believe it can achieve peak year sales of more than £3 billion.

For Shingrix, our ambition remains to achieve more than £4 billion in sales.

And finally, beyond Arexvy and Shingrix, we also have material growth opportunities with mRNA and our MAPS technology where we have decided to prioritise the pneumococcal 30 plus valent asset in adults to pursue the broadest potential coverage. And further build-out of our meningitis portfolio, the next step of which will be the launch of our MenABCWY vaccine in 2025.

Next slide, please.

Slide 13 | Specialty: +19% in Q3, +20% YTD[1], largest product area with new launches ahead

Specialty Medicines is an increasingly important driver of growth for GSK reflecting the combination of successful R&D and BD investment over recent years. It delivered another quarter of excellent growth, including HIV, which Deborah will cover shortly.

Respiratory/Immunology products were up 14%.

Nucala, our anti-IL5 biologic treatment was up 12%. In September, we announced positive headline results from MATINEE, a phase III trial evaluating Nucala in adults with COPD, a disease which affects more than 300 million people. Full results will be presented at a scientific congress next year.

We also presented SWIFT phase III data for our ultra-long-acting anti-IL5 biologic treatment, depemokimab in the quarter. Depemokimab demonstrated a 54% reduction in exacerbations versus placebo plus standard of care for patients with severe asthma after only two injections in a twelve-month period. This is a major benefit for provider and patients. In addition, positive data from the phase III ANCHOR study evaluating depemokimab in patients with chronic rhinosinusitis with nasal polyps was also announced this month. Alongside SWIFT, these data will support expected filing before the end of the year, with a view to a dual indication launch in 2025.

To remind you, combined, we expect our anti-IL5 portfolio to deliver more than £4 billion in peak year sales.

Benlysta was up 16% in the quarter with strong demand and volume growth in all regions. And Oncology, almost doubled, which I will cover in more detail on the next slide.

We expect momentum in this part of our portfolio to continue, especially given the launch opportunities we have in front of us. For this year, we are upgrading sales expectations for Specialty Medicines to high-teens percentage growth

Next slide, please.

Slide 14 | Oncology

Focusing on Oncology, sales almost doubled in the quarter, and we have delivered >£1 billion in turnover so far this year. Our focus on haematology and gynaecologic cancers is delivering strong progress evidenced by the success of new product launches in these areas.

Ojjaara, which has launched in the US, Europe and very recently in Japan, has seen quick adoption with high quarter-on-quarter growth. In the US it's maintaining its fast launch uptake and there is still a large opportunity remaining in first-line.

Jemperli sales also continue to grow strongly. In August, the US FDA approved Jemperli plus chemotherapy for the treatment of adult patients with primary advanced or recurrent endometrial cancer. This approval broadens the previous indication to include the 70-75% of patients diagnosed with endometrial cancer who have mismatch repair proficient / microsatellite stable tumours. Treatment options have been limited for this cohort, so it's important Jemperli is now available to these patients.

Zejula's growth continued in Q3, driven by US pricing effects and higher demand outside the US.

Looking ahead, we have a significant opportunity to strengthen our oncology business with the launch of Blenrep in H2 2025. We filed for approval with the US, EMA and Japan in the quarter.

Next slide, please.

Slide 15 | General Medicines: +7% in Q3, +7% YTD

General Medicines grew 7% in Q3, primarily driven by Trelegy.

Trelegy sales increased 16% to £600 million with strong growth across all regions reflecting patient demand, class growth and increased market share in the overall asthma and COPD market.

Use of authorised generic versions of Advair and Flovent are continuing to fully offset removal of the AMP Cap on Medicaid drug prices in the US.

Given our stronger performance this year, we now expect mid-single digit per cent sales growth for General Medicines this year.

Looking forward, for the total business the US is expected to face pressure from the implementation of the US Inflation Reduction Act legislation in 2025. We expect the overall impact to be in the range of £400-500m including HIV.

I'll now hand over to Deborah.

Performance | Deborah Waterhouse

Slide 16 | HIV: Growing 12% in Q3 2024, with strong performance in long-acting

Thank you, Luke.

Now turning to HIV, we continue to deliver strong performance and sustained double-digit growth, with Q3 sales up 12%.

This growth was driven by strong patient demand as well as favourable pricing dynamics. For 2025, we do not expect the favourable pricing dynamics to continue, in part due to the introduction of the inflation reduction act, however, we are confident that the underlying demand of our medicines will remain strong.

As leaders in oral two drug regimens and long-acting injectables, it is positive to see this continued momentum, delivering 2 percentage points of market share gain versus the previous year.

Dovato grew 23% for the quarter. This positive growth was supported by results announced in July from the PASO DOBLE study, a large head-to-head, randomised clinical trial of Dovato compared against the 3-drug regimen, Biktarvy. This study demonstrates Dovato's non-inferior efficacy and significantly less weight gain versus Biktarvy. This is important because we know people living with HIV are concerned about taking more medicines as they age, as well as the long-term risk of metabolic diseases that can come with weight gain. The performance of our long-acting portfolio also remains very positive, delivering 314 million pounds of sales and representing more than 50% of total growth for the quarter and year to date.

Cabenuva grew 40% driven by patient preference and proven and durable efficacy. The medicine now holds a market share of five percent or more in the majority of our key markets, demonstrating sustained quarter on quarter growth.

Apretude, the first and only approved long-acting option for HIV prevention, delivered 95% growth in the quarter.

At the ID Week conference earlier this month, we shared real-world evidence, reinforcing the more than 99% effectiveness for Apretude as well as an implementation study highlighting patient-reported results with a reduction in stigma and anxiety.

Looking further ahead, we are strongly focused on developing our ultra-long-acting pipeline. This includes development of new regimens for four monthly dosing, with ambitions to extend to six monthly dosing.

The potential for the long-acting market, remains significant, with the total HIV market today for treatment and PrEP together worth more than £22bn, with treatment accounting for around 90% of this and we believe treatment will continue to be the larger market going forward.

We are the leaders in long-acting innovation and are confident in our innovative pipeline for the future as well as the competitive profile of our medicines today, offering strong safety, efficacy and overall tolerability for people living with HIV and those who can benefit from PrEP.

With that, I will hand to Julie.

Performance | Julie Brown

Slide 17 | Q3 2024 performance and 2024 guidance

Thank you, Deborah and good afternoon, everyone.

Next slide, please.

Slide 18 | Specialty Medicines contributed >70% of YTD revenue growth

Building on the comments made by Luke and Deborah, this slide shows Specialty Medicines is an increasingly important growth driver for the group having delivered more than 70% of YTD growth. This has been supported by building scale and momentum in our respiratory, immunology and oncology businesses.

Although vaccines growth has been limited this year as Luke outlined, longer term we are very confident in this opportunity.

Next slide please

Slide 19 | Continued strong momentum in Q3 2024

Moving to the income statement for the third quarter, with growth rates stated at CER.

Sales increased 2%, reflecting continued strong momentum especially from Specialty Medicines, but also General Medicines, more than offsetting the decline in vaccines.

Core operating profit grew 5%, despite the significant decrease in Gardasil royalties.
Gross margin benefitted from the outperformance of high margin Specialty Medicines, pricing benefits and the annualization of prior year inventory provisions.

The decline in SG&A spend resulted from our disciplined approach to investment, the annualization of high prior year launch investments, and the phasing of spend across H2.
The Gardasil royalty loss impacted profit growth by -8% this quarter, meaning underlying operating profit was up 13%, demonstrating considerable productivity improvements this quarter.
Core EPS grew 5% (excluding COVID) in line with the operating profit growth.

Turning to the **Total results**, operating profit decreased materially year on year from £1.9bn last year to £0.2bn this year. The reduction predominantly reflected a £1.8bn charge relating to the resolution of the Zantac litigation.

Next slide, please.

Slide 20 | Q3 2024 core operating margin improved, despite royalty headwind

Moving to our margin bridge with commentary including COVID
Our Q3 **Core operating margin** increased 100bps YOY at CER to 35%, despite a 180bps headwind from the loss of royalties as we continued to deliver on our financial commitments and drive leverage within our business.

The strong underlying accretion was supported by three factors

(1) The outperformance of Specialty Medicines, where the portfolio has driven a positive mix impact in gross margin, and considerable opex leverage resulting from the strong sales growth
(2) The annualization of prior year inventory provisions in COGS and launch investments within SG&A and
(3) The phasing of SG&A spending with a greater weighting expected towards Q4 this year.

Next slide, please.

Slide 21 | 2024 YTD free cash flow of £1.9bn

YTD Cash generated from Operations was £5.3bn, representing an improvement of £0.9bn compared to last year.

This was primarily driven by improved operating profits and a working capital benefit compared to last year, benefiting from higher Arexvy collections earlier in the year.

Other CGFO was lower due to returns and rebates, partly offset by lower pension contributions

Free cash flow was £1.9bn, improving compared with £1.3bn last year, with improved CGFO partly offset by higher tax and higher BD including acquiring full rights to flu and COVID mRNA from Curevac.

Next slide, please.

Slide 22 | Capital deployment supports business growth and shareholder returns

Slide 22 shares our net debt position since 31 December and how we've actively deployed capital in the business in line with our framework.

Net debt in September was £13 billion, a reduction of £2bn compared to December 2023, given strong Free Cash generation and the Haleon monetisation.

Through the 9 months, we have deployed capital to strengthen the pipeline and platforms through BD, and as recently announced, we have expedited retiring the risk from Zantac. We expect this to result in a £0.8bn cash outflow in Q424, with the remaining £1bn being paid in the first half of 2025 and included in CGFO.

There is no change to our capital allocation priorities. We have a strong balance sheet, which provides optionality to accelerate future growth, organically and through Business Development, as we look to deploy funds to enhance growth and deliver attractive shareholder returns.

And now, with that, I'll now turn to our full-year expectations.

Next slide, please.

Slide 23 | 2024 Guidance confirmed (excluding COVID)[1]

For FY 2024, we confirm our guidance range of 7-9% sales growth and 11-13% profit growth and expect to land broadly around the middle of these ranges, notwithstanding the loss of Gardasil royalties, which will reduce profit growth by 6 percentage points this year.

Core EPS is expected to grow at 10-12 per cent, slightly below operating profit due to an increase in tax rate under OECD legislation.

The gross margin has been strong in the first 9 months of the year driven by mix and efficiencies. In Q4, we expect gross margin to be down YoY as we plan to make further investments to drive future supply chain efficiencies, with additional charges of around £100m. For the full year, we expect Gross Margin to be slightly ahead of 2023.

There is no change to our expectations for R&D to increase slightly below sales growth and for royalties to be around £600m in the full year. SG&A is expected to grow ahead of sales in Q4 due to the phasing of spend between quarters, investments into product launches, and the drive for efficiencies through increased digitisation. For the FY, we maintain our guidance of SG&A growth at a LSD %, given our focus on sharp resource allocation and improved productivity.

We will update you on our view of 2025 next year. But importantly, we remain very confident in achieving our group growth outlook for 2021-26 of >7% sales growth and >11% core profit growth albeit the shape of this could be more weighted to Specialty Medicines reflecting expected performance.

In summary, we have delivered another quarter of growth reflecting the breadth of our portfolio and the building momentum in Specialty. This, and our pipeline progress, mean we are very confident in achieving our full-year guidance as well as our medium and longer-term outlooks.

Next slide, please.

Slide 24 | IR Roadmap 2024 to 2025

Turning to our IR roadmap, significant progress has been made towards major milestones and value unlocks.

I have also highlighted here the 5 major regulatory approvals expected next year across 3 therapeutic areas.

We also look forward to our next Meet the Management event at the end of the year, which will be the first introduction to some of our early-stage pipeline.

And with that I'm pleased to hand back to Emma to conclude.

Summary | Emma Walmsley

Slide 25 | Focused on prevention and changing the course of disease

Thanks, Julie.

So, to summarise.

While Q3 has presented some challenges, our business has responded well, and we are on track to deliver our strong sales and profit guidance for 2024.

Looking ahead, we have a best in-class Vx business, an increasingly strong and growing Speciality business and a very profitable GenMed business. Together and combined with the momentum we continue to see in our pipeline and our careful - but meaningful - deployment of capital into BD. This means we are well positioned to deliver and sustain profitable growth through the decade, with scale health impact and attractive returns for shareholders.

All of this, by combining science, technology and the talent of GSK's people to get ahead of disease together.

With that, I will now open up the call for Q&A with the team.

Q&As

James Gordon (JP Morgan): One question is on the pneumococcal vaccine, so for Affinivax. I think you did have the 24 valent adult and I think that has been removed and you're switching to a 30 valent. What is the latest in terms of when this Affinivax product could come along, and is this connected to - Vaxcyte had some competitor data with a 31 valent. Is this for paediatrics and the adults that you are both shifting it? That is the first question please.

The second question would be 2025, I think there were a few comments on '25. If we are thinking about '25, should we be thinking that *Shingrix* and *Arexvy* might be down but also you could have some further significant SG&A leverage, you had a good performance on SG&A today, or might we need to think about you spending more on SG&A because you have new launches next year?

Emma Walmsley: Let's come, firstly, to Tony on the pneumococcal update. We are very much focused on getting to best-in-class vaccines as we have with our current portfolio. Then myself and Julie will come back on guidance questions.

Tony Wood: Thanks for the question, James. Let me start by underscoring the platform in general and I would say that, as we learn more about our platform, we become more and more confident in the fact that it presents a unique proposition, to Emma's comment about best-in-class. It does so because it provides both coverage of antigens, in particular serotype 3 because of the carrier protein proposition, and it does so without the diminishing immunogenicity that you see in the CRM-based platforms for which, as you add antigen coverage, immunogenicity diminishes. We have strong comparisons for our platform versus both the 20 and 13-valent PCV vaccines.

You are right, we have shifted our prioritisation in the adult vaccine towards a 30-plus proposition and, initially, you will recall of course that Vaxcyte are in a similar position. The Merck 21-valent vaccine which carefully chose serotypes established a vaccine efficacy ceiling against those chosen serotypes in the adult population that we believe makes the 30-plus proposition the most effective one. I think you see that reflected in the Pfizer strategy described yesterday as well. As I say, I remain confident in the properties of our platform based on the data that we are accruing and I expect to be able to start a 30-plus adult first-in-human study next year.

As far as the paediatric proposition is concerned, we remain developing both the 24 and 30-plus vaccines in that context, and I am confident about the competitive setting for both the 24 and 30-plus vaccines with regard to ultimate launch dates, although we have not disclosed those in detail.

Emma Walmsley: Thanks, Tony. In terms of looking into '25, obviously we are going to guide for '25 in '25 but I will ask Julie in a moment just to recap a little bit on some of the points we have made on the individual product areas to help you but also our confidence in the shape of the P&L too, because, make no mistake, we expect '25 to be another year of profitable growth for the company. We are very confident in our '26 outlooks and our '31 outlooks of more than 7% top line growth, more than 11% bottom line growth, more than £38 billion. Again, that doesn't yet include *Blenrep* where we have made great progress both on the data - we are looking forward to getting overall survival later on this year too - and we filed in multi regions this quarter.

As we look into '25 per the commentary, we expect the growth from our largest product area Specialty to continue to lead the way. We have, per Luke's comments, made assumptions to be conservative around any ACIP judgements and that there will be no change for next year - obviously, we are dependent on them - in terms of either revax or cohorts but we continue to bring data and we can comment more on that if you like. Make no mistake, medium-term whether it be in our confidence of growth both for *Shingrix*, ex-US, or for RSV, which is really in the very early days of its lifecycle, or because of the pipeline that's coming though per pneumococcal commentary or mRNA, or, very excitingly, all of that value unlock we are seeing across specialty medicines with five hopefully approvals that are not about just coming through in 2025, but driving more growth for that chapter beyond the end of decade. Julie, I think there are other specifics it's worth you recapping and particularly also those lines in the P&L where we are starting to drive some powerful leverage.

Julie Brown: Thank you very much and thank you for the question. I think Emma has articulated, and Luke earlier, the overall approach for vaccines. I would just like to draw attention to the Specialty Medicines business. It's now our biggest business, it's 37% of our business and it drove more than 70% of our growth year-to-date, and it's been one of the major contributors to the point you raised about the leverage, in leveraging the P&L, so we have just delivered year-to-date, 9% on the top line, 19% on the profit and that is absorbing the Gardasil loss as well.

There are a number of important therapeutic areas driving that. Obviously HIV, respiratory/immunology and oncology is mentioned. Our oncology business has more than doubled year to date to over £1 billion. So turning to 2025, we do see growth coming from *Nucala*, *Benlysta*. We obviously have COPD to come for *Nucala* having just been submitted and then we have the oncology strength coming from *Jemperli,* expanded population, and *Ojjaara* and then hopefully *Blenrep* following the recent submission.

In terms of the P&L leverage, as you can see year-to-date we have delivered very strong growth margin leverage, again this has been benefitted from specialty care and we continue to see the gross margin being

strong apart from this fourth quarter where we are going to put these additional charges through to drive future supply chain efficiencies.

Then in terms of the launches next year, as Emma mentioned we have five regulatory approvals and launches coming across Vaccines, Specialty and General Medicines, they are in our four key therapeutic areas where we already have a strong presence, be it respiratory, be it vaccines or be it also now in oncology so therefore you can expect us to continue to deliver profitable growth in 2025, as Emma clearly mentioned.

Kerry Holford (Berenberg): A couple of questions from me, please. Firstly in *Shingrix* in China, I wonder if you can comment there on the sales contribution and growth in Q3? And also just remind us the details of that contract with Zhifei in that market. Those numbers that you mentioned previously for Year 1 through to 3, are these set in stone or is there some degree of flex within that contract?

Then secondly on respiratory, specifically in COPD, when might we get to see the detailed Phase III *Nucala* data. Previously you said, that if you get a positive result here you would swiftly move depemokimab into Phase III, is that still your current thinking or now is the TSLP opportunity going to take a more important role in that space also? Many thanks.

Emma Walmsley: Thank you very much. I will come to Tony first on the IL-5 pipeline, which we are very excited about and then we'll come to Luke to comment on where we are at with China, remembering that there are a degree of macro pressures here, so obviously we have a great partnership there and we're trying to take a long term view on it. Luke, it would be good if you could update on where we are at and the view forward, but first Tony to you.

Tony Wood: Thanks for the question, Kerry. Let me just begin by reminding everyone that *Nucala* is the first and only biologic approved in four different EO-mediated diseases. What we showed with the MATINEE headline data, or we will show with the MATINEE headline and broader data is that it reduces exacerbations across the full spectrum of COPD patients. You get more detail on that, Kerry, in the first half of next year at an appropriate conference but, obviously, until we have had approvals of abstracts, I can't give you details on that. The important point to stress there that it is the broader performance of *Nucala* illustrated in MATINEE across the COPD population.

I might also take the opportunity just to remind everyone that what we said in the past is that in comparison with dupi, it is important to consider that the population studied in METREX, METREO and MATINEE are different to the dupi populations who are taking the broader COPD population including emphysemic patients. Of course, that is important when one considers that COPD is the third leading cause of death worldwide and 300 million people have COPD. A significant proportion of those, as high as 30% if I remember

correctly, are emphysemic. More from us on *Nucala* and the details of that at the beginning or in the middle of next year, as I indicated.

What I would highlight in terms of what follows from that with regard to the next wave portfolio plans, obviously it positions depe very favourably. What we know from asthma already, of course, is that it offers a significant advantage in two injections per year versus 26 in the comparison with dupi but I am also very pleased - and you will hear more about this in the Meet the Management - that we have long-acting options in both TSLP and IL-33. What we shall disclose to you there is how we think about positioning those three long-acting options into an emerging understanding of the subgroups of COPD disease.

Emma Walmsley: Thanks, Tony.

Luke Miels: Thanks, Kerry. On the Q2 call, I did flag that we were concerned about and would watch closely what is occurring in China, particularly in terms of tighter POB budgets and some of the flow of funding around those and, of course, the macro which is very broadly covered across many industries, so we are actually seeing that. A broader slowdown in the economy definitely impacts the market and just the capacity of local governments to then restock and purchase vaccines which are then subsequently purchased by individuals. These are having an effect on our volumes.

We are working closely with Zhifei. Again, if we look at the medium to long term, the partnership has started extremely well. These are impressive operators, they have got to a far number of points of vaccination than we could ever hope to get to with our infrastructure. You asked what we have sold: we have sold around 240 million out of the 0.4 that we had in the contract. There is flex in the contract, to call a spade a spade, so our intent is to be practical here and work through this with Zhifei, but we have our eyes on the long-term opportunity of about half a billion people in China who are 50-plus. That is where the focus is at this point.

Jo Walton (UBS): I am going to ask a broader question about IRA and the pressures that we might experience next year - some of the pushes and pulls here. We have already seen some companies show higher prescription growth as they go through the year and it is notable for *Benlysta* going up 6%, 9% and then 14%. Is any of that to do with people already experiencing lower copays; could that be a benefit to you going forward?

You have talked about pressures in the past for Respiratory. Where the authorised generics are and you have done so well, presumably payers are not getting the rebates that they want. Are you seeing more pressures for rebates elsewhere? You must be a long way through your negotiations for next year, so you should be able to tell us how your expectations are for access going forward?

A second question if I could, please. Could you just tell us a little bit about RSV ex-US: is that really not an opportunity at all until the dosing has been sorted out? Thank you.

Emma Walmsley: Thanks. Luke, let's come to you and we did flag 400-500 of IRA and then RSV ex-US.

Luke Miels: There is increased pressure there. I think PBMs will go looking for offsetting that amount. We are starting to see tactical decisions by physicians in terms of trying to push people through their coverage and I think that is across the whole portfolio. Specifically for us with 340B, we have about nine states that have legislation, there's another 10 which are working on it, so that impacts Speciality. There's also some impact on Vaccines of course, but they tend to benefit in aggregate because of the removal of the copay.

The other thing the fact that particularly with *Trelegy* – well, it is a *Trelegy*-driven element which is this $35 co-pay which will have an effect next year, and then longer term with Trelegy we expect it to be listed next year. I think the government has learnt through the first round, particularly around the influence and dynamics of the coverage gap, so we expect more pressure on pricing and that will flow through with *Trelegy* in 2026 and 2027 but we think we can start to return to growth after that with *Trelegy*, and of course ex-US it continues to do well.

The areas where we tend to see pressure with 340B are with products like *Zejula* and *Nucala*. Specifically on *Nucala* I think it's more driven by, we are starting to pivot and to look at nasal polyps. It's been very successful in Europe, we have been a little bit slower in the US to pivot to that and now we are really aggressively looking at that and seeing very good feedback. The ENTs are certainly willing to experiment with this molecule. We tested it in markets like Italy and saw a fantastic surge in *Nucala* so that's what we are now ramping up in all the key markets globally with *Nucala*.

Emma Walmsley: And RSV ex-US?

Luke Miels: I think now we know enough about this vaccine that we need to move forwards. The feedback we're getting is very encouraging. STIKO just did a broad vaccine contract in Germany at about €180, both us and the others guys, so that's encouraging, we should see good adoption there. And then the rest of the world, the basic elements of RSV, the morbidity, the mortality, these are very apparent. I think one thing we are watching is just different geographies emphasising older adults; other ones, more focused on maternal. So for example, PAHO in Latin America is more focused on maternal as is Australia, whereas the European marketsare more focused on older adults, including Japan. So early days, but I think we have a pretty good idea of the pricing point.

As I said earlier, we needed to sit out the UK tender. Canada was very, very price intensive so our whole strategy, as I said in Q2, is we want to play the longer term game. We have the best-in-class vaccine, we have

accumulated a very clear picture on the benefit, risk and the potency and the duration of effect, so now we are moving to contract.

Emma Walmsley: Thanks Luke. As you can see in our reported sales, international RSV sales are still a very small fraction, and in fact in the US there is still 80% of those that ACIP have said this vaccine is available to, not yet vaccinated. Obviously for the reasons Luke went through, it's a tougher year this year but fundamentally the benefit of this vaccine, all the data that surrounds it, the fact re-vaccination will come when you look at the waning that comes through by Year 3 - it's for ACIP to decide when - all of that means, when you look at where *Shingrix* is with nearly 60% of the business coming internationally, there is plenty of room for penetration of this high performing vaccine over time.

Simon Baker (Redburn): Thank you for the call. Two questions, if I may, please. Firstly on depemokimab, could you remind us what assumptions in terms of severity of asthma are assumed within the peak sales number? How far down the continuum of severity do you expect to go to get that number? Then secondly, a question on RSV, which maybe a slightly naïve one but if we have autumnal congestion in pharmacies and we have a vaccine that have multi-year efficacy, what is the feasibility of shifting the time of vaccination from the autumn to earlier in the year, to at least mitigate that issue that you have run into at the moment. Thanks so much.

Emma Walmsley: Thanks, so Luke to you on 'de-seasonalising' if that's a word. By the way I think when we get to combo vaccines, which obviously GSK wants to compete in that will also help in terms of share of arms space, but Luke, perhaps you can comment on that and then, Tony, we will come to you in terms of a profile of asthmatics with depe.

Luke Miels: Simon, I think you have hit the nail on the head there. It's tough right now with *Arexvy* and the class for the reasons we know, primarily because of the direction that ACIP have given in terms of narrowing the class on the basis of benefit and risk, but again, we think this will adjust over time for reasons that I'll go through in a minute.

Tony and I were texting each other as we watched the FDA presentation at ACIP and the benefit/risk, which I think was slide 10, that said for every million people that you vaccinate over a three-year period in the existing 75-plus, 60-74 at risk, it is about 2,000 fewer deaths, 15,000 fewer hospitalisations. The trade-off is 0 to 18 or about nine GBS cases. I think that will start to assert itself over time.

When we look at co-administration with RSV even just recently, it is really quite striking. In August, *Arexvy* 56% of the time was given with another vaccine, that jumped to 71% in September. What is remarkable, if you

look at what it was given with, in August it was flu 24% of the time, in September that was 12%. It was 3% with COVID in August and that jumped to 10% in September '24.

What is really interesting is the triple COVID/flu combination, that went from 5% of *Arexvy* shots in August to 27% in September. What that tells me is that there is an opportunity as we did with *Shingrix* - and we have more to do with *Shingrix* - to de-seasonalise this vaccine because of this longer window, which, again, is what pharmacists tell us they want in terms of managing their workflow, staffing levels, etc. I think we will get there in the mid to long term with this vaccine.

In terms of depemokimab, I don't think we have given the peak penetration rates but, if you look at biological penetration, it is still disappointingly low. It is about a third or just under a third of people who are actually eligible for a biologic. It is not an access issue, it is essentially about pulmonologists and allergists as well being willing to prescribe biologics in those patient groups.

What is attractive about depemokimab when we do our market research is that, first, you have this Part B dimension, a buy-and-bill component, which is not as prominent with *Nucala*. Then when you look at market research, the recent market research we have is that 80% of HCPs are extremely interested in that six-month profile, and about 58% say they will use it in naïve patients, and about two-thirds say they will consider switching.

Then when we look at patients, about 60% say six months is a lot more attractive and just under 90% would actually consider it if their doctor recommended it, so that translates to about a 20% jump in our models anyway based on market research. That is not real, you have to go and do it, but about a 20% uplift in biologic use because of that efficacy/frequency trade-off, so let's see.

The other thing is that, with the exception of COPD, we have all the life-cycle coming within two years of the initial approval, which is very different from *Nucala* which was around six years.

Emma Walmsley: Tony, I don't know if you have anything to add to that?

Tony Wood: The way to think about it is on the SWIFT-1 and SWIFT-2 studies which, of course, were designed to look at reduction of exacerbations on top of standard of care. The primary endpoint across both of those was netted at a 54% reduction. That is what we should have expected. Remember, we were matching exposure relative to *Nucala*, but just a few titbits to dig into the details a little further to emphasise the quality of depemokimab in terms of administration frequency, to build on Luke's point.

What we also see, for example, in the pre-specified analysis in secondaries through exacerbations requiring hospitalisation or an ER visit, is a 72% reduction. If you look across both SWIFT-1 and SWIFT-2, it is important to realise that in those studies 68% of the patients on depe experienced no exacerbations at all.

Emma Walmsley: I think this demonstration of capability from GSK on the value to patients and healthcare professionals of a long-acting medicine, as we see in our HIV business, to keep people out of hospital and improve compliance, as well as just being more user-friendly, is a very exciting field for us to continue to pursue and will contribute meaningful growth.

Graham Parry (Bank of America): Thank you for taking my questions. Just on *Arexvy*, looking into 2025, with no booster, I am just wondering what sort of cadence you would expect on first dose penetration? Should we be thinking increases like the 6%-10% we saw with *Shingrix* into the addressable populations assuming their expansion of that, and would that therefore lead to a drop in the US next year? Then the extent to which you think international can offset this if you are going to start going full launch into international territories which I assume, but if you could confirm, would be based on pricing for at least three seasons duration given you have that data now?

Then secondly on *Shingrix*, could you just help us to understand what level of inventories Zhifei are holding now and whether you expect to sell any more into Zhifei inventory in 2024, or is the £400 million essentially any more contractible, you are not going to be achieved, and then your confidence in achieving the £800 million and £1.2 billion going forwards. Thank you.

Emma Walmsley: Thanks, Graham. I will just repeat what we've said on China, and Luke said, in terms of the contracts that we have that are commitments to take a long term view of a very ambitious partnership here, and then, Luke, perhaps you can comment more on *Arexvy* in terms of ambitions ahead. We are still in the early foothills both of international and frankly US penetration and don't forget, Graham, this is an unusually slow season. I am not sure we are going to be forecasting that as a long term standard projection considering if you look at the last 15 years, but, Luke, do you want to comment on penetration?

Luke Miels: Yes. I think Graham the unpredictable component here is what ACIP does. They remain cautious, I won't re-quote the FDA figures but I think that they are important. The question is what happens with the rest of this year's season. Typically November is the classic RSV peak, that has changed since COVID, but I think that's informative. Also can ACIP get comfortable about the benefit/risk here as they get more data from this season and look at the overall benefit/risk?

Now, if you look at the penetration rates by group, in December 2023, 75-plus was 17% as of August, which is our most recent data. That is up 21%, so you have the effects of the June ACIP there in that 29 million people population, and if you look at the 60-74 that is definitely slowing, that was 10% at the end of last year and it's about 14% in August 2023, so that is the population to watch.

We were pretty clear in Q2 that that was not good news in terms of what ACIP had said around that population. There were other views on that, but we felt that would retard the uptake and I think the evidence is there. The other swing factor is the 50-59 and the 18-plus population so I think it's quite difficult to forecast 2025 with *Arexvy* because of that component. I feel a lot more confident about the mid to long term because of all the elements we have covered, but I think 2025 is going to be challenging until ACIP normalise. There is a clear signal sent there and I think HCPs have heard it, and let's hope over time that evidence in terms of benefit/risk is seen for what it is and uptake starts to recover. Tony, I don't know if you want to add anything else?

Tony Wood: No, just to build on that and perhaps unpack some of the headline conclusions from ACIP conversations. Let me start where you finished, Luke. What they concluded in the approved and recommended population is that the benefit/risk is proven and clear. I think it was actually a commentary that the confidence interval and so on, didn't overlap in assessing benefit versus risk. The FDA themselves conclude that the GBS signal, although becoming statistically significant, is rare, less than 10 cases in a million, and so that population I think continues to be clearly justified, and as I mentioned earlier, one in which there are a still a need to see an opportunity for further penetration to protect individuals. There is an opportunity to see expansion of the label into the originally indicated 60-plus population, we have data in the 50-59 population and in the 18-plus population, and the position on revaccination will become clearer as well.

Emma Walmsley: Just to reiterate in terms of what is behind your question, we have taken a conservative view on our 2025 outlook for Vaccines overall, i.e. no revax, no expansion of cohorts. Obviously, that will be in the hands of ACIP and we will continue to share data. We remain very confident in the medium and long-term contribution of Vaccines. The performance of our bigger business, Specialty, as evidenced this year in our delivery, will continue to lead strong, profitable growth in 2025 and underpins high confidence, alongside the five approvals we are expecting and hoping to get by the end of the year, in all of the long-term outlooks we committed to and increased at the beginning of this year. So a short-term challenge to digest but, fundamentally, the strength of the portfolio that we have been building, alongside the progress in the pipeline - always more to do - means that we see both Specialty and our Vaccines business continuing to drive a transformation in the shape of GSK and in its performance.

Emmanuel Papadakis (Deutsche Bank): Thank you. I am sorry, I am going to ask another question on *Arexvy*.

Emma Walmsley: That's fine!

Emmanuel Papadakis: How are you going to get to three billion people? Even with a modest degree of belated revaccination in the US, it doesn't seem like a return to blockbuster territory in the USA. Is this

really a statement about international potential or are we missing something on the US: what are the assumptions that lead you to think we can get to three billion?

Then I have a question on *Blenrep* which may be a more favourable topic. Just talk to us about the timelines in the US for you anticipating priority review either out of the FDA's generosity, or use of a voucher. Can you comment on the relaunch expectations commercially for next year? We have a relatively modest set of consensus expectations, so we would love to hear about what you think of those.

Emma Walmsley: Luke, I think you can pick up on both of these but I am just going to reiterate very briefly that there are 64 million people who suffer from RSV on a seasonal basis. More than 15,000 people die every year in America. This is a brand new vaccine with a cautious ACIP, we are in their hands in terms of how and when they come back on revaccination, which we are very confident there will be considering the waning to below 50% in season three over time, and expansion in cohorts and the penetration because, as Luke said, there isn't really a good reason to expect this to be very different from flu over time and we are still in the early days of that, and international expansion.

Luke, I don't know if there is anything else you would like to repeat on that one but we are being cautious in the near term; we are not banking that near term. Luke, I don't know if you want to add anything and then, obviously, very ambitious for *Blenrep*.

Luke Miels: I think we have said it all, I don't think there is anything new. One thing that is important is this focus on the peak sales, but the difference between a multi-year vaccine and an annual vaccine is that the volatility is much higher. What we need to concentrate on is the area under the curve which has changed.

In terms of *Blenrep*, the market research, the expert feedback that we have: there is an increasing respect for the profile of the product and there is a broader understanding of some of the challenges of employing bispecifics, particularly around infection risk: concomitant infusions, admission, CRS, neurotox, etc. andthe DREAMM-7 and DREAMM-8 studies have been well received.

I think the critical thing here is really supporting physicians on those first five patients around the infusion strategy, dose holds and educating them to reassure the patient that efficacy is not sacrificed if they do have to hold dose. This trade-off, again, just being realistic about the keratopathy and those elements and actual impact on the patient, the flexibility around the dosing, we know a lot more about this product now, and the opening opportunity in second-line with the progression of CD38s into the first-line. You add of those things up, plus we have gained a huge amount of experience clinically and also commercially as well as an organisation over the years, I think the DREAMM-7, the DREAMM-8 designs are evidence of that, as is the launch of momelotinib. We are humble about it, we are careful, we are working with the experts, but I think we are increasingly well-placed

to do this product justice subject to the FDA approving it, and I think also at the end of the year if we are able to achieve survival as well, that will obviously support the product in that second-line setting.

Richard Parkes (Exane BNP Paribas): Thanks for taking my questions. First, I would like to push a little bit on the confidence in the *Arexvy* in the re-vaccination market, because you seem very confident about that but it looks like the decline in vaccine efficacy has somewhat stabilised in the third year, and it sounds like ACIP wasn't fully convinced by your re-vaccination immunogenicity data. Can you just underline why you are so confident about that and maybe what impact that would have one your peak sales assumption if that didn't materialise?

Secondly on *Apretude*, that launch looks like it's lost a little bit of a momentum, could you just discuss what drives it from here and what the current PrEP market penetration is and how your thinking has evolved over contribution of PrEP to your long-acting sales target. Thank you very much.

Emma Walmsley: So Tony on re-vaccination, and then Deborah, please.

Tony Wood: So just quickly on re-vaccination, as you see the data particularly in the lower respiratory tract disease population show that there is a decline from season one to season three of 83% in season one and to I think 48% in season three. Importantly and to answer your question with regards to trajectory, Richard, we also know that natural infection does not cause life-time immunity for these mucosal infections, you don't see that, and so we think the available evidence and data would suggest that re-vaccination will be required and it will be between three and five years. Additionally, I will take the opportunity to stress what we also see through that, and you'll see more data from us next year on boosting, but there is a clear trend that, again is commonly the case in vaccines, that the time from prime to boost extends the significance of the boost increases.

Deborah Waterhouse: Thank you, Richard. Just to start by saying we are absolutely delighted by our performance in the quarter with the HIV franchise, 12% growth and we have been double-digit growth each quarter throughout the year so far, so really happy with the way our trajectory, particularly on our long-acting injectables, is progressing, but obviously our oral two-drug regimens are also doing extremely well.

Let's focus just on *Apretude*. I think it's worth remembering that the £22 billion plus market value in HIV is about £20 billion for treatment and $2 billion for PrEP so you normally expect big numbers in HIV because we are usually operating the treatment space, but actually you have to remember that this is a £2 billion market which is growing relatively rapidly between 10% and 15% at the moment in the US. The growth is strong, the market is robust and *Apretude* is doing well so we are seeing share continue to grow. We saw 95% growth in the quarter and actually it's in line with our expectations.

We are building a market here so we are ensuring that physicians understand the safety, efficacy, tolerability of this exceptional prevention medicine, but at the same time we are having to teach physicians as

we develop the market around how to navigate specialty pharmacy, buy and bill, and the other kind of barriers that you find with injectables in the US healthcare market. We are investing very strongly and we are seeing really good breadth of prescribing increases, not just in *Apretude* but with *Cabenuva* as well.

My summary would be that there is still a long way to go in this market, both PrEP and treatment. Long-acting injectables are really growing rapidly, are gaining share and are driving our growth in a very positive way which is why we have been able to deliver three-quarters of double-digit growth this year. Obviously we had a very strong performance driven by the same things in 2022 and 2023 as well, so real confidence in our long-acting injectables both this year and actually for next year as well.

Emma Walmsley: And the pipeline coming forward.

Deborah Waterhouse: And the pipeline coming forward. We have Q4M PrEP and treatment coming up and then we have our every six months which is progressing absolutely in line with our expectations and we will obviously come to talk more about that as data emerge.

Peter Welford (Jefferies & Co): Sorry, if we can go back to *Arexvy*, I'm afraid. Can we talk for a minute about the ACIP decision as I am trying to understand here on the safety side of things? It seems like a bit of a difficult situation in that the population to be able to making a better characterisation of the GBS risk is relatively low given the low number of vaccinations. Obviously, the FDA already have the data with regard to the risk side of the equation, i.e. the number of deaths and hospitalisations for the 60-74. It seems the only likely conclusion, potentially, is that there is a significant GBS risk eventually for that population too. I am curious as to how you think more data for that population will potentially make a difference and what you can provide incrementally to that to sway them on that population?

Emma Walmsley: We will finish up with Tony's response on that but just to reiterate our confidence, as has been said by all of the team, in the benefit/risk ratio of this vaccine considering the burden of disease, hospitalisation and death at a global scale.

Tony Wood: For me, the headline, as I said, for ACIP was, first of all, the clear conclusion that the benefit/risk for vaccination in the currently approved and recommended population was substantiated and it was substantiated by increasingly clear data on both the benefit and the risk associated with that population. Again, let me stress that the FDA conclusion of GBS was rare, less than 10 cases per million individuals vaccinated.

In the broader cases, what you will see is us bringing additional data related to vaccine effectiveness for the 60-plus population and immunogenicity in the 18-plus immuno-compromised populations, particularly in those who constitute the populations who are at greater risk of hospitalisation.

Emma Walmsley: Thanks and isn't it also right to say, Tony, that if you account for frequency of vaccination, there is no difference here versus -

Tony Wood: There is a comparison made on IRRs for flu, for example, and if you account for the frequency of vaccination and the fact that flu itself causes GBS, there is no significant difference in risk across those vaccinated.

Emma Walmsley: Thank you very much.

Thanks everyone for joining the call. As you heard, we are delighted to be reconfirming our guidance for the year - another year of strong operating performance - and also our confidence in the outlooks for '26 and '31. I look forward to catching up with you over the coming days. Thank you.

[*Ends*]