GSK plc

GSK plc - Q3 2024 Earnings Call

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Event Participants

Executives 6
Jeff McLaughlin, Emma Walmsley, Luke Miels, Deborah Waterhouse, Julie Brown, Tony Wood

Analysts 8
James Gordon, Kerry Holford, Jo Walton, Simon Baker, Graham Parry, Emmanuel Papadakis, Richard Parkes, Peter Welford

Jeff McLaughlin Executive

Hello, everyone. Welcome to today's call and webcast. The Q3 presentation was sent to our distribution list by e-mail and you can also find it on gsk.com.

Please turn to Slide 2. This is the usual safe harbor statement. We will comment on our performance using constant exchange rates, or CER, unless stated otherwise.

Please turn to Slide 3. Today's call will last approximately 1 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. [Operator Instructions] Turning to Slide 4. I will now hand the call to Emma.

Emma Walmsley Executive

Welcome to everybody joining us today.

Please turn to the next slide. I'm pleased to report that despite some challenges, this has been a positive quarter for GSK and we're delivering 9% sales growth and 19% profit growth year-to-date. 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 outlook for 2026 and beyond.

Importantly, we've made considerable progress in our pipeline this quarter. And with no admitted fault or failure, I'm delighted that we've 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 Specialty

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 U.S. 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 Vaccines sales were down due to lower sales of Arexvy and Shingrix. Recent guideline changes and prioritization of COVID vaccines in the U.S. 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 2 best-in-class vaccines offer to protect people from disease and to take pressure off health care systems remain.

And with appropriate recommendations from public health authorities, we fully expect them and our Vaccines pipeline to deliver significant future sales growth for 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're reporting further improvements in cash flow with cash generated from operations of GBP 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. Pipeline progress was strongly evident in the quarter with a series of findings and data readouts supporting future product momentum. So far this year, we've had 11 positive Phase III readouts, and we're 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 center 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 U.S.

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 breakthrough regulatory designations, recognizing 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 2 promising ADCs we have in clinical development and part of the next wave portfolio now emerging in R&D, which Tony is going to update you on at our next Meet the Management event in December.

Next slide, please. Building trust by delivering sustainable health impact remains a clear priority for all of us at GSK. We continue to make progress across our 6 key areas, and I'd particularly like to recognize our HIV business for its commitment to make at least 2 million doses of cabotegravir long-acting for prevention available in low- and middle-income countries during '25 and '26. This further commitment builds on long-standing action to deliver sustainable access and triple supply compared to 2024.

Please turn to the next slide. GSK is delivering consistent financial performance. Looking to the end of this year and beyond, we're even more confident that the progress we're making in portfolio development and in R&D support the delivery of our growth outlooks. For 2024, we continue to anticipate sales growth of 7% to 9% with double-digit profit growth. We also remain very confident in our outlooks for '26 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'll continue to pursue bolt-on business development to further enhance our pipeline and our technology platforms with a focus on our core therapeutic areas.

And so with that, I'll now hand over to Luke and Deborah to talk you through our commercial performance.

Luke Miels Executive

Thanks, Emma. Please turn to the next slide. Third quarter sales were up 2% to GBP 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 Gen Meds, offsetting the lower sales of Vaccines.

Specialty Medicines, the largest part of our business, grew 19%, reflecting strong performance of new products and the investment we've 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, I'm pleased to say sales were up 7% driven by strong performance of Respiratory.

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

All of these dynamics were broadly reflected in the performance of our regions with good growth internationally, and the U.S. 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. So I'll focus the commentary on Arexvy and Shingrix. Arexvy performance was impacted by 3 factors. Firstly, by changes in ACIP guidelines that restricted the recommended populations of older adults receiving RSV vaccinations. Secondly, by prioritization of COVID vaccinations in the U.S.

And thirdly, by a lower seasonal rate of RSV infections. In addition, it was a tough comparator given 2/3 of sales in Q3 last year were related to stocking.

Despite these dynamics, we retained our strong leadership market share.

Now we're still in the foothills of this vaccine's availability and usage. And in the U.S., 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 U.S., Arexvy has now launched in 35 markets, 16 with national recommendations and 6 with national reimbursement programs. More rollouts across Europe and international will come in 2025.

For Shingrix, year-to-date growth was driven outside the U.S., now 58% of the business. And the average immunization rate across the top 10 markets, excluding the U.S., is still around 6%. So there's still a large opportunity here.

Growth outside the U.S. was 9% this quarter, and U.S. penetration was 39% at the end of the second quarter. Adding to U.S. penetration remains a key focus, but the pace is slowing from around 6 to 7 points per year to around 3 to 5 points per year, making incremental growth more challenging.

And if you take a look, the visual on this slide also shows how U.S. sales moderate as the immunization rate slows.

Next slide, please. So looking ahead on Vaccines, this year we now expect Vaccine sales to decline low to single digits. And in 2025, we expect limited growth, reflecting the assumption that there will be no Arexvy revaccination or expansion of our 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 sales of more than GBP 3 billion.

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

And finally, beyond Arexvy and Shingrix, we also have material growth opportunities with mRNA and our MAPS technology, where we've decided to prioritize a 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 MenABCWY vaccine in 2025.

Next slide, please. Specialty Meds is an increasingly important driver of our growth for GSK, reflecting the combination of successful R&D and BD investment over the recent years. And it's delivered another quarter of excellent growth, including HIV, which Deborah will cover shortly.

Respiratory and Immunology products were up 14% and Nucala IL-5 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. And the full results will be presented at a scientific congress next year.

We also presented SWIFT Phase III data for our ultra long-acting IL-5 treatment, depemokimab, in the quarter. And depemokimab demonstrated a 54% reduction in exacerbations versus placebo plus standard of care for patients with severe asthma after only 2 injections in a 12-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. And to remind you, combined, we expect our IL-5 portfolio to deliver more than GBP 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'll 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. And for this year, we're upgrading sales expectations for Specialty Medicines to high-teens percentage growth.

Next slide, please. Focusing on Oncology, sales almost doubled in the quarter and we've delivered more than GBP 1 billion in turnover so far this year. Our focus on hematology and gynecologic cancers is delivering strong progress evidenced by the success of new product launches in these areas.

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

Jemperli sales also continued to grow strongly. And in August, the U.S. 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% to 75% of patients diagnosed with endometrial cancer who have mismatch-repair proficient microsatellite stable tumors. And 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 U.S. pricing effects and higher demand outside the U.S.

And looking ahead, we have a significant opportunity to strengthen our Oncology business with the launch of Blenrep in half 2 2025. We filed for approval in the U.S., EMA and Japan in the quarter.

Next slide, please. General Medicines grew 7% in Q3, primarily driven by Trelegy. And Trelegy sales increased 16% to GBP 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 authorized generic versions of Advair and Flovent are continuing to fully offset the removal of the AMP cap on Medicaid drug prices in the U.S.

And given our stronger performance this year, we now expect a mid-single-digit percent sales growth for General Medicines this year.

Looking forward, for the total business, the U.S. is expected to face pressure from the implementation of the U.S. Inflation Reduction Act legislation in 2025. And we expect the overall impact of this range to be around GBP 400 million to GBP 500 million, including HIV.

I'll now hand over to Deborah.

Deborah Waterhouse Executive

Thank you, Luke. Now turning to HIV. We continued 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 favorable pricing dynamics.

For 2025, we do not expect the favorable pricing dynamics to continue in part due to the introduction of the Inflation Reduction Act. However, we are confident that the underlying demand for our medicines will remain strong.

As leaders in oral 2-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 randomized clinical trial of Dovato compared against the 3-drug regimen, Biktarvy. This study demonstrates Dovato's noninferior 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 positive, delivering GBP 314 million 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 5% 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 the 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 4-monthly dosing with ambitions to extend to 6-monthly dosing.

The potential for the long-acting market remains significant. The total HIV market today for treatment and PrEP together is worth more than GBP 22 billion 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 could benefit from PrEP.

With that, I will hand to Julie.

Julie Brown Executive

Thank you, Deborah, and good morning, everyone. Next slide, please. 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 year-to-date growth. This is being supported by building scale and momentum in our Respiratory, Immunology and Oncology businesses. And although Vaccine growth has been limited this year, as Luke outlined, longer term we are very confident in this opportunity.

Next slide, please. 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 benefited 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 half 2.

The Gardasil royalty loss impacted profit growth by minus 8% this quarter, meaning underlying operating profit was up 13%, demonstrating considerable productivity improvements in Q3.

Core EPS grew 5%, excluding COVID, in line with the operating profit growth.

And turning to the total results. Operating profit decreased materially year-on-year from GBP 1.9 billion last year to GBP 0.2 billion this year. The reduction predominantly reflected a GBP 1.8 billion charge relating to the resolution of the Zantac litigation.

Next slide, please. Moving to our margin bridge with commentary including COVID. Our Q3 core operating margin increased 100 basis points year-on-year at CER to 35% despite a 180 basis point headwind from the loss of royalties as we continued to deliver on our financial commitments and drive leverage within the business.

The strong underlying accretion was supported by 3 factors. First, the outperformance of Specialty Medicines where the portfolio has driven a positive mix impact in gross margin and considerable operating leverage resulting from the strong sales growth. Secondly, the annualization of prior year inventory provisions and cost of goods and launch investments within SG&A. And third, the phasing of SG&A spending with a greater weighting expected towards Q4 this year.

Next slide, please. Year-to-date, cash generated from operations was GBP 5.3 billion, representing an improvement of GBP 0.9 billion compared with last year. And this was primarily driven by improved operating profits and a working capital benefit compared with last year benefiting from higher Arexvy collections earlier in the year, although CGFO was lower due to returns and rebates partly offset by lower pension contributions.

Free cash flow was GBP 1.9 billion, improving compared with the GBP 1.3 billion last year with improved CGFO, partly offset by higher tax and higher business development including acquiring full rights to flu and COVID mRNA from CureVac.

Next slide, please. Slide 22 shows our net debt position since the 31st of December and how we've actively deployed capital in the business in line with our framework. Net debt in September was GBP 13 billion, a reduction of GBP 2 billion compared with December '23, given the strong free cash generation and the Haleon monetization. Through the 9 months, we have deployed capital to strengthen the pipeline and platforms through business development. And as recently announced, we have expedited retiring the risk from Zantac.

We expect this to result in a GBP 0.8 billion cash outflow in Q4 '24 with the remaining GBP 1 billion 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 further growth organically and through business development as we look to deploy funds to enhance growth and deliver attractive shareholder returns.

And with that, I will now turn to our full year expectations. Next slide, please. For full year 2024, we confirm our guidance range of 7% to 9% sales growth and 11% to 13% profit growth and expect to land broadly around the middle of these ranges, notwithstanding the loss of Gardasil royalties, which we expect to reduce profit growth by 6 percentage points this year.

Core earnings per share is expected to grow at 10% to 12% and slightly below operating profit due to an increase in the tax rate under the 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 year-on-year as we plan to make further investments to drive future supply chain efficiencies with additional charges of

around GBP 100 million.

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 GBP 600 million for the full year.

SG&A is expected to grow ahead of sales in Q4 due to the phasing of spend between the quarters, investments in new launches and the drive efficiencies through increased digitization.

For the full year, we maintain our guidance of SG&A growth at a low single-digit centage 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 '21 to '26 of more than 7% sales growth and more than 11% core operating 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. Turning to our IR road map. Significant progress has been made towards major milestones and value unlocks. I've 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 am pleased to hand back to Emma to conclude.

Emma Walmsley Executive

Thanks, Julie. So to summarize, 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 Vaccine business, an increasingly strong and growing Specialty Business and a very profitable Gen Meds business. Together and combined with the momentum we continue to see in our pipeline and our careful but meaningful deployment of capital into business development, this means we're 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, let's now open up the call for Q&A with the team.

Jeff McLaughlin Executive

Okay. Thank you. [Operator Instructions] For our first question, we will go to James Gordon.

James Gordon Analyst

James Gordon. One question was on the pneumococcal vaccine, so for Affinivax. So I think you did have the 24-valent adult and then I think that's been removed and you're switching to 30-valent. So just what is the latest in terms of waiting for this Affinivax product to come along? And is this connected to -- I think Vaxcyte had some competitor data with the 31-valent.

Is this for the pediatrics and the adults that you're both shifting into? That's the first question, please.

The second question would be a few comments on '25. If we're thinking about '25, should we think that maybe Shingrix and Arexvy might be down, but also you could have some further -- significant SG&A leverage because you had a good performance on SG&A today? Or might -- we need to think about you're spending more on SG&A because you've got new launches next year?

Emma Walmsley Executive

Great. Well, let's come firstly to Tony on the pneumococcal update, very much focused on getting to best-in-class vaccines as we have with our current portfolio. And then myself and Julie will come back on guidance questions.

Tony Wood Executive

Yes. So thanks for the question, James. Let me just start by sort of 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. And 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 30-valent PCV vaccines.

You're right, we have shifted our prioritization in the adult vaccine towards a 30-plus proposition and that is 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 so 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're accruing, and I expect to be able to start a 30-plus adult first-in-human study next year.

As far as the pediatric proposition is concerned, we remain developing both 24- and 30-plus vaccines in that context, and we're confident about the competitive setting for both the 24- and 30-plus vaccines with regards to ultimate launch date, although we've not disclosed those in detail.

Emma Walmsley Executive

Thanks, Tony. so in terms of looking into '25, I mean, obviously, we're going to guide for '25 in '25. But I'll ask Julie in a moment just to recap a little bit on some of the points we've 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. And 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 GBP 38 billion. And again, that doesn't yet include Blenrep, where we've made great progress both on the data, we're looking forward to getting overall survival later on this year, too, and we filed in multi-regions this quarter.

As we look into 2025, per the commentary, we expect the growth from our largest product area, Specialty, to continue to lead the way. And we have, per Luke's comments, made assumptions to be conservative around any ACIP judgment and that there will be no change for next year. Obviously, we're dependent on them. But in terms of either revax or cohort, we continue to bring data. We can comment more on that if you like.

But make no mistake, medium term, whether it be in our confidence of growth both for Shingrix ex U.S. or for RSV, which is really in the very early days of its life cycle or because of the pipeline that's coming through per pneumococcal commentary or mRNA, or very excitingly, all of that value unlock we're seeing across Specialty Medicines with 5 hopefully approvals that are not about just coming through in '25, but driving more growth for that chapter beyond in the decade.

So Julie, I think there are other specifics that's worth recapping and particularly also those lines in the P&L where we're starting to drive some powerful leverage.

Julie Brown Executive

Yes, sure. Thank you very much. Thanks for the question. So I think Emma's 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've just delivered year-to-date 9% on the top line, 19% on the profit and that is absorbing the Gardasil loss as well.

And there are a number of important therapeutic areas driving that. Obviously, HIV, Respiratory/Immunology and Oncology, as mentioned. Our Oncology business has more than doubled year-to-date to over GBP 1 billion.

So turning to 2025, we do see growth coming from Nucala, Benlysta. We've obviously got COPD to come for Nucala having just been submitted. And then we've got 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've delivered very strong gross

margin leverage. Again, this has been benefited from Specialty Care and we continue to see the gross margin being strong apart from this fourth quarter where we're going to put these additional charges through to drive future supply chain efficiencies.

And then in terms of the launches next year, as Emma mentioned, we've got 5 regulatory approvals and launches coming across Vaccines, Specialty and General Medicines. They are in our 4 key therapeutic areas where we've already got a strong presence, be it Respiratory, be it Vaccines, albeit also now in Oncology. So therefore, you can expect us to continue to deliver profitable growth in 2025, as Emma clearly mentioned.

Jeff McLaughlin Executive

The next question is going to be from Kerry Holford.

Kerry Holford Analyst

Yes. Kerry Holford from 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.

And there, those numbers that you've mentioned previously for year 1, through to 3, are they 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? And previously, you had noted 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?

Emma Walmsley Executive

Thanks very much. We'll 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're at with China, remembering that there are a degree of macro pressures here. So obviously, we've got a great partnership there and we're trying to take a long-term view on it.

But Luke, it would be good if you could update on where we're at, at the [indiscernible]. But first, Tony, to you.

Tony Wood Executive

Yes. Thanks for the question, Kerry. Let me just begin by reminding everyone that Nucala is the first and only biologic approved in 4 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'll get more detail on that, Kerry, in the first half of next year at an appropriate conference. Obviously, until we've had approvals of the abstract, I can't give you details on that. But the important point to stress there is 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's important to consider that the population studied in METREX, METREO and MATINEE are different to the dupi populations. We are taking the broader COPD population, including emphysemic patients. And of course, that's important when one considers that COPD is the third leading cause of death worldwide and 300 million people have COPD, and a significant proportion of those, high 30%, if I remember correctly, are emphysemic. So more from us on Nucala and the details of that at the beginning or the middle of next year, as I indicated.

And then what I would highlight in terms of what follows from that with regard the next wave portfolio plans, obviously it positions depe very favorably. What we know from asthma, of course, already is that it offers a significant advantage in 2 injections per year versus 26 in the comparison with dupi.

But I'm also very pleased, and you'll hear more about this at the Meet the Management, that we have long-acting options in both TSLP and IL-33. So what we'll disclose to you there is how we think about positioning those 3 long-acting options into an emerging understanding of the subgroups of COPD disease.

Emma Walmsley Executive

Thanks, Tony. Luke?

Luke Miels Executive

Yes. Thanks, Kerry. So on the Q2 call, I did flag that we're concerned about and would watch closely what's occurring in China, particularly in terms of the tighter [POB] budgets and just some of the flow of funding around those and of course, the macro, which is very broadly covered across many industries. And so we're actually seeing that it definitely impacts a broader slowdown in the economy, definitely impacts the self-pay market and also just the capacity of local governments to then restock, purchase vaccines, which are then subsequently purchased by individuals. So these are having an effect on our volumes.

We're working closely with Zhifei. Again, if we look at the medium to long term, I mean, the partnership has started extremely well. These are impressive operators. They've got to a far number of points of vaccination than we could ever hope to get to with our infrastructure.

You asked what we've sold, we've sold around [GBP 240 million] out of the [GBP 0.4 billion] 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 0.5 billion people in China who are 50-plus. So that's where the focus is at this point.

Jeff McLaughlin Executive

Great. Our next question is from Jo Walton.

Jo Walton Analyst

I'm going to just ask a broader question about IRA and the pressures that we might experience next year, some of the pushes and pulls here. We've already seen some

companies show higher prescription growth as they go through the year and it's notable for Benlysta going up 6%, 9% and then 14%. Is any of that to do with already experiencing lower -- people already experiencing lower co-pays? Could that be a benefit to you going forward?

You've talked about pressures in the past for Respiratory where the authorized generics are and you've 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?

And a second question, if I could, please. Could you just tell us a little bit about RSV ex U.S.? Is that really not an opportunity at all until the dosing has been sorted out?

Emma Walmsley Executive

Thanks. So Luke, let's come to you. And we did flag GBP 400 million to GBP 500 million overall on IRA and then RSV ex U.S.

Luke Miels Executive

Yes. I mean look, there is increased pressure there. I think PBMs will go looking for offsetting that amount. I think we're starting to see tactical decisions by physicians in terms of trying to push people through that coverage, and I think that's across the whole portfolio.

Specifically for us, I mean, with 340B, we've got about 9 states that have got legislation. There's another 10 which are working on it. So that impacts Specialty. There's also some impact on Vaccines, of course, but they tend to benefit in aggregate because of the removal of the co-pay.

The other thing to factor, 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 learned 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 '26 and '27, but we think we can start to return to growth after that with Trelegy.

And of course, ex U.S., it continues to do well.

The areas where we tend to see pressure with 340B products like Zejula and Nucala. Specifically on Nucala, I think it's more driven by -- we're starting to pivot and to look at nasal polyps. It's been very successful Europe. We've been a little bit slower in the U.S. to pivot to that, and now we're really aggressively looking at that and seeing very good feedback.

And the ENTs are certainly -- they're willing to experiment with this molecule. And we've seen -- I mean, we tested it in markets like Italy and saw a fantastic surge in Nucala. So that's what we're now ramping up in all the key markets globally with Nucala.

Emma Walmsley Executive

And RSV ex U.S.

Luke Miels Executive

Sure. I think now we know enough about this vaccine that we need to move forward. The feedback we're getting is very encouraging. STIKO just did a broad RSV vaccine contract in Germany at about EUR 180 for both us and the other 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, mortality, these are very apparent. I think one thing that we're watching is just different geographies emphasizing older adults, other ones are more focused on maternal. So for example, PAHO in Latin America is more focused on maternal as is Australia, whereas the European markets are more focused on older adults, including Japan. So early days, but I think we've got a pretty good idea of the pricing point.

As I said earlier, we did set out the U.K. tender. Canada was very, very price-intensive. So our whole strategy here is, as I said in Q2, we want to play the longer-term game. We have the best-in-class vaccine.

We've accumulated a very clear picture on the benefit/risk and the potency and the duration of effect. So now we're moving to contract.

Emma Walmsley Executive

Thanks, Luke. I mean, I think as you can see in our reported sales, international RSV sales are still a very small fraction. And in fact, in the U.S., I think we -- there's still 80% of those that ACIP have said this vaccine is able to who are not yet vaccinated.

Obviously, for the reasons that Luke run through, it's a tougher year this year. But fundamentally, the benefit of this vaccine, all the data that surrounds it, the fact revax will come when you look at the waning that comes through by year 3, that's for ACIP to decide when, all of that means we're -- 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.

Jeff McLaughlin Executive

The next question is from Simon Baker.

Simon Baker Analyst

Two questions, if I may, please. Firstly, on depemokimab. Could you remind us what assumptions in terms of severity of asthma is assumed within the peak sales number? How far down the continuum of severity do you expect to go to get that number?

And then secondly, a question on RSV, which may be a slightly naive one. But if we have autumnal congestion in pharmacies and we have a vaccine that has multiyear 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've run into at the moment?

Emma Walmsley Executive

Thanks. So Luke, to you on deseasonalizing, if that's the word. By the way, I think when we get to combo vaccines, which obviously GSK wants to compete in, that would also help in terms of share of arm space. But Luke, perhaps you can comment on that. And then, Tony, we'll come to you in terms of the profile of asthmatics.

With that, Luke?

Luke Miels Executive

Yes. I mean, Simon, I think you've hit the nail on the head there. It's tough right now with Arexvy and the class for the reasons we know, I mean, primarily because of the direction that ACIP has 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.

And I mean, Tony and I were texting each other as we watch the FDA presentation at ACIP and the benefit/risk slide, I think it was Slide 10, which said that for every 1 million people that you vaccinate over a 3-year period, in the existing 75 plus, 60 to 74 at risk, it's about 2,000 less deaths, 15,000 less hospitalizations. And the trade-off is 0 to 18 or about 9 GBS cases. So I think that will start to assert itself over time.

When we look at coadministration with RSV, even just recently it's really quite striking. In August, if you -- Arexvy 56% of the time was given with another vaccine, that jumped to 71% in September. And 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%. And what really moved was it was 3% with COVID in August and that jumped to 10% in September of '24.

What is really interesting is the triplet COVID-flu combination, that went from 5% of Arexvy shots in August to 27% in September. So what that tells me is there is an opportunity, as we did with Shingrix and we've got more work to do with Shingrix, but as we did with Shingrix to deseasonalize this vaccine and because of this longer window, which again, that's what pharmacists tell us they want in terms of just managing their workflow, staffing levels, et cetera. So I think we will get there in the mid- to long term with this vaccine.

In terms of depemokimab, I don't think we've given the peak penetration rate. But if you look at biological penetration, it is still disappointingly low. It's about 1/3, which is just under 1/3 of people who are actually eligible for a biologic, and it's not an access issue. It's essentially pulmonologist being willing, and allergists as well, to prescribe biologics in those patient groups.

What is attractive about depemokimab when we do our market research is that, first, you've got this Part B, B for bravo, dimension, a buy-and-bill component, which is not as prominent with Nucala. And then when we look at market research, I mean, the recent market research, we've got about 80% of HCPs who are extremely interested in that 6-month profile and about 58% say they'll use it in naive patients and about 2/3 said they'll consider switching.

And then when we look at patients, around 60% say 6 months is a lot more attractive and just under 90% would actually consider if their doctor recommended it.

So that translates to about a 20% jump in our models anyway based on market research. I mean, that's not real. You've got to go and do it, but about a 20% uplift in biologic use because of that efficacy frequency trade-offs. So let's see.

The other thing is we've got all of the -- with the exception of COPD, all the life cycle coming within 2 years of the initial approval, which is very different from Nucala, which was around 6 years.

Emma Walmsley Executive

Yes. Tony, I don't know if you've got anything to add to any of that?

Tony Wood Executive

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

What we also see from, for example, in the prespecified analysis of -- in secondaries through exacerbations requiring hospitalization or an ER visit, a 72% reduction. And actually, if you look across, both SWIFT-1 and SWIFT-2, it's important to realize that in those studies, 68% of the patients on depe experience no exacerbations at all.

Emma Walmsley Executive

I mean, I think -- and then we'll move on to the next question. But this demonstration of capability from GSK on the value to patients and health care 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, I think, a very exciting field for us to continue to pursue and will contribute meaningful growth.

Jeff McLaughlin Executive

Great. The next question is from Graham Parry from Bank of America.

Graham Parry Analyst

Just on Arexvy, looking into 2025 with no booster, just wondering what your sort of cadence should we expect on first-dose penetration. So should we be thinking increases like the 6% to 7% that we saw with Shingrix into the addressable populations, assuming no expansion of that? And would that, therefore, lead to a drop in the U.S. next year?

And then the extent to which you think international can offset this if you're going to start going sort of full for launch into international territories, which I assume, but if you could confirm, would be based on pricing for at least 3 seasons' duration given you have that data now?

And then secondly, on Shingrix, could you just help us to understand what level of inventories

Zhifei is holding now and whether you expect to sell any more into Zhifei inventory in 2024? Or is the GBP 400 million essentially not going to be -- minimum contracted volume not going to be achieved? And then your confidence in achieving the GBP 800 million and GBP 1.2 billion going forward?

Emma Walmsley Executive

So thanks, Graham. I'll just repeat what we've said on China in terms of -- and Luke said in terms of the contracts that we have, but our commitment 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're still in the early foot fields, both of international and frankly U.S. penetration.

And don't forget, Graham, this is an unusually slow season. I'm not sure we're 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 Executive

Yes. I mean, I think, Graham, the unpredictable component here is what ACIP does. And they remain cautious. I won't requote the FDA figures, but I think that they are important. The question is what happens with the rest of this year's season?

I mean, typically, November is the classical RSV peak, but that has changed since COVID. But I think that's informative. Also just 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 '23, 75-plus was 17% as of August, which is our most recent data, that's up 21%. So you've got the effects of the June ACIP there and that 29 million people population.

And if you look at the 60 to 74, that is definitely slowing. So that was 10% at the end of last year, and it's about 14% in August '23. So that's the population to watch.

We were pretty clear in quarter 2 that, that was not good news in terms of what ACIP has said around that population. There were other views on that, but we felt that, that would retard the uptake and I think the evidence is there.

Then the other swing factor is the 50 to 59 and the 18-plus population. So I think it's really -- 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 that we've covered.

But I think '25 is going to be challenging until ACIP normalize. There's a clear signal set there, and I think HCPs have heard it. And let's hope over time the evidence in terms of benefit/risk is seen for what it is and uptake starts to recover.

I don't know, Tony, if you wanted to add anything else?

Tony Wood Executive

No. I mean, just to build on that and that sort of impacts some of the headline conclusions

from the ACIP conversations. And 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, in fact, a commentary that the confidence interval [sign] 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 1 million. And so that population, I think, continues to be clearly justified. And as we mentioned earlier, one in which there are 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 to 59 population and in the 18-plus population and the position on revaccination will become clearer as well.

Emma Walmsley Executive

And just to reiterate in terms of what is behind your question. We have taken a conservative view on our '25 outlook for vaccines overall i.e., no revax, no expansion of cohorts. Obviously, that will be in the hands of ACIP and we'll 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, we'll continue to lead strong profitable growth in '25 and underpins -- high confidence alongside the 5 approvals we're expecting and hoping to get by the end of the year, underpins our serious confidence in all of the long-term outlooks we've been -- 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 also its performance.

Jeff McLaughlin Executive

Thanks. The next question is from Emmanuel Papadakis.

Emmanuel Papadakis Analyst

I'm sorry, I'm going to ask another question on Arexvy. How are you going to get to GBP 3 billion peak? I mean, even with a modest degree of late revaccination in the U.S., it doesn't seem like we'll return to blockbuster territory in the U.S.A. So is this really a statement about international potential? Or are we missing something on the U.S.?

Or what are the assumptions that lead you to think we can get to GBP 3 billion?

And then perhaps a question on Blenrep, maybe a more favorable topic. Just talk to us about the time lines in the U.S. Are 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've got a relatively modest set of consensus expectations.

We'd love to hear what you think about those.

Emma Walmsley Executive

Thanks, Emmanuel. So Luke, I think you can pick on both of these. But I'm just going to reiterate very briefly, there are 64 million people that suffer from RSV on a seasonal basis. 14,000, 15,000 people die every year in America.

This is a brand-new vaccine with a cautious ACIP, but we are in their hands in terms of how and when they come back on revaccination, which we are very confident they will be considering the waning to below 50% in season 3 over time and extension in cohorts and the penetration because, as Luke said, there isn't really good reason to expect this to be very different from flu over time, and we're still in the early days of that and international expansion. So Luke, I don't know if there's anything else you'd like to repeat on that one. But we are being cautious in the near term, right? We're not banking that near term. But Luke, I don't know if you want to add anything and then obviously very ambitious with Blenrep.

Luke Miels Executive

No. On Blenrep, I mean, I think the -- because we've said it all. I don't think there's anything new. I mean, one thing I think that's important is there's this focus on the peak sales, but the difference between a multiyear vaccine and an annual vaccine is the volatility is much higher. And I think what we need to concentrate on is the area under the curve, which has changed.

In terms of Blenrep, I mean, I think the market research, the expert feedback that we've got, I think there's an increasing respect for the profile of the product. I think there's also a broader understanding of some of the challenges employing bispecifics, particularly around infection risk, concomitant infusions, admission, CRS, neurotox, et cetera.

And the DREAMM-7 and DREAMM-8 studies have been well received. I think the critical thing here is really supporting physicians on those first 5 patients around the infusion strategy, dose holds and also educating them to reassure the patient that efficacy is not sacrificed if they do have the whole dose.

So this trade-off, again, just being realistic about the keratopathy and those elements and the 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 CD38 into the first line.

So you add all those things up, plus we've gained a huge amount of experience clinically and also commercially as an organization over the years, I think the DREAMM-7 and DREAMM-8 designs are evidence of that as is the launch of momelotinib.

So we're humble about it. We're careful. We're 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're able to achieve survival as well, that will obviously support the product in that second-line setting.

Jeff McLaughlin Executive

The next question is from Richard Parkes.

Richard Parkes Analyst

Firstly, I just like to push a little bit on the confidence in the Arexvy revaccination market because you seem very confident about that. But it looks like the decline in vaccine efficacy has somewhat stabilized in the third year, and it sounds like ACIP wasn't fully convinced by your revaccination immunogenicity data. So can you just underline why you're so confident about that? And maybe what impact that would have on your peak sales assumption if that didn't materialize? And then secondly, on Apretude.

That launch looks like it's lost a little bit of momentum. And 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?

Emma Walmsley Executive

So Tony, on revax and then Deborah, please.

Tony Wood Executive

Yes. So just quickly on revax, as you see the data, particularly in the lower respiratory tract disease population, show that there is a decline from season 1 to season 3, of 83% in season 1, 2; I think, 48% in season 3. Importantly and to answer your question with regards to trajectory, Richard, we also know that natural infection does not cause lifetime immunity for these mucosal infections. You don't see that and so we think that the available evidence of that data would suggest that revax will be required and it will be between 3 and 5 years.

Additionally, I'll 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. But again, is commonly the case in vaccines that as the time from prime to boost extends, the significance of the boost increases.

Emma Walmsley Executive

Thank you. Deborah?

Deborah Waterhouse Executive

Brilliant. Thank you, Richard. So just to start by saying we're absolutely delighted by our performance in the quarter with the HIV franchise, 12% growth, and we've been double-digit growth each quarter throughout the year so far. So really happy with the way our trajectory on particularly our long-acting injectables is progressing. But obviously, our own 2-drug regimens are also doing extremely well.

Let's focus just on Apretude. So I think it's worth remembering that the GBP 22 billion-plus market value in HIV is about GBP 20 billion for treatment and GBP 2 billion for PrEP. So you normally expect big numbers in HIV because we are usually operating in the treatment space, but actually you've got to remember that this is a GBP 2 billion market, which is growing relatively rapidly. So between 10% and 15% at the moment in the U.S.

So the growth is strong. The market is robust. And Apretude is doing well. So we're 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're ensuring that physicians understand the safety, efficacy, tolerability of this exceptional prevention medicine. But at the same time, we're 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 U.S. health care market. And we are investing very strongly, and we're seeing really good breadth of prescribing increases, not just in Apretude actually but with Cabenuva as well.

So my summary would be there's still a long way to go in this market, both PrEP and treatment. Long-acting injectables are really growing rapidly, are gaining share and driving our growth in a very positive way, which is why we've been able to deliver 3 quarters of double-digit growth this year. And obviously, we had a very strong performance, driven by the same things in '22 and '23 as well.

So real confidence in our long-acting injectables, both this year and actually for next year as well.

Emma Walmsley Executive

And the pipeline coming forward.

Deborah Waterhouse Executive

And the pipeline coming forward. So obviously, we've got Q4 PrEP and treatment coming up. And then we've got every 6 months, which is progressing absolutely in line with our expectations and we'll obviously come to talk more about that as data emerges.

Jeff McLaughlin Executive

Yes. We have time one final question, and we are going to go to Peter Welford from Jefferies.

Peter Welford Analyst

I wouldn't -- sorry, if we can just go back to Arexvy, I'm afraid. Could we just talk a little bit about the ACIP decision. I'm just trying to understand here on the safety side of things because, I guess, it seems like it's a little difficult situation in that obviously the population to be able to make a better characterization of the GBS risk is relatively low given the low number of vaccinations. And obviously, FDA already has the data with regards to the risk side of the equation, i.e., the number of deaths and hospitalizations for the 60 to 74. So it seems the only likely conclusion potentially is that there is a significant GBS risk eventually for that population, too.

So I guess I'm curious what you think -- how you think more data for that population will potentially make a difference and what you can, I guess, provide incrementally to that to sway them on that population?

Emma Walmsley Executive

So I think we'll finish up then with Tony's response on that. But just to reiterate, our confidence has been -- as has been said by all of the team in the benefit/risk ratio of this vaccine

considering the burden of disease, hospitalization and death at global scale. Tony?

Tony Wood Executive

Yes. And Peter, let me just -- so 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.

In terms of -- and again, let me stress that the FDA conclusion of GBS was it was rare with 1 and less case for -- less than 10 cases, sorry, per 1 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 immunocompromised populations, particularly in those that constitute the populations that are at greater risk of hospitalization.

Emma Walmsley Executive

Thanks. And isn't it also right to say, Tony, that if you account for frequency of vaccination, there's no difference here versus...

Tony Wood Executive

Yes. There was 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's no significant difference in risk across those vaccinations.

Emma Walmsley Executive

Thank you very much. So thanks, everyone, for joining the call. As you heard, we're 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.

We look forward to catching up with you over coming days. Thank you. Bye-bye.