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GSK plc

# GSK plc - Q3 2025 Earnings Call

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## Event Participants

### Executives 5

Emma Walmsley, Luke Miels, Deborah Waterhouse, Julie Brown, Tony Wood

### Analysts 8

Peter Verdult, Matthew Weston, Michael Leuchten, Luisa Hector, Sachin Jain, Simon Baker, Sarita Kapila, Zain Ebrahim

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### Operator Operator

Ladies and gentlemen, a very warm welcome to the GSK Q3 2025 Results Call.

I'm delighted to be joined today by Emma Walmsley, Luke Miels, Deborah Waterhouse, and Julie Brown, with Tony Wood, David Redfern, joining for Q&A.

Today's call will last approximately 1 hour with a presentation taking around 30 minutes and the remaining time for your questions. Please ask only one to two questions so that everyone has a chance to participate.

Before we start, please turn to Slide 3. This is the usual safe harbor statement. We will comment on our performance using Constant Exchange Rates, or CER, unless otherwise stated.

I will now hand over to Emma on Slide 4.

### Emma Walmsley Executive

Thank you, and welcome to everybody joining us today. Please turn to the next slide. Our third quarter results once again demonstrate GSK's continued strong performance with positive momentum driving an upgrade in our guidance for the year. They also further demonstrate the quality and strength of GSK's portfolio with sales driven by sustained growth across specialty medicines in RI&I, oncology and HIV. Total sales were up 8% for the quarter, with leverage delivering core operating profit up 11% and core earnings per share up 14% to 55p.

Alongside this, we're continuing to make excellent progress in R&D, strengthening our late-stage portfolio and already securing four FDA approvals this year, including BLENREP last week and with the fifth, depemokimab before year-end.

Cash generation also continues to be very positive at GBP 6.3 billion for the year so far. This supports investment in our growth priorities and returns to shareholders, including a dividend of

16p for the quarter.

And finally, I'm very proud of the progress we continue to make with our trust priorities, in particular, this quarter with the positive Phase III data reported for our low-carbon version of Ventolin. This successful transition will reduce GSK's carbon footprint by up to 45%, and it's a meaningful development for the 35 million patients who rely on Ventolin worldwide, and we expect to launch in 2026.

Next slide, please. Our #1 priority remains investing for growth, and I'm pleased with the progress we are making, both in the late-stage portfolio and in the work ongoing to build the next wave of innovation at GSK. With the addition of efimosfermin, the long-acting FGF21 for steatotic liver disease, we now have 15 scale opportunities with peak year sales potential of greater than GBP 2 billion, all with the potential to launch before 2031.

By the end of the year, we expect new pivotal trials to have started for several of these 15 opportunities, depemokimab for COPD patients, efimosfermin in MASH, GSK'981 for second-line GIST and our GSK'227 ADC in extensive stage small cell lung cancer. It's worth noting that those last 3 assets have all come from focused, successful business development and BD remains a key driver of our pipeline expansion.

And we continue to add high-value innovation at earlier stages of development. For example, I'm excited by GSK'261, a new monoclonal antibody for polycystic kidney disease, which received orphan drug designation by the FDA. Lastly, and very importantly, we continue to optimize our supply chain to scale up capacity for our new medicines and vaccines.

Last month, we confirmed our intention to invest \$30 billion in R&D and advanced manufacturing in the U.S. over the next 5 years, including the imminent construction of a new biologics flex factory in Pennsylvania. Next slide, please. Since 2021 and then GSK's successful launch as a new focused biopharma company, we've delivered 18 consecutive quarters of profitable sales growth, upgraded annual guidance each year, improved our medium-term outlooks and upgraded long-term outlooks twice from an initial GBP 33 billion by 2031 to now more than GBP 40 billion, all underpinned by a much stronger balance sheet.

We've all been resolutely focused on this step change in sharper operational performance alongside accelerating investment in R&D and significantly improving the quality and scale of GSK's innovation. So today, GSK is a very different company in performance, pipeline and prospects. And this team is determined to sustain and improve upon this track record. As we look ahead, we are again upgrading our guidance for the year with meaningful improvement for 2025 sales and profits.

And this momentum positions us well as we go into 2026 and to deliver on the long-term commitments for growth we've set out for shareholders. So let me now hand over to the team to take you through more of the detail on our performance, starting with Luke. Next slide, please.

**Luke Miels** Executive

Thanks, Emma. Please turn to the next slide. In Q3, we delivered growth across all our product areas and in the regions with GBP 8.5 billion of sales, up 8% versus last year. Growth in the quarter was driven by Specialty Medicines, up 16%. And another quarter of strong Shingrix, Arexvy and meningitis demand in Europe.

And in the U.S., we navigated the impact of the Medicare redesign from the IRA and the impact is now expected to be closer to the lower end of our GBP 400 million to GBP 500 million range.

Next slide, please. Specialty Medicine continues to be the most important driver of our diversified business with double-digit growth once again in all therapy areas. Starting with RI&I, sales were up 15%, driven by strong demand. Benlysta, our treatment for lupus grew 17% with global guidelines supporting earlier use of biologics and recommending Benlysta as a preferred treatment option.

84% of bio-naive patients are now starting on Benlysta, and we continue to differentiate with strong organ damage prevention data and a well-characterized safety profile. Nucala, our anti-IL-5 biologic, grew 14% in the quarter, driven by COPD uptake and continued growth across all in-line indications. Moving to our growing oncology portfolio, which is up 39%. Jemperli sales were up for the 10th quarter in a row as our teams continue to differentiate Jemperli from the competition, as the only immuno-oncology medicine to demonstrate overall survival in endometrial cancer. Jemperli's global market share in endometrial cancer is now higher than the leading competitor in DMMR.

And Ojjaara sales were up 51% in the quarter, driven by increasing first- and second-line patient demand in the U.S. and volume growth in Europe following EHA, where new data emphasized the importance of early intervention. And BLENREP is now in the early days of launch with approval in 8 markets and more on that in a minute.

And with the strong momentum we're seeing across RI&I and oncology and the continued performance of ViiV, we are now increasing our full year specialty guidance from low teens to mid-teens percentage growth. Next slide, please. In Q3, we had a very strong start for Nucala and COPD with the latest NBRx data showing we are now getting close to 1 out of every 2 prescriptions.

Our differentiated label is enabling us to reach a wide spectrum of COPD patients, including those with emphysema and EOS counts down to 150. We've now reached 95% of our top ACP targets and have a broad formulary coverage. In this population, hospitalizations remain a critical unmet need with 1 in 2 patients dying within 5 years of their first admission, and there is plenty of room to grow in this market with less than 5% biologic penetration in the U.S.

The success we have had with this launch gives us further confidence in the potential we have for depemokimab, our long-acting IL-5, which we expect to launch early next year. There are 4 compelling reasons underpinning why we believe depe will be a very material medicine. First, there's plenty of room to grow in the market, starting with bio-naive patients as only 27% of them currently receive a biologic.

Second, patients discontinuing therapy is an issue with up to 65% of new patients on current biologics discontinuing therapy within the first 12 months. And unsurprisingly, less adherent patients have worse clinical outcomes, including around a 30% increased rate of inpatient and emergency department visits. The 72% reduction that depe has demonstrated in hospitalization with just 2 doses a year is material. And finally, we know ACPs want this medicine with 86% of pulmonologists surveyed believing it could become a standard of care.

Next slide, please. Our oncology portfolio is progressing well. Starting with BLENREP, we now have approval in 8 markets, 7 in Europe and international regions in the second-line plus population and now the U.S., where just last week, we received approval in the third-line plus setting. This U.S. approval is a significant step forward for the U.S.

patients and the indication granted reflects that BLENREP has demonstrated superior efficacy versus the standard of care daratumumab triplet and now gives us certainty and the ability to

launch.

Data from DREAMM-7 in this population is very compelling with a 51% reduction in the risk of death and a tripling of median progression-free survival versus the data-based triplet. We see a significant opportunity here as of the 71,000 patients in the U.S. receiving treatment today, over 1/3 are treated in the third-line plus setting.

And BLENREP is the only anti-BCMA option, which is practically able to be used in the community where 70% of patients are treated and could benefit from a much needed novel MOA. We also have a new and significantly simplified REMS program, including, importantly, the use of optometrists versus the original REMS, which required ophthalmologists only. This will make it much easier for patients and HCPs to manage eye care. And while we anticipate a slower ramp-up in the U.S. with the initial third-line plus label, as we said previously, we will take the time to ensure a positive patient and provider experience to achieve the long-term potential of this highly effective drug.

Our clinical development and evidence generation plan continues. And again, working closely with the FDA, this will now be expanded in the U.S. and will support the use of BLENREP in earlier and all stages of multiple myeloma globally. In summary, we expect BLENREP to meaningfully advance treatment options for patients with multiple myeloma, and we continue to expect BLENREP to be a material growth driver for GSK in the next 3 to 4 years.

Moving to future indications for Jemperli. We're looking forward to the opportunity we have to change the lives of patients with rectal cancer. And following the transformative data showing a 100% complete response rate in Phase II, we initiated the AZUR-1 pivotal trial and expect to see results in the second half of 2026. And additional trials are ongoing to understand the benefit Jemperli can bring patients with colon and head and neck cancer.

Finally, we continue to progress our key oncology pipeline assets, starting with our B7-H3 antibody drug conjugate or GSK'227. We're now recruiting for our Phase III trial in second-line extensive stage small cell lung following a clear signal we saw in the early-stage clinical data from Hansoh, our partner. And our KIT inhibitor for GIST, GSK'981 acquired earlier this year, will start Phase III in second line by the end of the year and first line in 2026.

And GSK'584, our B7-H4 antibody drug conjugate is expected to advance to Phase III in endometrial and ovarian cancer next year. And overall, this oncology portfolio offers significant future growth opportunity for GSK and is a clear priority for investment and resources alongside RI&I.

And with that, I'll now hand over to Deborah to cover our great momentum in HIV.

### **Deborah Waterhouse** Executive

Thank you, Luke. Our HIV portfolio continues to deliver double-digit growth, up 12% in the quarter, primarily driven by 10 points of strong patient demand growth for our long-acting injectables and Dovato. Demand continues to increase across all regions and major markets, particularly the U.S., which grew 17% and where we saw total share gain outpacing the competition.

We are delighted with the continued transition we are seeing to long-acting injectables. More than 75% of our growth now comes from long-acting injectables. And in the U.S., they already represent around 1/3 of our sales. Cabenuva, the first and only long-acting injectable HIV treatment regimen grew 48%, driven by strong patient demand. Our competitive performance is

reinforced by the acceleration of Cabenuva switches from competitors in the U.S., which this quarter reached 75%.

As we anticipated, in long-acting prevention, we saw continued positive momentum of Apretude in the U.S. with competitive growth also of 75%. This quarter, we shared results from CLARITY, a Phase I study comparing acceptability and tolerability of single-dose CAB LA for PrEP marketed as Apretude and lenacapavir. We know patient experience is an important factor for injectables.

Results showed 69% of participants found CAB LA to be totally or very acceptable with 90% of participants and 86% of HCPs preferring CAB LA over lenacapavir in terms of injection experience after a single dose. These data add to the growing body of clinical and real-world efficacy, safety and tolerability data we have for Apretude and will help inform expectations and decision-making when initiating long-acting injectables for HIV prevention.

We expect continued growth momentum in Q4. And so today, we are upgrading our 2025 guidance from mid- to high single digit to grow around 10%. Next slide, please. Our industry-leading pipeline with best-in-class integrase inhibitors at the core continues to progress and have multiple long-acting options with strong profiles that deliver what we know patients want and need.

This pipeline will further drive the transition we are making in our portfolio to ultra-long-acting regimens and will help us navigate the dolutegravir loss of exclusivity towards the end of the decade. Building on our established 2 monthly injectable regimens, we believe 4 monthly dosing in PrEP and treatment will be important options, delivering longer dosing intervals and ensuring continuity of care.

We have a confirmed date from Janssen on rilpivirine Phase III clinical trial supply that leads to a delay to the start of Quattro, our Q4M treatment registrational study to H1 2026. Despite this, we remain on track to file in 2027, and we look forward to launching this next wave of innovation in 2028. Building on continued strength and performance of our Q2M Cabenuva, the world's first and only LAI for HIV treatment.

At the launch of Q4M treatment, we still expect to have the only long-acting injectable treatment regimens on the market for years to come. Looking ahead to our twice yearly injectables, we're on track to confirm the dosing regimen for Q6M treatment in 2026 and expect to file and launch both Q6M for treatment and PrEP between 2028 and 2030. For Q6M treatment, we remain excited about the potential of VH184, our third-generation INSTI, which has the best resistance profile seen to date and IP protection through to at least 2040.

To partner with our selected INSTI, we are evaluating 2 assets, VH499, a capsid inhibitor and N6LS, one of the broadest and most potent bNAbs in development. Regarding N6LS, this quarter, we again showed more positive results from Part 2 of our Phase IIb study in BRACE and are pleased to confirm the next phase of this study is now fully recruited.

As a reminder, Q6M for treatment in PrEP is not yet in GSK's outlook for 2031. Our long-acting injectable portfolio is backed by 3 years of real-world evidence and implementation science. As we look to the future, we expect our industry-leading long-acting pipeline powered by unparalleled patient insight to deliver 5 launches through 2030. We remain confident in our ability to drive sustained long-term performance and look forward to sharing more at meet the management investor event in Q2 2026.

With that, I'll hand back to Luke.

Thanks, Deborah. Turning to Vaccines. Sales were up GBP 2.7 billion in the quarter, up 2%, driven by continued strong demand for Shingrix, Arexvy and Bexsero, particularly in Europe, which was up 35%. Shingrix sales grew 13% overall, largely due to the strong performance in Europe, up 48%, where we're driving across multiple markets and with significant new uptake in France, and a strong performance in Germany, the Netherlands and Poland.

In international, sales in Japan continue to grow following the expanded public funding. Ex U.S. sales now account for around 70% of global Shingrix sales. And in the U.S., penetration is now 43% of the eligible older adult population with immunization rates slowing as expected as we access harder-to-reach patients.

In meningitis, our portfolio was up 5%, driven by double-digit growth for Bexsero in Europe, where the updated recommendation and reimbursement in Germany continues to pull through and in France following a meningitis B outbreak and the implementation of mandatory newborn vaccination requirements, along with new reimbursed cohorts.

Also in the quarter, even though the ACIP recommendation came slightly after the back-to-school season window, we booked the first sales of our pentavalent vaccine, Penmenvy in the U.S. with initial CDC purchases. We expect this vaccine to simplify immunization schedules and contribute to increased coverage and protection against a serious life-threatening illness.

Turning to Arexvy. Growth was driven by Europe with good commercial progress in Germany, Spain and Belgium. International also grew driven by tender volumes in Canada. And in the U.S., we maintained our market-leading share in the older adults population. However, the U.S.

declined due to lower preseason channel inventory build and slower market uptake in the 60-plus population.

In Q3, our flu vaccines were down in part due to competitive pressure in the market where we compete for healthy younger cohort populations who are harder to activate in older adults for flu vaccines. And Established Vaccines were down primarily due to the prior year impact of our divested brands. So in summary, with the Vaccines business, we now expect to land towards the top of our vaccines guidance range of declining low single digit to stable.

And as we look forward, although we continue to remain cautious in the near term on vaccines in the U.S., we are confident in the prospects pipeline and benefit this business offers over the long term. Next slide, please. Turning to General Medicines. Sales were up 4%, driven by the strong growth of Trelegy in all regions, up 25% in the quarter.

And the SITT class remains very strong, up around 23%, driven by GOLD guidelines, new data and competitive share of voice. Within the SITT class, Trelegy continues to gain more share than any other brand and is the top-selling brand for both COPD and asthma globally. We also have completed IRA negotiations on Trelegy in line with expectations and our outlook.

The remaining portion of the portfolio was stable, reflecting continued generic competition and expected adjustments in rebates and returns. We continue to expect sales to be broadly stable in 2025 and are looking forward to future opportunities in this portfolio, including launching low-carbon Ventolin and further establishing our anti-infective portfolio through building access in the U.S. for Blujepa in uncomplicated urinary tract infections and also filing tebipenem in complicated UTIs by the end of the year. All 3 of these represent practical innovation for important areas of medical need.



I'll now hand over to Julie.

**Julie Brown** Executive

Thank you, Luke, and good afternoon, everyone. Next slide, please. Starting with the income statement for the quarter with growth rates stated at CER. As already highlighted, sales grew 8%, driven by the specialty portfolio across HIV, oncology and RI&I. Core operating profit grew 11%, reflecting a 5% increase in SG&A as we continue to invest to support key asset launches alongside driving productivity.

R&D growth of 10% was driven by accelerated pipeline investment across key specialty medicines. Our royalty income benefited from the Kesimpta performance as well as new RSV and mRNA royalty streams. Core EPS grew 14%, aided by a tax rate of 16% in the quarter and benefits from the share buyback, partially offset by higher NCLs relating to ViiV's strong performance.

Turning to our total results. The significant growth reflects the Zantac settlement charge taken in Q3 last year. Next slide, please. The operating margin improved 90 bps in the quarter, largely driven by SG&A margin improvement of 70 bps. This increase demonstrates the efficiency gains achieved through our returns-based approach as we invest in new product launches whilst continuing to generate productivity improvements in the promotion of the existing portfolio.

Additionally, in the quarter, gross margin improved, reflecting mix benefits from the continued transition towards specialty and R&D expenditure increased as we reinvest additional royalty income into our pipeline, supporting the acceleration of the ADC programs and pivotal trial starts for efimosfermin and GSK'981 in second-line GIST. Year-to-date, our operating margin is now 33.9%, up 100 bps at constant exchange rates, driven by sales mix, productivity gains and growth in royalties.

Next slide, please. Turning to the cash flow with commentary before the one-off impact of Zantac payments. Cash generated from operations year-to-date was GBP 6.9 billion, improving GBP 1.7 billion, benefiting from increased operating profit, favorable movements in return and rebate provisions and the CureVac IP settlement announced in August. This was partially offset by increased working capital, impacted by higher Arexvy and Shingrix collections in Q1 of last year.

Free cash flow increased GBP 1.8 billion versus last year, driven by strong CGFO and favorable phasing of tax payments, partially offset by higher spend on in-licensing deals. Zantac payments year-to-date totaled nearly GBP 0.7 billion, and we expect the remaining GBP 0.5 billion to be paid by the end of the year, drawing a line under the settlement agreed and disclosed last October.

Next slide, please. Turning to capital allocation. In line with our framework, we continue to deploy cash in a disciplined manner and underpinned by a strong balance sheet. Our net debt to core EBITDA ratio remains broadly aligned with the end of 2024 at 1.3x. Our priority is always to invest for growth as demonstrated by our sustained acceleration of late-stage R&D, the next wave of pipeline innovation and targeted BD.

In 2025, we have signed multiple deals, including the acquisition of IDRX-42 and efimosfermin as well as the Hengrui licensing agreement and earlier-stage pipeline and platform technologies. We have also made GBP 3 billion in shareholder distributions so far this year through the

dividend and the buyback program, of which GBP 1.1 billion has been executed so far with a cumulative total of GBP 1.4 billion expected to be completed by the end of the year.

Next slide, please. As Emma shared, we are upgrading our guidance on the back of the continued strong performance this year. We are raising our full year sales expectations from 3% to 5%, to 6% to 7%, with underlying upgrades for Specialty, including HIV, and we now expect to be towards the top of the vaccines range.

Alongside this, we're also raising our guidance ranges for operating profit to 9% to 11% and EPS to 10% to 12% -- looking through the P&L guidance, we maintain that gross margin will benefit from product mix, partially offset by supply chain charges of around GBP 100 million to be taken in Q4. SG&A will grow at low single digits for the year as committed, including Q4 charges of around GBP 150 million to fund further productivity initiatives.

And R&D continues to increase ahead of sales as we reinvest incremental royalty income into our pipeline. We are upgrading our expectations for higher royalties to GBP 800 million to GBP 850 million, supported by income from the CureVac settlement announced in August and lower net interest costs than previously guided due to the strong cash generation and the later timing of Zantac payments.

Finally, in line with previous guidance, we expect the tax rate to be around 17.5%. In summary, we look forward to delivering a fourth consecutive year of double-digit EPS growth, notwithstanding the Q4 charges of around GBP 250 million, demonstrating the successful execution of our strategy since we became a stand-alone biopharmaceutical business.

As a reminder, our guidance is inclusive of tariffs enacted and indicated thus far. We are positioned to respond to these with mitigation actions identified. And looking beyond, we remain very confident in our medium and longer-term outlooks to 2026 and '31. Next slide, please. Moving to our road map, which illustrates our progress towards major milestones and upcoming value unlocks.

We have made good progress through 2025, and we expect to continue to build momentum as we move towards 2026. Over the coming months, we will continue to focus on flawlessly executing the 5 key asset launches. The FDA regulatory decision for depemokimab is due this December. And we are looking forward to delivering multiple pivotal readouts across our 15 scale opportunities, including bepirovirsen, cabotegravir, camlipixant, depemokimab in EGPA and Jemperli in rectal cancer next year.

And with that, I am pleased to hand back to Emma.

**Emma Walmsley** Executive

Thanks, Julie. So in summary, our Q3 results demonstrate the continued momentum in our business with strong financial performance reflected again in our increased guidance for 2025 and through meaningful R&D progress. Our portfolio continues to demonstrate strength and quality and we're excited by the prospects in our pipeline.

All of this positions GSK strongly for the next phase in the company's development to deliver our long-term outlooks, outstanding impact for patients and sustained value for shareholders. So I'm now going to open up the call for Q&A with the team. But before I do so, of course, we know that alongside questions on our results, many of you will be eager to ask our new CEO designate for his views on the future.



Well, Luke and I both respectfully ask that you don't. I am, of course, so delighted and very proud to be passing the baton to Luke, but that is in January. And today, we'd like to focus on our Q3 performance. So with that, let's please now open up the call for your questions with the team.

**Operator** Operator

Thank you very much, Emma. The first question comes from Peter Verdult from BNP Paribas.

**Peter Verdult** Analyst

Pete Verdult here, BNP Exane. Two quick questions. Firstly, for Julie or Emma, there's a EUR 6 billion revenue gap between market expectations in 2031 and the GSK revenue target over EUR 40 billion. If we move BLENREP's obviously a major point of disconnect. But can you just remind us which other assets you believe are being materially underappreciated?

And then secondly, I hear you about not asking questions about strategy, which I will -- won't go down, but just a factual question for Luke. Is it your intention to either reiterate or tweak the go-forward strategy at the full year results? Or do we have to wait for your unveil later in '26?

**Emma Walmsley** Executive

Thanks. Well, I'll ask Julie just to comment on the difference between our full team shared confidence in the short, medium and long-term outlooks and where the market is today. As we've said before, it is largely in oncology and RI&I.

The only other point I would make is that as well as a gap between the top line, there is also quite a material difference, as we've said before, in our view of the continued leverage of SG&A and where the market currently sits. But Julie, do you want to comment just quickly on that?

**Julie Brown** Executive

Yes, sure. Thank you very much, Emma. Peter, for the question. So the major areas, as Emma mentioned, oncology and respiratory, immunology and inflammation. And we do think the data readouts and commercial execution will make the difference here.

But clearly, the BLENREP launch is one of the areas. Within oncology, I think people are also waiting for the rectal readout in Jemperli.

And then the other difference, of course, is the ADCs recently licensed in from Hansoh, which we're very optimistic about in terms of the future. Within respiratory, I have to say the gaps are closing. They've improved. So we've obviously got the depe PDUFA date in December this year. People are clearly waiting for that.

And then the other one, of course, is camlipixant, where we've got the data readout from CALM this year and then CALM-2 next year. So we think these are going to be the key trigger points that will make a difference between ourselves and consensus.

**Emma Walmsley** Executive

Thanks, Julie. And as you pointed out before, it's always we know, going to be a combination of the launch execution delivery as well as the data that comes. And it is quite pleasing with our upgraded guidance this year as a reminder that our initial outlook of 33 billion to be delivered by 2031. We are well on track to be delivering this year, 6 years early.

So Luke, the second part of the question was related to what's coming despite our shared request in what's coming for 2026. And as usual, we are not going to give a huge amount of detail now about what's coming in '26, but we do want to all as a team reiterate our very high confidence in those not only '26 outlooks, but also '31 outlooks, which are forecasted by this team and committed by this team, as you've heard us all do together again today.

At the beginning of -- with the full year '25 results, you'll hear the outlook for '26. And then later on in the year, the building blocks to delivering that longer-term '31 outlook. But Luke, I know you don't want to say too much, but is there anything else you'd like to add to that?

**Luke Miels** Executive

Sure. Thanks, Emma. Thanks, Peter. Look, what I'll say is, look, the number 40 is doable, and I stand behind it. Look, the majority of the products in it were forecast by me.

**Emma Walmsley** Executive

Right. Well, that's clear. And you'll hear more next year. So next question, please.

**Operator** Operator

Next question comes from Matthew Weston, UBS.

**Matthew Weston** Analyst

Two questions, please. The first for Luke on Shingrix. There was a great benefit ex U.S. from the rollout in France, both in Q2 and Q3. Can you give us some help for the pushes and pulls on Shingrix into '26?

Should we assume that there's been a France bolus, which wanes next year? And then we need a geography to take up the baton. If so, which one? Or do you think there's just consistent rollouts, which mean Shingrix ex U.S. can keep growing?

And then the second one for Julie, another quarter of great margin leverage. I know this -- I promise it's not really a '26 guidance question. But can you at least help us with pushes and pulls on OpEx? So obviously, a statement about R&D reinvestment in 4Q -- how much should we assume that carries on, but also depemokimab, Nucala COPD and BLENREP launches, should we think of needing more next year?

**Emma Walmsley** Executive

Right. So Luke, first on Shingrix and then Julie, on our continued drive for meaningful SG&A leverage, please?

**Luke Miels** Executive

Thanks, Matthew. I mean the short answer in Europe is yes. I mean if you step back, we've quietly pursued a 3-stage strategy, and I've mentioned this on multiple quarterly earnings calls when Shingrix has come up in line with the current label. The first step, of course, was max the U.S. and get to a point where we penetrated and where that starts to slow.

So we've got an immunization rate of 43%, which is in line with the 3% to 5% increment that we've signaled.

It's very much linked to flu though, and flu is softer. And then the plan, of course, was within the U.S., which we started to pivot on to focusing on the comorbid and high-risk subgroups. And that's just started now in June, and I think the results are encouraging. Maybe with hindsight, we could have gone there earlier. But again, we're getting traction there.

So that's a good sign, but the U.S. will still be tough because of sort of macro factors around vaccines, which I doubt we'll get into later.

In Europe, I mean, really, the strategy was to maintain pricing discipline and then build the evidence of the launch in Europe and Japan, and that's exactly where we are now. So the average immunization rate in the top 10 markets ex U.S. is around 10%, about 9.7% to be exact. So there's more opportunities, more work to do as we broaden those populations in those countries.

And then the third part, which we're really not in yet, is a pivot to emerging markets in the midterm with more pricing flexibility. We did start there with China. We had a bit of a challenge there, but we've got a pathway, again, focusing on comorbid and that is resonating despite a tough backdrop. So it's very much a midterm story with China and emerging markets. But yes, net-net, I think we're in good shape with Europe, and we just need to keep that going.

**Emma Walmsley** Executive

Right. Thanks, Julie?

**Julie Brown** Executive

Thank you very much. Thanks for the question. In terms of -- first of all, we're confident in reaching '26 margin target that we laid out of more than 31%. To your point about investment in R&D, we have deliberately been putting more investment behind R&D now for a number of years, and we expect the same next year that R&D will grow ahead of sales. And then in terms of the investment in the launches, we are totally investing in the new launches.

We're here to grow the business. So definitely investment gone already into BLENREP, depemokimab coming up, et cetera, Nucala COPD. These are big areas of investment. The thing that we're doing in parallel, as you've probably seen, is that we are driving productivity benefits also through SG&A and the gross margin.

And basically, we're looking at operating model cost and tech to modify and simplify what we do. These are really important components. And we now have a track record of doing this. We've guided at more than a 31% margin by '26. This will be over 500 basis points of accretion for the company between '21 and '26, which is really a considerable achievement as well as funding those launches.

**Emma Walmsley** Executive

Yes. And as I said, I think we all expect that to continue. I mean just don't underestimate how much technology is changing the way you can effectively and efficiently do sales and marketing work very differently than it has been the history of this industry, and we're all seeing that change happen whilst allowing us to invest very competitively behind the launches that you're considering -- continuing to see us deliver competitively on. Next question please.

**Operator** Operator

Next question comes from Michael Leuchten from Jefferies.

**Michael Leuchten** Analyst

Two questions for Luke, please. One for depemokimab with the pending approval. Luke, can you update us on your latest thinking on phasing of access, likely source of business for the product into 2026? And then BLENREP, there's been a lot of debate after the approval on label, scope, REMS and the like. Is there any learnings you can point to from the -- albeit early experience in Europe or small experience in Europe that helps us understand sort of how the shape of the curve could look like in the U.S.

**Emma Walmsley** Executive

Luke?

**Luke Miels** Executive

Thanks, Michael. I mean I'll start with BLENREP first. Yes, I think there's a number of lessons. I chair a task force every 2 weeks to look at this to ensure cross-functional learnings, and we're certainly incorporating those. I think the key, again, no surprise is that once people have experience with this product, they tend to be, how would I say, pleasantly surprised by the reputation leading into this versus the experience of using it.

And that's why we've been very focused on supporting physicians with those first 5 patients to ensure that they understand the dosing and how to manage that and how to hold doses and integrate that into their practice. And that's everything that we will then take into the U.S. We also have close to 8,000 patients now who've been exposed to BLENREP globally.

So we've got a lot of clinical and operational experience in those centers as well. On depe, look, it's obviously a competitive environment right now. So I'll be careful around some of the phasing around access and our strategy there. But what I will say is I think this is quite a fascinating opportunity.

The basic facts when I try and look at that sort of simplify things is that you've got a lot of eligible refractory patients who, by definition, are at risk of exacerbation. And in the U.S., access is actually extremely good for all biologics. Yet the conundrum, the paradox is that only 27% of them actually get a biologic. And then I think a few physicians must scratch their heads on this one.

Those that do get a biologic, we see this with our data, it's true with Dupixent, Fasenra, et cetera. After 12 months, you're losing around 2/3 of them. So -- and of course, if you're not adherent, you are put on a biologic for a reason. And if you're not adherent, then you have a higher risk of an exacerbation and subsequent ER visit, for example. So for us, there's a clear opportunity here for ATP-driven administration with long intervals between dosing and a strong efficacy that's associated with that.

The market research is very, very consistent. This is probably the most market research product in GSK. And yes, 86% of pulmonologists say this could be a new standard of care when we show them the target label and 82% of pulmonologists said they would consider using this product ahead of other MOAs. So our strategy is very simple. We will be focusing on the naive new patients that are first going on to biologics.

**Emma Walmsley** Executive

I think this is just an extraordinary opportunity when you see the material difference in compliance the material reduction, 72% reduction in the kind of attacks that cause

hospitalization and consequently, a very significant cost sparing benefit for health care systems in such a scale disease as asthma. And then, of course, we're very excited about taking depe into COPD and other indications, too.

**Operator** Operator

Next question comes from Luisa Hector from Berenberg.

**Luisa Hector** Analyst

And maybe I could take this chance, Emma, end of an era. So thanks to you on behalf of all of us, many insightful conversations and I think many significant achievements whilst navigating some of the challenges. So thank you very much.

And my questions would be on business development because we've seen a very neat series of small deals. So where are we now in terms of appetite capacity for the next round of deals and any changes in terms of size or area phasing, et cetera? And perhaps a quick check on the comments you made on J&J and rilpivirine. Should we assume that they can now supply everything you need and that this would not be any kind of constraint when you get closer to filing and launch?

**Emma Walmsley** Executive

Great. Yes. I mean I think we are really supremely confident in our long-acting portfolio, both because of the momentum in the business and the prospects in the pipeline. I'll ask Deborah to talk about that. And in terms of Look, and once again, Luke and Tony and David have been all been co-architects of some deals that we are extremely pleased with the progress on.

It's great to see 3 out of the 4 Phase III or the pivotal trials that are due to start at the end of this year are from deals that we've been very pleased to sign. We're thrilled with the discipline we've put through in terms of value and returns when we look at these deals, whether it's in the -- what's become more fashionable FGF21 market or indeed our ADC plays or of course, we're very excited to see what's going on in terms of pipeline development in China and thrilled to see where that partnership with Hengrui will do.

And then, of course, once again, we added a couple more deals just this week in our earlier stage pipeline because we're all very focused and you're all very focused on the models of what's happening with the [ Core ] 15, but I know how much the team are also thinking about that next wave of development through the 2030s when we come out the other side of successfully digesting dolutegravir.

So I think you should expect that BD will continue to be a very -- it's about half of our pipeline, and it will continue to be a very material contributor to our pipeline with a focus on RI&1 and onc and the kind of scale and pace. But we're always going to be looking out at things and review it very, very regularly.

And obviously, the market stays competitive, and we're right in the middle of that. So not much more, I think, to add on that. But let's get back to long-acting. Now 1/3 of our -- or 30% of our business in the U.S. already.

So Deborah, do you want to talk about that and the pipeline question?

**Deborah Waterhouse** Executive

Yes. Thanks, Emma. So just to start, delighted with the Cabenuva performance, 75% growth in the quarter. And actually 75% of our Cabenuva switches now come from competitors. And our long-acting injectable performance is at the heart of why we've been able to upgrade our HIV guidance this quarter.

So let's just talk a little bit about Q4M. So our Q4M QUATRO Phase III study start is going to be delayed into H1 2026, and that's due to a delay in the delivery of recovering clinical trial supply by Janssen.

There is no ongoing issue, which would cause us anything but complete confidence from Janssen. They're a great partner. This is just a one-off. I think the key thing to communicate is that this is a clinical trial, supply delay is not related to efficacy or tolerability concerns at all, and we remain committed to 2027 file and 2028 launch of Q4.

We've looked over the financials and there's no material impact on outlook from the delay because we've got Cabenuva in the market already, and that product is performing so well. Demand is high. We've got really fantastic momentum. And whilst we're disappointed, obviously, not to be able to launch Q4M at the end of 2027, as we originally said, actually, this is a marketplace where there's no competitor for a long, long period of time.

So we are the only long-acting injectable in treatment, and we're going to remain that way for the foreseeable future. Cabenuva will power on, and we will do everything we can to get Q4M into the marketplace as soon as we can. And then obviously, we've got Q6M coming next year. We will be doing our regimen selection for Q6M, and then we will be launching that asset as the next phase of our long-acting injectable journey.

**Emma Walmsley** Executive

It's just so important to remember that we are the only one on the treatment market for a very long time ahead, and that is a business that continues to accelerate momentum.

**Deborah Waterhouse** Executive

And there are obviously, Emma, as we've seen ourselves, some sort of bumps in the road of long-acting injectables that we and our competitors experience. So I think it's just a complicated area, mainly around CMC. But in terms of the patient benefit, really significant and the demand from patients is also very material.

**Operator** Operator

Next question comes from Sachin Jain from Bank of America.

**Sachin Jain** Analyst

Just a follow-on actually to the Q4M question. So thank you for that update, Deborah. I wonder if you could just talk about the commercial impact of delay relative to Gilead's weekly oral len plus islatravir, which is probably 6 to 12 months ahead. We hear mixed KOL feedback on weekly oral versus Q4.

Secondly, I wonder if you could just update on U.S. policy. So any color you're willing to give on ability to do a deal with the administration given your high Medicaid exposure? And then how is dialogue around IRA going? And then just one quick clarification, if I can chance my arm for Luke as a follow-on to earlier question on BLENREP depe.



Clearly bullish commentary, Luke, but just trying to triangulate versus '26 consensus for both, which is around GBP 200 million. I know it's a tough question, but any color directionally would be helpful.

**Emma Walmsley** Executive

Luke, do you want to say anything on that?

**Luke Miels** Executive

Look, I would just say these are big assets in the long term. I can't give any sort of color, but clearly we're going to approach both assets very aggressively. And I would just point to the performance in Nucala COPD, where in May, we had 0% market share, and we've now got 46% of those new patients in COPD against Dupixent. That's not a read across depemokimab.

It just tells you that the team is very effective at executing, and we're going to be focused on that asset and BLENREP already in the field and receiving very good feedback. Again, it's going to be more of a stage process to give people experience and confidence to use the product more broadly.

**Emma Walmsley** Executive

Great. So on MFN, I'm not really going to give any more detail or get ahead of anything, except to say, as you would expect, we're engaging, as I've said, very constructively with the administration. Medicaid is 10% of our total U.S. business. I'm really confident in our ability to navigate this over the last 4 years through a variety of different environments.

The strength and quality of our portfolio has continued to allow us to do repeated upgrades and navigate through these kinds of challenges.

The U.S. is our #1 priority market. We've committed to very material investments there. And we fully agree that we should be partnering and working towards being in a place where step change innovation can be made affordably available and sustainably available for innovators to American patients. And we also fully agree that we'd like to see all countries recognize the value that innovation can bring -- to bring down the demand care on health care.

So the demand, sorry, curve and therefore, the cost on health care. So continue to engage here and we'll keep you updated and very much bearing in mind and sits with a strong underpin to our confidence on our outlook overall. You mentioned IRA. I think Luke already said it. We're very pleased to have concluded the latest rounds of IRA negotiations and all fully factored into our outlook.

So nothing more to report on that. And on islatravir, I think that is an important point to remind people of.

**Deborah Waterhouse** Executive

Yes. Thanks, Sachin. So there is an expectation that LEN plus islatravir will launch in 2027. All of the research that we have done indicates that the once weeklies will cannibalize other orals. And actually, there is on that particular asset, a bit of a mixed view, firstly, because of the history of islatravir and the CD4 depletion.

But secondly, I mean, we absolutely believe that you need to have an integrase at the core of any 2-drug regimen, whether it is an oral weekly or a long-acting injectable because integrase have

got incredible potency, tolerability, high barrier to resistance and 78% of those people who are on treatment today are on an integrase inhibitor because they are the cornerstone of HIV treatment.

Now we know that obviously, the other once weekly from our competitor, which is the prodrug of LEN and an integrase inhibitor is on clinical hold. So again, you've just got the islatravir plus the lenacapavir option in '27, and we don't think that's going to be a challenge to our Q4M, one, because the long-acting injectables is a very unique value proposition; two, because we've got an entity at the core of that particular regimen. So we're feeling very confident about our ability to keep driving our HIV business forward and growing strongly and helping GSK navigate through the loss of exclusivity of dolutegravir.

**Operator** Operator

Next question comes from Simon Baker from Redburn.

**Simon Baker** Analyst

Two, if I may, please. Luke, going back to something I asked you on the BLENREP call on Friday around the 2031 target. Back in '21, you gave a number of peak sales estimates for products in RSV, BLENREP, Juluca and Jemperli. You've reiterated the EUR 40 billion target. I just wonder if you could give us thoughts on the pushes and pulls.

You always said that there were a lot of factors going towards the aggregate figure, but just a check on where you see the pushes and pulls there would be very helpful. And then for Deborah on HIV and the Q4 slight delay, that pushes it a little bit closer to the Q6 launch, but not materially so. So I'm guessing you've always thought that it's not one duration fits all. I just wonder if you could give us some thoughts on how the long-acting market will pan out with the various injection duration options that you will be offering?

**Emma Walmsley** Executive

So I'm going to come to Deborah first on this. But also -- and I will turn back to Luke. But just to be clear, as we've already said, it will be beginning of next year when Luke will give an outlook for '26 and more likely much later in the year when he will talk about the building blocks to deliver on more than 40 and his more than 40 in 31. So I just want to give Luke the permission not to get into detail of the ups and downs as the portfolio continues to mature. But Deborah, let's come to you first.

And Luke, if you want to add anything to that, then I'll let you.

**Deborah Waterhouse** Executive

Thanks for the question, Simon. So with Q2M, 15% of patients would be willing to take that regimen to treat their HIV. When you get up to Q4M, it doubles to 30%. And then when you get to Q6M, half of the people who are living with HIV and all of our research say that they would be willing and keen to take a 6-month long-acting injectable.

Within the research, though, and with physicians, too, you are right. Some people say, actually, I would like to give Q4M to my patients on an ongoing basis because I like to pull them back into the doctor's office 3 times a year to have viral load testing, sexually transmitted disease testing and all the things that they do to care for their patients. Others are very keen to see that their patients go to Q6M.

So there will not be one size fits all, but what there would be is a market expansion that is significant as we extend the duration between administration from 2 to 4 to 6. And obviously, when we get to Q6M, it's a brand-new set of medicines because you've got the third-generation integrase inhibitor, VH184, which has a unique resistance profile and is a third-generation integrase inhibitor.

And then you have a capsid inhibitor or N6LS depending on which regimen we select for our Q6M, and it's great to have options. So feeling very bullish about the future of Q6M, but also see a place for Q4M as patient choice remains critical.

**Emma Walmsley** Executive

Thanks, Deborah. Luke, any comments you want to add?

**Luke Miels** Executive

Thanks, Simon. I mean I would just say, again, confident overall in the late-stage assets. And yes, we look forward to updating everyone with the team next year. In terms of BLENREP, I mean, look, it's going to be material.

I said that over the next couple of years. And the key is obviously the initial launch and then the pathway to second line, which Tony is very much in hand and the usual pushes and pulls with competitive data sets.

**Operator** Operator

Next question comes from Sarita Kapila from Morgan Stanley.

**Sarita Kapila** Analyst

Thanks for the color on Nucala. I was just wondering if we could have a little bit more on the rollout in COPD, how the launch is going versus your initial expectations and where you're seeing the most use? Is it in the 150 to 300 eosinophil group? Or is it in the over 300 where it would be more head-to-head with Dupixent? And then the second one on Jemperli, please.

It seems to be a very strong rollout in the U.S. or momentum in the U.S. How penetrated are you now in endometrial cancer? And is this momentum sustainable into 2026? And should we think about Jemperli being able to get to your guide of over \$2 billion in the existing indications?

Or would you definitely need the pipeline to hit that?

**Emma Walmsley** Executive

So we'll come to Luke on both Nucala and Jemperli, but I think it would be good as well when we've heard on the Nucala launch, just to hear a little bit from Tony because I think we are all want to know, we're all getting more and more ambitious on the portfolio for COPD, whether that's depe or the other assets that we're bringing forward.

I know when we announced the deal we just did, the statements that it's going to be the leading cause of hospitalization in coming years. And we're talking about hundreds of millions of people. So this is really a scale disease where we have a lot of expertise for the pipeline coming forward. But in terms of what's in hand right now, do you want to comment on Nucala and?

**Luke Miels** Executive

Yes. I mean -- thanks, Sarita. It's broad. I mean when I was talking to the BU head in the U.S. about this, he said broad several times, broad label, broad uptake, broad resonance.

And I mean, another market research point that's interesting is 9 out of 10 U.S. pulmonologists strongly agree that preventing severe exacerbations is essential to COPD management.

I'm not sure about the 1 in 10. I don't suggest you go and visit them. Yes, clearly, it's landed well. But as I've said on other calls, this is a population of prescribers that only use it in 1 in 3 patients for many reasons. So that is just a balancing caution, but how we're going against Dupixent is very encouraging.

Yes, it's across the label, both bronchiectatic emphysema and different EOS levels.

**Tony Wood** Executive

Just moving on and on Jemperli. In terms of endometrial, obviously, we're pleased that we have the only and first label with dual primary endpoints of PFS and OS and endometrial cancer. We're following that up with a study called DOMENICA, which is looking at evaluating gemperirdine a chemo-free regimen. Importantly, as well, obviously, the rectal studies continue to progress well, where we have fantastic complete responses.

Just a quick reminder on some of those programs for you, AZUR-1, which is the locally advanced MSI-H rectal results, which we're expecting to read out in the second half of '26. AZUR-2, which is colon cancer, and there's an interim for that in '28 and the JADE study, which is in the unresectable head and neck setting for which we're also expecting readouts in '28. So lots of momentum going around Jemperli to continue to support the growth of that medicine.

**Emma Walmsley** Executive

Anything you want to say on COPD?

**Tony Wood** Executive

On COPD, just look, I'm delighted with where our COPD portfolio is currently sitting. You may have noticed we have now 3 Phase III studies starting in COPD. There are the ENDURA-1 and 2 studies in the more typical COPD population and a study called VIGILANT, which is looking at earlier COPD patients.

These are individuals who are not treated typically with bios, but for which they have secondary factors. that predispose them to rapid progression. Coming along behind all of that solidly is the long-acting TSLP and IL-33 options. And as Emma has mentioned, the ongoing option in PD3/4 and the latest deal that we have with Empirical that was announced this week with an entirely new novel mechanism, which is [ oligo-based ].

**Luke Miels** Executive

Yes. And Sarita, back on your question on Jemperli and endometrial. And I think the good news overall, if you just look just in the last 12 months, you've gone from 80% of ONK using IO typically in endometrial to now 96%, which is great. 90% of these patients are now on some form of IO. For us, there are clear opportunities if a physician can accurately cite the RUBY overall survival figure, then the likelihood of using the drug is double that versus someone who can't.

So that's our focus is the DMMR population. We do have the broad label, of course. MMRP tends to be more dominated by pembro. But globally, there's about a 5% difference in market share in our favor against pembrolizumab, which is very encouraging.

**Emma Walmsley** Executive

Yes, lots coming on.

**Operator** Operator

Next question comes from Zain Ebrahim from JPMorgan.

**Zain Ebrahim** Analyst

This is Zain Ebrahim from JPMorgan. So my first question is on BLENREP. You talked about it, but you mentioned that you expect to see a material growth driver over the next 3 to 4 years. So how much of that growth do you expect to come from the U.S. based on the current label versus ex U.S.?

And how much of that is driven by the expected indication expansion in 2028? That's my first question. And my second question is just on general medicines. It sounds like the Trelegy IRA negotiation was in line with your expectations. So how are you thinking about the development of general medicines over the midterm?

**Emma Walmsley** Executive

Yes. I mean, on GenMed, we're not going to change our '21 to '26 guidance, which we upgraded slightly because of the operating performance. So there's no more update on that. And I'm not sure, Luke, how much you want to itemize. I know Darzalex is about half x.

**Luke Miels** Executive

Yes, that's right, Emma. I mean, I think, look, the priority is to get to second line in the U.S. to match the rest of world label. The U.S. initially will be ahead of Europe because we're launching.

But as markets like Germany and Japan come online, that should balance out over time.

**Emma Walmsley** Executive

Yes. And I think as Luke can tell you went through in great deal of detail on the calls. There is a material opportunity in third line, and we have a good pathway to getting to second line. And in fact, studies planned, as you all know, in first line, too. So I think this is definitely one to watch as part of our broader oncology portfolio, which continues to build.

So look, I just want to say one last thing because I know that was our last question, and we went -- because we had a technical issue, I think, at the beginning, so apologies if you were made to wait. You do know this -- I know this is my last quarter to report as CEO. And I do want to just take a moment to thank everyone on this call for your time and engagement with me and most of all, with this tremendous team who over the last 9 years together have transformed our great company's performance, pipeline and prospects.

And in doing so, we've set out a clear pathway for patient impact at serious scale, already 2 million -- 2 billion, sorry, people around the planet. And I firmly believe that GSK's value for shareholders will be fully recognized and sustained. And when you step back and reflect, it's

really hard to think of a sector that matters more than ours, where innovation and trust really can change people's lives and drive sustained performance and value for shareholders.

And all of us, whether it's those of us here in this room or everybody on the call, well, we're all part of a really extraordinary incredible industry, and it's a privilege to be part of it, and it is not a responsibility to leave lightly. I am so delighted and very proud to be passing the baton to Luke and to be leaving all that GSK has to offer in such fantastically good hands.