GSK plc

GSK plc - Q3 2023 Earnings Call

Wednesday, November 1, 2023 8:00 AM

Event Participants

Executives 6
Nick Stone, Emma Walmsley, Tony Wood, Luke Miels, Deborah Waterhouse, Julie Brown

Analysts 10
Graham Parry, Kerry Holford, Simon Baker, Andrew Baum, Richard Parkes, James Gordon, Mark Purcell, Steve Scala, Peter Welford, Emily Field

Nick Stone Executive

Hello everyone, it's Nick Stone, Head of Investor Relations. Welcome to our year-to-date and Q3, 2023 results conference call and webcast for investors and analysts.

The presentation was sent out to our distribution list by e-mail, and you can also find this on GSK.com. Please turn to Slide 2.

This is the usual safe harbor statements, we'll comment on our performance using constant exchange rates, or CER unless stated otherwise. As a reminder, the following the Consumer Healthcare demerger in 2022 to form Haleon, representing performance and growth of the continuing operations for GSK. Please turn to Slide 3. Today's call will last approximately 1 hour, with the management presentation taking around 30 minutes, and the remaining time for your questions. [Operator Instructions]

Our speakers are Emma Walmsley, Tony Wood, Luke Miels, Deborah Waterhouse and Julie Brown, with David Redford joining the rest of the team for the Q&A portion of the call.

I'll now hand the call over to Emma.

Emma Walmsley Executive

Thanks, Nick, and welcome to everybody joining us today. I am delighted to be presenting to you all with another set of excellent quarterly results. Please turn to the next slide.

Sales and profits grew double-digits for the quarter, with sales up 16% to GBP 8.1 billion. Adjusted operating profit up 22% to GBP 2.8 billion. And adjusted earnings per share up 25% to GBP 50.4p, all excluding Pandemic solutions.

Our strong performance was broadly based and benefited particularly from the outstanding U.S. launch of our RSV vaccine, Arexvy, on track to be a blockbuster in its first year on the

market. This excellent execution, together with our drive for efficiency and margin accretion means we can upgrade our 2023 sales, adjusted operating profit and adjusted EPS guidance.

For the year, we now expect sales to increase between 12% and 13%, adjusted operating profit to increase between 13% and 15%, and adjusted EPS to increase between 17% and 20%.

Within sales, we are upgrading the outlooks across all segments for the year, reflecting our clear momentum. Our performance also clearly demonstrates delivery of the strategic choices we've made to invest in prevention as well as the treatment of disease.

New products launched since 2017 have contributed sales of GBP 7.8 billion so far this year, with nearly 80% of them coming from vaccines and specialty medicines.

Approvals this year for Arexvy and Apretude, together with 2 important oncology medicines, Jemperli, and most recently, Ojjaara, further strengthened this new product portfolio and other meaningful sources of profitable growth.

So taken all together, this is a strong and sustained performance heading into 2024. Next slide, please.

This quarter further underscore the importance and strength of our vaccines business. Prevention is an increasing focus for health care systems all around the world. GSK is a world leader in vaccines and is extremely well placed to deliver innovation and offer value to both individuals and payers.

The introduction of Arexvy in the U.S. is evidence of this, demonstrating our strong launch capabilities, with over GBP 700 million of sales in its very first quarter as we protect people at scale, from this life-threatening disease and especially those with comorbidities.

Generating further clinical evidence for Arexvy remains a clear priority, and we were pleased to present positive data in adults aged 50 to 59 years at the CDC's Advisory Committee on Immunization Practices last month.

We also added to the outstanding clinical profile of the Shingrix this quarter. Results of a large post marketing study in China, demonstrating 100% efficacy. And alongside this, we're additionally significantly expanding availability of Shingrix in China. Our exclusive partnership with Zhifei signed last month is going to support and accelerate our goal with Shingrix annual sales of more than GBP 4 billion by 2026, and with opportunities to expand this partnership further, including potentially with Arexvy.

Our innovation in RSV, shingles, meningitis and pediatrics all demonstrate our world's leading vaccines capabilities. And we have further substantial innovation in the pipeline where we have our comprehensive and leading suite of vaccine platform technologies, including next-generation mRNA, our multiple antigen presenting system or MAPS, as well as, of course, as our adjuvant systems.

All of these offer exciting new opportunities in seasonal respiratory bacterial and chronic viral infections, and we continue to explore the science beyond infectious diseases. Next slide, please.

Alongside delivering stronger shareholder returns, we also continue to build trust by delivering across the 6 key areas we prioritized for ESG. This quarter, I'm highlighting our continued commitment to fight malaria with innovation. GSK scientists, working with Johns Hopkins Institute and others, published their groundbreaking discovery in the naturally occurring bacteria and that can significantly reduce the malaria parasite [load] in mosquitoes, indicating the potential to inhibit transmission of malaria to humans.

And we also continue to deliver our environment and diversity, equity and inclusion goals. Further details, along with more on all 6 key areas, are included in the Q3 results announcement.

Now, let's hear more from the team on our progress, starting with Tony and R&D.

Tony Wood Executive

Thank you, Emma. My priority is investing in our pipeline and accelerating R&D to deliver new vaccines and medicines to patients.

Today, the pipeline comprises 67 assets in clinical development, 2/3 disease prevent and treat infectious diseases and HIV.

During the quarter, we've seen continued progress. In infectious diseases, we're focused on seasonal respiratory viruses, bacterial, fungal and chronic viral infections. In seasonal respiratory viruses, Arexvy received approval in Japan as the country's first RSV vaccine for older adults.

And we also shared positive data for 50 to 59 year olds, with the advisory committee on immunization practices in the U.S. In chronic viral infections, we will present data later this month on bepirovirsen, a potentially transforming treatment for chronic hepatitis B. I'll talk more about these data shortly.

In HIV, the European Medicines Agency approved Apretude as the first and only HIV prevention option in combination with safer sex practices to reduce the risk of sexually acquired HIV infection in high-risk adults and adolescents.

For respiratory, Japan accepted the regulatory submission of Nucala for chronic rhinosinusitis with nasal polyps. And later this month, alongside Luke, I look forward to providing you with insights into our respiratory strategy and medicines at the next focus to meet the management event.

For oncology, the European Medicines Agency recommended not renewing conditional marketing authorization for Blenrep. As a reminder, given the changing regulatory environment, our expectation to remain low for the event-driven DREAMM-7 and DREAMM-8 Phase III trials. We now expect to read these out in 2024.

This quarter, we also reached an exclusive licensing agreement with Hansoh for a Phase I B7-H4 targeted antibody-drug conjugate or ADC. We believe this has best class potential in ovarian and endometrial cancer with opportunities in other solid tumors.

Lastly, we are delighted with the U.S. FDA approval of Ojjaara or momelotinib, which is

indicated for treating myelofibrosis in adults with anemia. And the approval of Jemperli, our highly effective PD-1 inhibitor, as the first new frontline treatment for patients with dMMR/ MSI-H, primary advanced or recurrent endometrial cancer.

The profile with for Jemperli was strengthened by the recent interim analysis of RUBY [Part 1], which reported a statistically significant and clinically meaningful survival benefit in the overall population enrolled. We aim to present these OS data at a conference early next year. Next slide, please.

Last week, we presented further safety and immunogenicity data for Arexvy to ACIP. The vaccine met its co-primary endpoints and demonstrated non-inferiority in people aged 50 to 59 years of age when compared with adults of 60 years and older, including those at increased risk of RSV lower respiratory tract disease.

These data continue to demonstrate the consistent strength of Arexvy profile in protecting the most vulnerable. We will make a supplementary biological license application to the U.S. FDA before the end of this year, in time for next year's ACIP to further support potential label updates.

For Shingrix, we continue to build our knowledge with new data, demonstrating 100% efficacy in the prevention of shingles in China for adults aged 50 and over, a remarkable result. We expect to publish these data in a peer-reviewed scientific journal before the end of the year. Slide 11, please.

Continuing with infectious diseases, bepirovirsen, our triple-action antisense oligonucleotide has the potential to be the cornerstone of functional cure for patients with chronic hepatitis B. It inhibits viral replication, reducing viral DNA, and thus the production of viral proteins, including the hepatitis B surface antigen. And importantly, it stimulates the body's innate immune system.

We believe this triple mechanism of action is the reason for bepirovirsen's unique profile.

There are more than 300 million people living with hepatitis B, and our goal is to provide patients with the first clinically meaningful functional cure for hepatitis B, eliminating the need for continued therapy and ultimately reducing the long-term risk of developing liver cirrhosis and cancer.

We now have 2 completed Phase II trials, for which data are consistent, and demonstrate the patients with low surface antigen have the greatest chance of a functional cure when treated with bepi. In the case of B-Together, this has not significantly improved by sequential Peg-interferon treatment.

However, the recent exclusive license of Janssen's Phase II small interfering RNA-based therapeutic provides a complementary opportunity to develop a potential novel sequential regimen to benefit a broader patient population and potentially drive higher functional cure rates.

Lastly, we hope data from B-Sure will be presented later this month at AASLD. This will demonstrate a durable response for a significant proportion of patients treated with bepi.

Our Phase III trials, B-Well 1 and B-Well 2 are progressing as planned in 31 countries, with data anticipated in 2025.

Turning to my final slide. This slide highlights important clinical data readouts and regulatory events over the upcoming months. You can find a comprehensive overview in the appendix.

In summary, I'm pleased with our progress so far this year. We have clear plans to move forward at pace, deliver on our key objectives for R&D and support GSK's overall growth ambitions. I'll now hand it over to Luke on Slide 13.

Luke Miels Executive

Thanks, Tony. In Q3, we again delivered growth across vaccines and specialty medicines in each region with GBP 8.1 billion of sales, up 16% versus last year, excluding pandemic solutions. Please turn to Slide 15.

In Vaccines, we saw strong growth of 34% in the quarter, excluding Pandemic Solutions, led by the excellent launch of Arexvy which contributed GBP 709 million.

On the same basis, we now expect full year vaccine sales growth to be around 20%.

On Arexvy, I want to highlight the excitement our organization has had behind the launch that we've seen in the U.S. Following an initial inventory build, we saw high demand and received 2 out of every 3 retail prescriptions.

In the quarter, we saw around 50% of Arexvy doses were co-administered with flu, and we're pleased with our commercial positioning in all major pharmacies, including competitive contracts with 11 key accounts. We strategically chose to highlight our 94.6% efficacy in the comorbid population, and that message seems to resonate well with strong HCP brand recognition.

There's a long runway for Arexvy in the U.S., where during the quarter, we've vaccinated more than 1.4 million adults of the 83 million at risk, and ex U.S. as launches are underway across Europe and Canada.

In September, we also received approval in Japan.

We remain confident in our peak sales being greater than GBP 3 billion. For the full year, we expect sales to be between GBP 0.9 million and GBP 1 billion based on an analog of flu vaccination seasonality. However, there continue to be unknown factors, including annual vaccination patents, formulational projection and what revaccination recommendations might be. We will continue to keep you informed, of course, as we learn more. Next slide, please.

Moving to Shingrix. This remains an important vaccine for our portfolio, up 15% versus last year, with the ex U.S. contribution, now representing 50% of sales.

In addition to the U.S., Shingrix is available at 38 additional countries, with less than 3% penetration in most markets, and we continue to have unconstrained supply.

In the U.S., we've reached the most motivated consumers with 33% penetration of more than

120 million adults recommended to receive Shingrix. We remain encouraged by the growth in retail, which was up 4% in the quarter, and are investing in strategic initiatives to actively target consumers and ACPs to access the next tranche of customers. In October, we announced a deal with Zhifei to copromote Shingrix in China, and this partnership materially expands the number of Chinese adults who can benefit from Shingrix over the next 3 years through a company with a track record of driving access to innovative medicines and vaccines in China.

Zhifei has a significant reach across China with an extensive service network, covering more than 30,000 points of vaccination versus the current 9,500 we have now. As Emma mentioned, we expect this partnership to support and accelerate our expectations for Shingrix sales to reach more than GBP 4 billion by 2026. Next slide, please.

In specialty medicines, including HIV, which Deborah will cover shortly, we've increased our sales by 17%, excluding [indiscernible]. For the full year, we now expect low double-digit sales growth.

Our market-leading medicines, Benlysta and Nucala continues to deliver double-digit growth. Benlysta was up 20% in the quarter, with growth across all major markets and a promising opportunity with updated [ULI] guidelines now recommending use earlier as part of a standard of care for lupus and lupus [erythematosus]. Nucala is up 19% in the quarter and remains the first and only biologic approved in 4 eosinophilic diseases. We expect to see COPD data for Nucala in the second half of next year. Both of these medicines continue to have room to grow with relatively low buyer penetration and life cycle opportunities underscoring our confidence in the long-term opportunity for both.

In oncology, sales were up 26% in the quarter, with Jemperli now being used in the first line for appropriate endometrial cancer patients. And Zejula is up 22% due to stocking of our new tablet formulation, providing an improved patient experience. We expect this stock will be utilized by the end of the year.

And on this slide, I wanted to highlight the recent approval of our myelofibrosis medicine, Ojjaara, in addition to a line-agnostic label in the U.S., regulators acknowledge our unique benefit in anemia, an especially important characteristic for these patients. As we know that anemia status and requirements of transfusion directly correlate with poor survival prognosis and quality of life. And as you can see on this chart, if you have myelofibrosis, patient with no anemia, you have a median 8-year life expectancy. Conversely, you have a 2-year life expectancy if you're severely anemic. So for example, your hemoglobin level is below 8.

We look forward to making this medicine available to patients and have already recorded sales in September. And with these updates, we're raising our full year oncology sales expectations to increase to low single digit. Please turn to Slide 18.

Finally, our General Medicines portfolio continues to contribute more than GBP 2 billion in the quarter, led by Trelegy, which was up 23%. Trelegy is the fastest-growing triple therapy for COPD and asthma, with room to grow as the SITT class still only has 28% penetration of the COPD patient class share in the U.S.

Overall, General Medicines were down 2% for the quarter, due to negative RAR impact,

slightly offset by Trelegy demand and continued post-pandemic recovery of the EU and international antibiotic market. Taking everything into account, we now anticipate low to mid-single-digit growth this year.

And with that, I'll now hand over to Deborah to cover HIV.

Deborah Waterhouse Executive

Thank you, Luke. Our HIV business delivered sales of GBP 1.6 billion in the third quarter, growing 15%. This growth was primarily driven by patient demand, which contributed 10 percentage points of growth, with the majority of the remaining 5 points from tender phasing in our international business. Our continued strong performance during this quarter means we are now increasing our guidance for full year growth to around 10%. Our performance benefited from strong patient demand for our oral 2-drug regimen and long-acting injectable medicines, which are now 53% of our total portfolio value.

Dovato delivered GBP 477 million in the quarter. Market performance reflects HCP belief in Dovato, which has firmly consolidated its position as the leading oral 2-drug regimen.

I'd like to spend a few moments describing our expectations around dolutegravir loss of exclusivity. In Europe, the composition of matter patent expires in July 2029. In the U.S., dolutegravir is protected by a composition of matter patents until April 2028, which includes an additional 6 months of exclusivity, following the completion of our pediatric studies.

Dovato and Juluca are also protected by formulation and other patents in the U.S., which have expiry dates after the composition of matter patent. Therefore, we anticipate a longer exclusivity period in the U.S. for Dovato until December 2029, and Juluca until July 2030.

Turning to our long-acting injectable portfolio. Cabenuva sales for the quarter were GBP 182 million, reflecting strong patient demand with higher levels of market access and reimbursement across the U.S. and Europe. Cabenuva continues to be supported by strong label evolution and data, which underpins confidence. Patient awareness of Cabenuva is high at over 70%, and around 2/3 of switches are coming from competitor products.

Moving on to prevention. [Cabotegravir], the world's first long acting injectable for the prevention of HIV delivered GBP 37 million in the quarter, and we are pleased by the momentum across the U.S. This, alongside the desire by prescribers, payers and governments for a new solution to help in the HIV epidemic gives confidence that the PrEP appropriate market in the U.S. will continue to grow strongly. We were also pleased to receive European approval for Apretude in September.

We're also pleased by the progress of our pipeline, which is focused on innovative long-acting regimens. We have 3 clear target medicine profiles to provide the world's first, sub-administered, long-acting regimen for treatment, and to provide ultra-acting regimens for treatment and prevention.

In our recently HIV Meet the Management event, we confirmed that we are currently on track to deliver on every 4-month injectable regimen. This would enable us to double the dose interval, enabling clinic visits to be halved to just 3 per year, meaningfully increasing the

benefit of long-acting measure for patients and health care systems.

For 4-monthly dosing and prevention, we said we can expect approval in the 2026 time frame and for 4-monthly agreements in 2027. We also provided greater clarity on our road map to further extend the dosing interval of our long-acting regimens in treatment to prevention to enable every 6 months dosing towards the end of the decade.

To conclude, we remain very confident in our ambition to achieve a 5-years sales CAGR to 2026 of 6% to 8% and to maintain our innovation leadership in HIV. This combined with the continued growth of the long-acting market, gives us the potential to significantly replace the revenue from the Dolutegravir loss of exclusivity. I will now hand over to Julie.

Julie Brown Executive

Thank you, Deborah, and good afternoon, everyone. As you've heard from the team, we've made great progress on our road map since the second quarter results, and we're well positioning into the end of the year. We continue to be focused on execution, our pipeline, capital allocation and investor engagement. And as Tony mentioned, we've had several regulatory approvals, including Ojjaara and Jemperli during the third quarter. And following our HIV Meet the Management Event in September, we look forward to holding a similar event focused on respiratory on the 30 of November.

Please now turn to Slide 22.

Turning to the quarter, as I will cover the financials references to growth are at constant exchange rates, and I'll focus my comments on adjusted results.

So starting with the income statement. Sales increased 16%, excluding COVID solutions, were up 10% overall, reflecting continued strong execution with the extremely successful launch of Arexvy. Gross margin improved 80 basis points, excluding COVID, and 360 basis points CER, including the impact of lower sales of [indiscernible]. SG&A growth was 14%, excluding COVID. And as a reminder, in Q3 last year, we had foreign exchange gains on the [Wyeth] collaboration, which contributed 3 points of reported SG&A growth this quarter due to the credit last year.

Adjusted operating profit grew 22%, excluding COVID solutions, and 15% overall. The margin increased to 34%, driven largely by cost of goods improvements and operating leverage.

Turning to the reported results. Total operating profit increased 83% to GBP 1.9 billion, and this was driven by overall performance, as well as favorable CCL movements and fair value gains from our stake in Haleon. The reconciliation of total to adjusted results is included in the appendix. On currency, there was an adverse 6-point impact on sales, and 9 points on adjusted operating profit primarily due to the strengthening of sterling against the U.S. dollar.

Please now turn to Slide 23.

Moving to the adjusted operating margin dynamics in the quarter. The margin increased to 170 basis points to 35% at CER and improved 180 basis points, excluding COVID solutions. Overall, cost of goods have been favorable, primarily reflecting reduced sales of lower margins of Xevudy and an improvement in mix towards specialty and vaccines.

Regarding SG&A, we are in an investment cycle, supporting our priority products. Our spend is focused on maximizing the launch of Arexvy, building awareness of RSV and catalyzing the global market expansion opportunity for Shingrix. We now have approval in 39 countries for Shingrix, and 18 countries for Arexvy. Specialty Medicines is also a targeted investment area, with clear opportunities for the long-acting HIV franchise and the launch of Ojjaara in oncology.

We confirm our guidance for SG&A this year, with growth broadly in line with sales. It is important to say that following a period of investment, we now expect to move to a period of delivering returns on that investment and building on the great foundation of performance. In this new cycle, SG&A growth will step down and will be accretive to profits in 2024. Next slide, please.

Adjusted earnings per share grew 17% overall and benefited from lower net finance expense, following debt restructuring and a favorable tax rate, partly offset by higher range profits, leading to an increase in noncontrolling interests. Next slide, please.

Cash generated from operations was GBP 4.4 billion in the year-to-date and GBP 1.4 billion lower than the prior year. There are 2 major items to call out. Firstly, the receipt of the Gilead settlement last year of GBP 0.9 billion, and secondly, the increase in working capital influenced by stronger Arexvy sales in Q3, and lower Xevudy collections.

The Arexvy sales will come through in the fourth quarter cash flow. Free cash flow more than doubled to GBP 1.7 billion in the third quarter, and brought the 9-month year-to-date to an inflow of GBP 1.3 billion. Cash expectations for the year have improved, but we still anticipate that 2023 cash generated from operations will be slightly lower than 2022 due to the one-off received from Gilead last year. We confirm our commitment of more than GBP 10 billion of cash generated from ops by 2026. Net debt stands at GBP 17.6 billion, with free cash inflow and proceeds from the Haleon stake, partly deployed through business development and the acquisition of BELLUS Healthcare.

Turning now to the guidance on Slide 26. Given our sustained strong performance across all segments of the business, we are upgrading our guidance at CER for the full year. And as a reminder, guidance excludes the impact of COVID-19. We now expect sales to increase 12% to 13%. We expect adjusted operating profit to increase between 13% and 15% and adjusted earnings per share to increase 17% to 20%.

The strength of the Arexvy launch has been ahead of our initial expectations. That is the main source of the guidance upgrade. Q3 sales of Arexvy benefited from strong demand and initial channel inventory build, with TRx volumes representing around 1/3 of the volumes sold.

As Luke referenced, we are projecting our forecast for the season in line with the high dose flu analogs, and therefore, we expect full year sales of around GBP 0.9 million to GBP 1 million. There is, however, still much to learn, given the novel nature of this new vaccine, including annual vaccination patterns, duration of protection competitor dynamics and what expert recommendations might be. And we anticipate further insight following the end of the U.S. flu season, which will inform our outlook for 2024. We look forward to updating you further as part of our full year results.

I remain confident in our longer-term revenue ambition for Arexvy.

Turning to the dynamics within upgraded guidance. Within sales, we're increasing our expectations across all product groups. We now anticipate vaccine growth of around 20%. Specialty medicines to grow low double-digits, and within this, HIV to grow around 10%. And general medicines to grow low to mid-single digits.

Moving down the P&L to operating profit. We now expect royalties to be around GBP 900 million, with no change to our expectations for the other lines of the P&L. To EPS, we expect lower interest expense to between GBP 650 million and GBP 700 million. In terms of currency, FX exchange rates were to hold at the closing rates on the 30th of September for the rest of the year. The estimated adverse impact on sterling turnover growth for the full year would be minus 2%.

And on adjusted operating profit growth, it would be minus 4%.

Finally, we remind you of a few modeling assumptions in 2024, namely the impact of [indiscernible], the loss of Gardasil royalties and the tax rate likely being a couple of percentage points higher due to OECD legislation. More details on these are included in our pre-quarterly [indiscernible], and I look forward to guiding more fully at the end of the year.

And thank you. And with that, I will hand back to Emma.

Emma Walmsley Executive

Thanks, Julie. Turning lastly to Slide 27.

So in summary, we are seeing strong and sustained improvements in our performance. This quarter marks the seventh consecutive quarter of competitive sales and profit growth, which supports an upgrade to our guidance for the year.

We also remain very focused on strengthening our pipeline and our longer-term outlook with progress in vaccines, development of our long-acting HIV portfolio and new prospects in respiratory, all pointing to new growth opportunities for GSK.

We have strong performance as we enter 2024, and we look forward to keeping you updated on our progress.

Thank you for listening. And let's now please -- we'll move to the Q&A.

Nick Stone Executive

[Operator Instructions] With that, I'd like to take our first question from Graham Parry.

Graham Parry Analyst

Great. So I'll start with Arexvy. So there's a question on the level of discounting in the initial launch. So 2/3 of your 709 million was inventory and you've administered some, I think, 1.4 million, 1.5 million doses. That means underlying sales were in the sort of 230 to 240 range, and that would imply net price, probably more than 30% below the list price.

So can I just check that's the right sort of ballpark? And is that mostly wholesaler discounting

or retail pharmacy discounting to drive the initial inventory build, and something which we might see sort of ameliorate a little bit over time? Or is that just kind of where the competitive nature of the market is at the moment?

And then secondly, I know Julie touched on this, but dynamics into next year. Just be interested in sort of what you're internally planning at the moment for 2024. You obviously don't have the initial inventory build. But how much of that inventory do you think is just sort of seasonal inventory builds as a pace to initial inventory build? And of course, you don't have the return of the HPV vaccinated this year, just be interested in sort of what you're internally planning at the moment for 2024.

You obviously don't have the initial inventory build. But how much of that inventory do you think is just sort of seasonal inventory builds as a pace to your initial inventory build? And of course, you don't have the return of the page, people vaccinated this year. So any thoughts you have so far on how far penetrated you are into the easy wins of the [indiscernible], et cetera. and how much tough it might be to get return or to new people to get vaccinated next year?

Emma Walmsley Executive

Well, we'll come to Julie in a minute on guidance and thoughts around next year. Although, obviously, we will mainly be giving you thoughts around next year, when we come to February 2024.

And I would just remind everybody that whilst we are absolutely delighted with the fast and competitive start here on RSV, it is just the start of the first season, we remain very ambitious for the 3 billion at least that we expect this asset to represent.

But let's go to Luke first. Noting Graham, you will fully understand, we're not going to be declaring all our commercial details on this call. But Luke, do you want to comment more broadly?

Luke Miels Executive

Yes, Graham. I mean I think we've been quite disciplined, taking a longer term around pricing and contracting, and it's landed quite well. I won't give you any more color than that in terms of the percentages at this point because I'm sure our friends in New York probably got up a little bit early this morning.

But what I would say is, to build on Emma's point, I think in the short term, things are uncertain. We're very happy with the launch. In the long term, we're very certain. I think so far, if we look at some of the metrics, which I can try and help you with, it's about 50% co-administration with flu. There's a very large overlap with that population.

And interestingly, around 15% of people are getting 3 shots when they come into the pharmacy. 85% is that 65 to 84 age population. So again, very similar to high-dose flu.

And yes, I think for the rest of the year, in terms of demand, you're still seeing good market research in terms of ACPs recommending it. So it's about 64% based on our latest market research, which is encouraging. And of course, the CDC is advising doctors to keep going. So

that's on the positive side of the ledger.

But the fact is this -- our working hypothesis is this is more of a flu-like trajectory. And as people stop coming into pharmacies and we see a reduction in staffing levels of pharmacy who actually delivered these vaccines, then we're going to see a drop-off in demand. And that's a hypothesis at this point.

We'll obviously have a lot more color in Q4 to give you an update. And then as Emma said, I think we're very, very confident in terms of the 3 billion number that we've outlined in the past.

Emma Walmsley Executive

And obviously, looking forward to rolling forward with that 50 to 59, data 2, which is another essentially meaningful cohort. Julie, anything else you want to add?

Julie Brown Executive

No, I think actually Luke covered it extremely well. I think we've obviously looked at the levels of stock in the channel. We've looked at the rate of immunizations. We've seen the correlation with flu, as Luke mentioned, very, very close, and that's really informed our guidance.

And in terms of 2024, I mean, I think we're going to -- as we come through the U.S. flu season, we're going to have a much clearer view of 2024 when we give our full year results. So we'll definitely update you at that stage more fully.

Nick Stone Executive

Okay. Next question is going to be from Kerry Holford at Berenberg.

Kerry Holford Analyst

I have a couple of questions for Tony, please, within R&D.

So firstly, on the [indiscernible]. So now you've got the full reach of your Phase II data, and you have recently signed that deal with JNJ to look at sequential therapy. Do you still remain confident you can offer [HBV] patients a functional cure, at least a proportion of them? And what do you expect that JNJ, siRNA to add here? And do you stand by your more than GBP 2 billion sales target for that asset?

And then secondly, a broader question on R&D budgets. So here, we've seen significant growth in your budget over the past 18 months or so. And based on the pipeline you have ahead of you, and you're broadly happy with the annual budget that you've effectively been given this year. And the run rate looks to be about GBP 5.5 billion, or should we expect that R&D budget to continue to grow in the sort of low double-digit range that we've seen year-to-date going forward?

Tony Wood Executive

Kerry, Let's get started with HBV. And then I'll comment on the pipeline, but perhaps Emma, you might want to make a comment on R&D budget.

So first of all, I'm really pleased with this deal, Kerry. Let me just remind you because I'm going

to anchor it in what we are, what we know about bepi and becoming increasingly confident about that is in the context of monotherapy, on top of nucleoside treatment that we achieve a durable functional cure for a significant proportion of the HBV population, the chronic HBV patient population.

And that's for individuals to have a surface antigen count of less than 3,000. Just as a reminder, that's about 40% of the 300 million individuals who are living with chronic hepatits B.

To put it in a nutshell, what the new deal with the JNJ siRNA does, it takes the broader population down to that target population of about 3,000 and below. So you should expect, and we're excited about the prospects, therefore, of seeing both in increased coverage in an ITT population and also a deepening of the therapeutic effect. And this is important, if you look at the mechanism of action of the JNJ siRNA, it works in complementary fashion to bepi. So further lowering viral DNA and the consequences of that, as I mentioned in the presentation.

The other more important thing is that we've built a complex PK/PD model around response, which this will add to -- and in addition, using AI/ML and some really deep phenotyping on nearly 500 patients, established an understanding of the immune status required at the beginning of treatment for response. We're going to continue to add to that because with the deal in question, we got a number of ongoing Phase II studies.

So I'm really very pleased about where we are with that particular deal. For me, it strengthens on my expectations in terms of our ability to deliver a functional cure for a broader population of patients living with this disease.

Let me just start, in terms of the question about R&D budget and growth, perhaps I'd just say a few brief things about the portfolio and then hand over to Emma.

So again, I'm really very pleased with where we are in the portfolio. Emma mentioned the, the strength that we have in our growing vaccines portfolio, particularly next year as you'll see more data coming from our mRNA platform, from MAPS and we have a number of important studies like, for example, therapeutic Herpes Simplex vaccine readout on POC that will again continue to hopefully deepen the importance of our adjuvant technology that is underscoring, I think, it's a fantastic clinical performance we see for Shingrix and for Arexvy.

Luke and I will say more the management about the cornerstones of depemokimab, Nucala and camlipixant in our respiratory portfolio, of course, I've just mentioned bepi.

And then moving just briefly into oncology, Jemperli, most recently through the OS data that I mentioned earlier, continues to show its credentials as a very highly effective PD-1 inhibitor.

And with all of that in place, I think we're well set with regards to our future ambitions and the budget required for that ambition. I'm in good shape about it. Emma?

Emma Walmsley Executive

Thanks, Tony. I mean I think the -- there are 2 important things to emphasize strongly here. First of all, we've been very clear in our capital allocation framework, the #1 priority for the

company is to invest in the pipeline, organic and inorganically. And that is why over the last 5 years, you've seen a significant step up in our R&D spending.

What matters is not how much you spend but that you spend it super smartly. And that is ever improving and that we're continuing to fuel competitive profitable growth for our shareholders. So first thing is it is a priority, but it's about how we spend it. And I think we are broadly to more industry normal levels in terms of spending, but very much focused on the returns of that.

And the second thing is we are absolutely committed to profitable growth, and we're in that chapter now. We're now in, I think, 7 consecutive quarters of competitive growth. Glad to upgrade guidance for the year, very confident about our 26 outlooks and our double-digit profit CAGR.

This year, we expect R&D spend to increase slightly below our turnover levels, and we're not going to set an explicit target around it, but you can be very confident that the outlooks we've previously laid out, we are completely committed to and delighted about our progress against. Next question, please.

Nick Stone Executive

Okay. Next question is from Simon Baker at Redburn.

Simon Baker Analyst

Two, if I may, please, both on the pipeline. And apologies if I missed it. I did lose sound at 1 point.

But it looks like depemokimab is running slightly ahead of our previous expectations. I'm just wondering if you could give us an update there on the shift in the switch to study timeline?

And then secondly, on the Janssen ADC. I wonder if you could just elaborate a bit on what attracted you to that asset? Obviously, we've not seen much data. You will have seen more than us. And I was wondering if it was data driven or whether it was driven by the fact that the payload and the linker bar 1 or 2 carbons is identical to Dato-DXd and therefore, gives you a high level of confidence in the potential of that ADC?

Emma Walmsley Executive

Well, coming to Tony on both of those, but just to flag, please do join us on the 30th -- or at least Tony and Luke, I should say, on the 30th of November, when they will update you on some -- the very exciting scale assets we have in respiratory, obviously, our homeland and our heartland, including depi and camlipixant as well.

But Tony, you might want to comment a bit more on the trials that are ongoing and then also on the ADC, which is obviously completely in line with our ONC strategy.

Tony Wood Executive

Sure, Simon. Yes, I'm pleased with the progress we're making on SWIFT-1 and 2. As you spotted, we've seen a slight acceleration in that. That was associated actually with also an

acceleration in the ANCHOR study for nasal polyps.

What that means is that the safety database that we need to underpin the file is now complete. You should expect, though, that we'll stay on schedule with regards to the analysis and publication of the data, and I won't be doing that until we get the results for the second SWIFT analysis, which still places us in the first half of next year. As far as the ADC deal is concerned, Simon, so yes, as you quite right, you point out in terms of linker payload, there are similarities to date to Dato-DXd, and therefore, we derive confidence from the improved profile that you see for ADCs carrying that linker payload.

Two important things, though, to stress in the context of this deal. One, the antigen B7-H4 is selectively expressed on gynecological cancers. That's why we went after the mechanism in line with our strategy to focus on women's cancers and heme. And lastly, in that area as well, there is ample evidence that the use of [indiscernible] inhibitors as on standard of care for chemotherapy, that's related in part probably to the fact that you see a lot of DNA instability in those cancers. And as I'm sure you're aware, [indiscernible] summarizes work on that mechanism.

Emma Walmsley Executive

Next question, please.

Nick Stone Executive

So next question is going to be from Andrew Baum at Citi. Andrew, you're there?

Andrew Baum Analyst

Yes, I am sorry about that. Two questions, please. One for Luke, and the other one for Tony.

So for Luke, could you talk to the impact of the removal of the Medicaid cap, the MP cap on your Genmab business, particularly respiratory next year in terms of quantifying the impact on revenue and earnings?

And then for Tony or I guess, Kim, if she's on. There was recently reported the Athena cohort with cabotegravir rilpivirine, there was a number of cases of viral rebound resistance, particularly in patients with high BMI or weight gain. Should we expect any label change as a function of observations in that cohort? And it was a limited number, but still it was notable that remarked upon.

Emma Walmsley Executive

We'll come to Deborah, actually, on the HIV pipeline first. And then Luke, back to you on the onco.

Deborah Waterhouse Executive

Andy. So the Athena is a cohort study, it was presented at AICS 8 to 10 days ago. Actually, the finding is exactly in line with our clinical studies. So as you know, there are kind of characterize things that give you a higher likelihood of failing with cabotegravir rilpivirin, weight is one, so high BMI is one. And then obviously, A6, A1, sort of subtypes.

And then lastly, if you resistant to rilpivirine. So we clearly guide that those patients, if you have 2 of those risk factors, you're more likely to fail. We guide that. And that's exactly what we saw in the Athena study in terms of the characteristics of those that failed. And it was in proportion with what we saw in the clinical study, which is obviously less than 1%.

So no surprises, whatsoever, exactly what you would expect. And it just makes it more important that we continue to communicate through our sort of multi-barrier analysis data for whom Cabenuva is right and who probably shouldn't be taking the medicine, but it's a tiny proportion of the overall patient base that will get benefit from this medicine and nothing new. Luke?

Luke Miels Executive

Sure. I mean, as I said at Q2, the exposure is USD 700 million. But of course, we've had notice. So we've got authorized generics in place. We've done some withdrawals that we've announced.

We've done WACC adjustment with [indiscernible]. The other products impacted, of course, the Advair and Flovent and [indiscernible].

Look, I think the impact is going to be sizable. We started to reflect that in RA adjustments now. But we need to judge to see what level of returns ultimately come back. There's also some variables in terms of the percentage of switch to authorized generics. But we do have competitive generics, for example, with Flovent.

So they may pick up more volume making it a bit hard to forecast.

So long story short, I mean, we've been prepared for this. We've been working on it for a couple of years. I think we're in the strongest position possible but there is going to be a material impact on that USD 700 million. And that's why it's reflected in the outlook for General Medicines next year.

Emma Walmsley Executive

I mean, that's the really important point is it's a '24 ahead, but it's all included in our medium-term guidance of being broadly flat in this business where we've obviously seen a nice uptick in performance, not least as [indiscernible] continues to power forward and lead the way. So all factored in and planned for. Next question, please?

Nick Stone Executive

So next question is going to be from Richard Parkes at BNP Paribas.

Richard Parkes Analyst

Yes. Just a couple of questions. Firstly, on Arexvy. Can you talk about the unmet need in terms of severe disease in the 50 to 60 year old patient population, just so that we can get a sense of -- and also, kind of what you would expect in terms of ACIP recommendation, so we can get a sense of how that label update might impact the opportunity going into next year?

And then second question is on Jemperli. Just wondered if you could talk about your

confidence in expanding the approval into the MMR proficient population. Obviously, I think there's sort of 2 options there. One is the overall survival data from part 1 of the study. So maybe you could talk about consistency of that benefit across those subgroups.

And then the PARP inhibitor arm of Part 2 of the trial, I notice you don't include Zejula when you talk about Part 2 as an opportunity. So I just wondered about your confidence in the PARP inhibitor maintenance on the that study as well.

Emma Walmsley Executive

We'll come to you any minute on oncology, but perhaps let you can talk about the 50 to 59 opportunity, which is another 40 million people, by the way, in the U.S.

Luke Miels Executive

Yes. Yes. I mean I think there's 2 advantages. One is just the 40 -- access to the 40 million people. And again, that lines up nicely with the overall Shingrix cohort.

So there's lots of synergies there we can achieve. And then there's the broader advantage when we're contracting in the retail and non-retail settings because we'll be the only one there.

Our expectation at this point is it's going to be shared clinical decision-making. But as we speculated before the launch, and I think so far that's holding up, that's not been a barrier during this initial base of adoption. If you look at that 50 to 60 plus population, there's a sizable proportion of them that also have one or more comorbidities.

So it's attractive. And certainly, it resonates well with primary care doctors in terms of their support of the brand, which is around 71% in terms of their preference overall for Arexvy.

Tony Wood Executive

And in terms of RUBY, particularly RUBY Part 2, just -- and indeed the MMRP population from the results that we described earlier this week.

Important to recognize that the RUBY Part 1 study was not powered to look at OS in the MMRP population, but rather OS for the overall population.

The way to think about this in context of both Part 1 and Part 2 is definitely isolating out the MMRP population and asking under what circumstances are we likely to see the most meaningful therapeutic effect for those. There are, for example, genotype considerations associated with part response in the Part 2 population that are important.

I don't want to get caught on the details of those at this point in time. We're still waiting for the readouts, but it's fair to say that the filing strategy that we'll put around Jemperli in first-line will take account of all of the factors that I've just described as well as the competitive position.

Luke Miels Executive

Yes. And I think to build on that competitive position, I mean, I think we're optimistic in terms

of how the NCCN may read that. Of course, as you know, [GY-18] is not designed around an overall survival signal.

And it's very interesting since that initial label, we've gone from 300 to 900 accounts now stocking Jemperli in the U.S., so that has a flow-on effect and sales are up 10x after SGO. And it's intriguing just looking at the market shares. If you look at that first line setting when it was obviously non-promoted initially, I mean, Keytruda was picking up around 40% of that business. Chemo have dropped from 40% down to 27%. And we had around 13% of that market.

So I think there's an opportunity now to start to make the case versus [GY-18], the elements of the design and the survival signal to try and expand the usage of Jemperli in that setting.

So that's something we're quite excited about. And then, of course, Jemperli helps inform the thinking around RUBY 2.

Tony Wood Executive

Exactly, just a couple of things to underscore to Luke's point to remind you about [GY-18] different patient population. We had a larger degree of [indiscernible] and also arcona patients, which are harder to treat. And importantly as well, the resist sampling frequency for our study was smaller, which obviously is going to pick up failures. -- more quickly than the [GY-18] case dose. So important to bear those 2 things in line when you consider the comparison of the of the 2 studies.

And Luke, I think as guided you correctly in thinking about [indiscernible] as being informative with regards to how we might interpret the Part 2.

Emma Walmsley Executive

Next?

Nick Stone Executive

So next question is from James Gordon at JPMorgan.

James Gordon Analyst

James Gordon, JPMorgan. I'm going to stick to Arexvy for my 2. The first one was about Arexvy and stocking. So it looks like about GBP 460 million of Arexvy restocking this quarter. And the guide for this year implies about GBP 200 million to GBP 300 million of sales in Q4.

But what does this assume in terms of stocking unwind in Q4? How much stock do you need to keep in the market to support the product as an ongoing run rate?

And also, what are you thinking about ex U.S. stocking in Q4? Could there be a U.S. site stock up that we saw in Q3 in Q4?

And the second question is a lead into that, which is Arexvy and the ex U.S. launch. So ex U.S. sales, I think, were only 1 million this quarter, where the product was approved in the EU back in June. And my understanding is you're not capacity constrained.

So could ex U.S. start to ramp in Q4 this year? And looking into next year, could we see a big launch for ex U.S. Arexvy, could that be a big growth driver for next year? Or is it going to take a bit longer in Europe to get this going?

And what are the gating factors to get ex U.S. Arexvy ramping, like what we've seen this quarter in the U.S.?

Emma Walmsley Executive

Okay. Well, we'll go to Julie first, just to deconstruct the guidance for Q4. And then, Luke around the globalization.

But you're absolutely right. This is a global opportunity, and I'll even include in that, the recent commercial deals we've been doing in second biggest market in the world, there could be an option on that for the future.

And just to repeat, we're very ambitious for this being a multibillion asset as we've committed before.

But in terms of the very short term in its first season, Julie, do you want to comment on the guidance?

Julie Brown Executive

Yes. So what we've definitely found so far is of the sales of 709, in terms of immunizations into people's arms, we've got around equivalent of about GBP 230 million to GBP 250 million.

We were expecting -- I mean, the launch has been massively successful. We were expecting a stocking at this point because it's very, very analogous to what's happening with flu.

So I think I'll hand over to Luke in terms of the amount of inventory we expect to carry. You figure for Q4, by the way, was absolutely spot on in terms of the level of sales we expect to see in the remainder 200 to 300, and it's all to do with the stocking. So over to Luke.

Luke Miels Executive

Yes. I mean if you look at the total marketing, it's about 2.71. And we've got 1.7 billion of that in arm.

Yes, I won't give you much more color. I mean, as Julie said, it's 2/3 of sale so far. And we'll obviously try and burn through that towards the end of the year to position ourselves well.

What we don't want is empty shelves or any window that Pfizer can get in there. That's why I'm being a little bit cute with the numbers here because it's very dynamic at this point.

In terms of EU, look, it's very early days. It's private. We've kept the price in a very tight collar with the U.S., like we've done with Shingrix, and our expectation is that we need to now navigate access. We've got early wins in Canada. We've got some very encouraging signs coming in Europe and other markets.

So we'll see the full effect of that in 2024.

And of course, the advantage in the European markets like Japan and other international markets is once we get the NIP, then the level of resourcing we need to do to drive patients is significantly lower.

And so from a P&L point of view, it's also very attractive. So 2024 for rest of world for Arexvy and yes, good start in the U.S.

Emma Walmsley Executive

And just to repeat, we are definitely seeing increased openness and recognition of the value literally financial value of investing in prevention. And so that is indefinitely in part where we're seeing this faster rate, even currently in the private market of approvals because it's just a lot cheaper and there isn't a health care system more budget that isn't burdened at the moment.

And they have more infrastructure in place, not least through pharmacy channels for distribution in many countries.

So all of this underpins this broader confidence, but we're phenomenally [tight], listening from Luke's team as he's alluded to around the shape of the financial contribution. Next question, please?

Nick Stone Executive

So I'm mindful we're just over the hour mark. We still got 6 individuals with hands raised.

So what I propose is that we try and work through as many of those as possible to a quarter past the hour, and then we'll close the call there.

So our next question comes from Mark Purcell at Morgan Stanley.

Mark Purcell Analyst

On Arexvy, a little bit more color. I just wondered if there's any early indications of out of seasonal demand for RSV vaccination.

[indiscernible], there may be more of a sort of a Prevnar flu hybrid model. I know you'll know more by the end of the year, but any early indications there?

And in pharmacies where Pfizer is fully stocked alongside you, given that they talk about how they're not fully launched yet, what is your market share in those pharmacies where both products are present?

And then a quick one for Tony. In terms of the inflation reduction and considerations on R&D, where you have assets just like your IL-18, where you could run parallel trials across a multiple number of indications. Do you see the sort of pressure to do that? And so like IL-5, could you do a BRIDGE study or would you have to do a separate study in COPD?

Emma Walmsley Executive

Okay. Luke and Tony?

Luke Miels Executive

Mark. We're beating them everywhere so far. The aim is to keep that happening. So yes, I mean, look, it's really -- it's interesting. I mean when you look at pharmacist prioritization, RSV is up there with flu [indiscernible].

You've seen COVID volumes drop off. And last week, we still get growing with Arexvy, which is encouraging. I was sort of wondering whether it would start to slow down.

So this next couple of weeks, script data will really be interesting. It's more than 90% in the retail setting, and that's another critical component in your assumptions. And we don't actually expect that to materially change. We think vaccines, the maternal in OBGYN and PCP offices will occur, which will something will have to back out in future calculations.

But we think the old adult market is going to be very much like flu, very much like Shingrix heading in the direction of retail.

So we'll just see what people's enthusiasm is over the next couple of weeks. Clearly, awareness is very high. intention to recommend is very high. So again, I'm very happy to sort of back the truck up with everything that we know in Q4 and give you much more color around the market research that we will have at that point.

Emma Walmsley Executive

Great. Thanks. And Tony, anything to add?

Tony Wood Executive

Yes. Just 2 very quick ones then in terms of the IL-18 question. Look, the key question we're asking with IL-18 at the moment is its efficacy relative to [indiscernible] in atopic dermatitis, for the medium term as we build out our biomarker strategy, and look for markers of efficacy at Phase I. That's exactly the underpinnings that I would then want to have the confidence to go forward into multiple indications.

You probably have in mind that in case of IL-8 in the mandatory randomization also points to inflammatory bowel disease, obviously, a range of considerations there beyond just IRA in terms of whether not that's a path to go.

And then lastly, for MAT2A and the BRIDGE for depi, let's see where we go when we get the [indiscernible] results. Obviously, we're focusing very much on the role of EOS in driving the morbidity and mortality associated with COPD. So will be part of our strategy, but I'm focused at the moment on making sure we get the results out to [indiscernible] and to bring success. Emma, any color to that?

Emma Walmsley Executive

Yes. And of course, any allocation of capital is a combination of forecast forecast now has to take into account the area under the curve, whether it be by format or anything else.

Nick Stone Executive

Next question is from Steve Scala, TD Cowen.

Steve Scala Analyst

I'm just curious of Arexvy shipments in October support your conservative guide for the full year. So were they essentially 0? I would note that in the first quarter of 2018, GSK called out stocking for Shingrix, and then went on to beat in 10 of the next 12 quarters in the U.S.

Second, I know you're beating Pfizer in RSV everywhere. But to what should we attribute the success they have had? Previously, you've said that you have a better vaccine, you're stronger in the commercial setting, yet they put up a big number as well. So to what do we attribute that?

Emma Walmsley Executive

Well, I'll ask Luke to overlays, Stephen, but thanks for the questions.

And this is the first season that we've been through. We've given our dive for the reasons that I won't repeat, since we're under some timing pressure, but we will know a lot more Q4. And obviously, we remain extremely ambitious for this and our competitive focus is make sure that not only the size of the market is big, which is why we welcome competition, but that we are able to effectively reach the patients that need us, which is this more vulnerable [indiscernible] cohort. Luke, anything you want to add?

Luke Miels Executive

Yes. And look, I think Shingrix's a different case, right? I mean, I was in the middle of that, we canceled the global launch. We redirected all of the volumes to the U.S. And we also, in the middle of the later year, had some synergies in manufacturing, which were surprising upside in terms of loss and packaging.

So that's why we're able to get that volume ahead for Shingrix. Look, I think in terms of us versus Pfizer, first it's growing, companies are out driving volume, because this is an awareness game. You know, no one had heard of RSV, if you're -- a person in a population before that.

So having 2 companies promote. It's good. We have enormous respect for Pfizer. We like competing with them. They are a strategic competitor for us, if you look across PCV, meningitis, RSV and potentially shingles at some point.

So it's nice to have this strong start. And again, yes, we want to keep this going.

Emma Walmsley Executive

Next question?

Nick Stone Executive

Yes. Next question is from Peter Welford at Jefferies.

Peter Welford Analyst

I'm afraid, I'm sticking with Arexvy. Could you just -- You mentioned that retail was over 90% of the volume so far. Curious, are you why you're so confident that, that mix will continue? I mean

obviously, Shingrix, it's varied over time. But I think your competitor made some comments that they think potentially in the fourth quarter and the back half of the season, it's going to switch more towards the non-retail segment where they see perhaps a greater competitive advantage.

I wonder if you could comment, I guess, on both of those, both from a capacity advantage point of view, and also how potentially this could change, I guess, during the course of the season?

And then just secondly, I wanted to stick with vaccines. But wondering if Tony could possibly give us an update at all on how you're thinking about mRNA. I know, we come back to this almost every quarter. There obviously have been some competitive developments in there. So I wonder if you could just give us a quick update on how you're looking at your strategy and updates from new flow we could get for your mRNA portfolioin 2024?

Emma Walmsley Executive

Yes, we're very excited about mRNA. I'm going to come to Tony first. And remember, the 90% is all the asset add up, but we'll come back on that to Luke in a minute. But Tony, mRNA?

Tony Wood Executive

So just very quickly then, I'm very pleased about the platform and how it's moving forward. We're now moving into Phase II in both COVID and flu, and our Phase II program for flu includes a range of options and doses that we've deduced from our Phase I study, looking at up to 8 antigen components, which we feel is the path forward to, I presume, resolving the B strain coverage question that exists.

Also worthwhile pointing out that, that's likely to become a slightly simplified proposition as the [indiscernible] strain is probably going to be removed in '24. But more on this when I've got the readout from the Phase II data.

Emma Walmsley Executive

Luke, anything to add on that?

Luke Miels Executive

Yes, Peter, I mean, I just sort of look at it at a macro level. You've got 83 million who are over 60. You add the 50, 59, that's another 40. So that's a 120. We think 90% of those are going to still come through.

If you look at a typical birth cohort, it's 4 million a year. So if I look at between now and the end of the year, that's about 1 million pregnant women. And then it's unknown how many of those will get a vaccine. There's the influencing availability, the antibody as well.

I think the other thing to keep in mind, and we're seeing this with Shingrix is there are a lot of practices that are driving patients to pharmacy because they are -- they don't want to navigate the IRA dimensions and then have a separate track for the commercial patients. So they're actually sending patients through to the pharmacy rather than sort of persisting with that themselves. So that's a bit unknown. But definitely, those maternal vaccines will be given

in OB/GYN offices. We don't have the label there.

So we'll need to exclude that from our market share calculations going forward.

Emma Walmsley Executive

I think we've got time for one more?

Nick Stone Executive

We do have time for one more. So apologies to those of you that we won't get to, but our last question comes from Emily Field at Barclays.

Emily Field Analyst

And maybe I'll just ask one last one about Ojjaara. I was wondering if you could provide some context about how you're thinking of speed of uptake of this launch, particularly now that you did get the line-agnostic legal and if you're expecting more sort of upfront usage versus second-line use, and any early indicators you could give us?

Luke Miels Executive

So first, we've got about 172 patients on so far. The bulk of those are sort of jack failures, highly anemic, so pretty severe cases. So that initial bolus, I think, will work through.

Our working assumption is that between 40% and 50% of patients presenting are anemic at diagnosis. And as you know, we've got an outstanding recommendation there in terms of 2-A, and the most competitive profile in that subgroup.

And we also know that around 46% of patients require a transfusion within 1 year of diagnosis. So that's our target. That's our target market.

We think right now, yes, third line it's a couple of months, but we'll work our way up. second-line typical treatment length is 18 months, but we should be able to start to penetrate in 2024 that first line where typical treatments around 26 months of duration.

And we got the NCCN data into them 2 hours was in an approval, and we were very happy with the recommendation.

So, so far so good, a lot of academic interest, that's about 55% of the volume right now, 45% in the community. Of course, we expect that to change in time. But a lot of excitement, and this is clearly a visible problem for hematologists. And yes, they're very supportive of momelotinib. So, so far, so good.

Emma Walmsley Executive

Wonderful. Thanks, Luke. Well, look, we'll look forward to coming back to more of your questions over the coming days and weeks. So I just want to leave you with the recap that we are delivering strong and sustained performance momentum with another quarter of double-digit sales and the earnings growth.

This is broadly based performance, but of course, benefiting specifically from the very fast

start of Arexvy, which we're looking forward to seeing its progress ahead.

Pleased to have an upgrade, but also really delighted with the momentum as we look ahead to delivering our '26 results and continuing to strengthen that longer-term outlook, as we keep aggressing the vaccines pipeline, longer acting HIV and exciting prospects in respiratory.

So thank you to everybody, and we look forward to catching up soon.