

# GLAXOSMITHKLINE

## Q3 2021 Results

Wednesday, 27 October 2021

**Nick Stone (Head of Investor Relations):** Good morning, good afternoon. As you've just heard, I am Nick Stone, Head of Investor Relations at GSK. It's my pleasure to welcome you to our third quarter 2021 conference call and webcast for investors and analysts. The presentation was posted to gsk.com and was also sent to our distribution list a little bit earlier today.

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

This is the usual safe harbour statement, and we will be making comments on performance using constant exchange rates, or CER.

### **Agenda**

This is today's agenda, where we will plan to cover all aspects of our results. The presentation will last approximately 25 minutes, in order to maximise the opportunity for questions. For those on the phone, please join the queue by pressing \*1, and we request that you ask a maximum of two questions, so that everyone has a chance to participate.

Our speakers today are Emma Walmsley, Luke Miels, Deborah Waterhouse, Brian McNamara and Iain Mackay. For the Q&A portion of the call we will be joined by Dr Hal Barron, Roger Connor and David Redfern.

With that, I will now hand the call over to Emma.

### **Q3 2021 Progress**

**Emma Walmsley (CEO):** Thanks, Nick, and a warm welcome to everyone.

### **Q3 2021: Continued business momentum; accelerating execution of strategic priorities**

I am delighted to announce another quarter of strong financial performance and continued progress against our strategic priorities. Third quarter sales and adjusted EPS were both up 10% at CER. These excellent results were driven by strong commercial execution and underlying demand, with double-digit growth in Pharma and Vaccines, 24% growth in new and specialty medicines, proof that our pipeline is bearing fruit, and an

acceleration in Consumer Healthcare growth. Continued cost discipline supported this performance.

Today's results demonstrate the building momentum of the business, which has enabled us to improve our full-year 2021 adjusted EPS guidance, and narrow the range to between -2% and -4% at CER. The guidance excludes any contribution from COVID-19 solutions, which we now expect to contribute an additional 7-9% to this adjusted EPS for the year, a very positive result.

Alongside our strong financial performance we continue to make excellent progress in R&D: additional indications have been approved for *Nucala* in respiratory and *Jemperli* in cancer. We also received US FDA priority review of *Cabotegravir* for the prevention of HIV.

Following the positive headline results announced in July for *Daprodustat*, another potential best in class new medicine for treating chronic kidney disease, we will present key data in a late-breaking session at ASN Kidney Week.

The de-merger, and creation of a world leader in Consumer Healthcare, continues to be fully on track, and we were delighted to unveil exciting plans for a new global campus and innovation centre here in the UK.

Lastly, as we look ahead together, we are all strongly committed to delivering health impact at scale and maximising value for shareholders. Our resolute focus remains in world class execution and successful delivery of our stated key strategic objectives, beginning with a step change in growth in 2022, an exciting and important year for our company.

### **Continued progress across all three strategic priorities**

Progress in the third quarter was reflected across all three of our strategic priorities. In Innovation we continued to build a high value pipeline across prevention and treatment of disease through organic and inorganic delivery. I just mention some of the highlights, and several more are listed on the slide. Among them I am also delighted we are now playing a meaningful role in the COVID-19 response, through our antibody treatment, *Xevudy*. We have several COVID-19 vaccine programmes soon to read out and we remain agile as the environment continues to evolve.

In Performance, continuously improving commercial execution is driving robust growth, and strong share performances in new and specialty products. For *Shingrix* specifically, we have seen an impact as a result of the surge in the Delta variant, but we are increasingly confident we are on the recovery track. The initiatives we have put in place, and the underlying demand, will drive strong growth in 2022, with the potential to deliver record annual sales. Luke is going to take you through the detail of this in a minute, as well

as our confidence in the medium-term opportunity for *Shingrix*. In Consumer, strong brand performance also drove a significant acceleration in growth in the quarter, as Brian will speak to.

Lastly, on Trust, we continue to maintain leadership in ESG with a recent announcement of significant renewable energy investment and carbon reduction initiatives at our manufacturing sites in the UK and US. We also announced a new R&D programme to reduce greenhouse gas emissions from our metered dose inhalers, which are responsible for 45% of the company's carbon emissions, and these new initiatives support the continued progress on our environmental commitments to be net zero and nature positive by 2030, which we will share more on at COP26.

I also, of course, welcome the recent WHO recommendation for a broader deployment of our malaria vaccine. Malaria kills more than 250,000 children a year in sub-Saharan Africa, and this is the first and only vaccine shown in pivotal long-term clinical trials to significantly reduce childhood illness and death from malaria.

## **R&D Pipeline**

### **Upcoming select late-stage milestones**

I want to take a moment to expand on my comments on innovation. In our Investor Update in June we shared how we had significantly improved R&D productivity since 2017, with a top quartile performance versus our peers for a number of launches with approval of 11 major medicines and vaccines. We have more than doubled the number of assets in Phase 3 or pivotal studies, from 11 to 23, and created a pipeline of over 60 medicines and vaccines, many with first in class or best in class potential.

The result of all of this work and targeted investment is an increasingly valuable pipeline with real momentum. It is worth restating that major pipeline approvals delivered from 2017 to 2021, plus anticipated pipeline approvals, will drive more than 100% of our forecasted sales growth from 2021 to 2026.

Over the next 12 months you will see a number of readouts and regulatory progress which will support the confidence we have in the outlooks we provided for GSK in June. Specifically, we expect to report key readouts on up to seven of the 11 assets we highlighted, including our older adults RSV vaccine in the first half of 2022, as well as proof of concept data on our potential hep B therapeutic. We are planning a regulatory submission for *Blenrep* in third line multiple myeloma and, as I mentioned previously, you will hear a lot more on *daprodustat* at ASN Kidney Week and our Investor Science Event, which is also scheduled for early November.

## **Progressing towards demerger at pace**

Lastly, I want to take a moment on the timelines for demerger of our world-leading Consumer Healthcare business. We are in countdown mode and moving at pace with our plans to unlock the potential of both GSK and Consumer Health, strengthen GSK's balance sheet and maximise value for all our shareholders. We are committed to the demerger of at least 80% of GSK's holding and for the remaining 20% to be monetised in a timely and pragmatic manner.

As momentum builds towards this important event, you will see several important steps in the process. Most visible will be the announcement of a Chair-designate, and subsequently an appropriately skilled Board for Consumer Health. In the first quarter of 2022, we plan to hold a Capital Markets Day which will set out in detail the performance and compelling prospects for Consumer Health as a new and independent company. We will then proceed with the premium listing of the new Consumer business on the London Stock Exchange, creating two companies set up for independent delivery of competitive growth, shareholder value and scale impact on human health.

Now, let me hand over to the team to take you through the growth drivers in detail. Luke, first, over to you.

## **Growth drivers**

**Luke Miels:** Thanks, Emma.

We made strong progress in the quarter on commercial execution and competitiveness, which you have seen come through in the revenue and market share numbers. For today, I want to focus my remarks on our strong performance in New and Specialty, and our confidence in the growth prospects for *Shingrix*.

### **New and Specialty: strong double-digit growth (+24%CER) in Q3 2021**

Growth in our New and Specialty Pharma medicines accelerated to 24% in the third quarter, taking us to 18% growth, year-to-date. These figures include HIV, which Deborah will cover in a few minutes.

As we have seen throughout 2021, *Trelegy* continues to deliver, with 77% growth in Q3. The asthma indication is proving to be a unique differentiator and our leading position in this space remains unchanged, with *Trelegy* holding 90% of the single-inhaled, triple therapy market in the US.

Our market-leading IL-5, *Nucala*, also contributed double-digit growth, up 20% in the quarter. We continue to hear from physicians that a clear and targeted approach to EOS-driven disease is preferred and we remain confident in *Nucala*'s market opportunity as we launched nasal polyps in the US in July and received positive CHMP opinion for EGPA, HES and nasal polyps in Europe.

Additionally, *Benlysta* had its 17<sup>th</sup> consecutive quarter of double-digit growth, up 35% in Q3. Our convenient subcut formulation and lupus nephritis indication in the US, build on the established leadership we have in SLE, while we continue to build the market in other parts of the world, like China.

Finally, our Oncology portfolio continues to growth. We received an additional approval for *Jemperli* in August and, in Q3, grew *Zejula* sales by 14%. We continue to see one in two new PARP patients receiving *Zejula*, despite a tough external environment where, unfortunately, diagnosis rates remain about 16% below pre-COVID levels. Encouragingly, and based on new patient start data, we are also seeing *Zejula* as the preferred choice for new patients across three lines of therapy.

For *Blenrep*, we now have more than 4,000 patients treated globally and we are expanding use in the community, where the majority of multiple myeloma patients are. We look forward to the opportunity of more patients benefitting from *Blenrep*, as two pivotal studies – DREAMM-3 and DREAMM-8 – read out.

### **Vaccines: Performance in Q3 2021 driven by *Shingrix***

In Vaccines, we delivered a strong quarter of growth, with *Shingrix* on the recovery track following pandemic-related disruptions that impacted performance earlier this year. The performance of *Shingrix* in the quarter primarily reflected a favourable impact from inventory movements and also a larger proportion of *Shingrix* being administered in HCP offices – a trend we have been tracking through the course of the pandemic as retailers prioritise vaccination for COVID-19. Performance outside the US is also encouraging, with recovery underway in Germany and several successful launches in new markets.

As you can see on this slide, *Shingrix* TRx volumes are improving as we move through the year, despite disruption from the Delta variant, slowing the pace of the recovery.

With the challenging comparator in Q4 ahead and prioritisation of COVID booster vaccinations in the near term, we now expect the year-to-date performance, which is -11% CER, to be a good indication for the direction of travel for *Shingrix* for the full year.

While this is below our previous sales expectation, we consider these as deferred, not lost sales. Our confidence in this transformational vaccine remains unchanged, and the underlying demand remains strong.

Our market research confirms that patients that have been fully vaccinated for COVID rank their interest in getting a shingles vaccine higher than any other adult vaccine except flu, and we are implementing activities to drive recovery with multi-channel direct-to-consumer campaigns, engaging healthcare providers, and further strengthening our relationships with US retailers.

Looking ahead, we continue to launch in new markets with our unconstrained supply position and we expect continued US recovery as we work through COVID boosters in the near term.

Taken together, we anticipate *Shingrix* to deliver strong, double-digit growth in 2022, and, assuming an improved operating environment, we expect next year to be a record year for *Shingrix* turnover. Further, we remain confident in our ambition to double revenues in the next five years, protecting more than 100 million adults along the way.

Now let me hand over to Deborah, please turn to slide 12.

## **HIV: delivering sustainable mid-single digit growth**

**Deborah Waterhouse:** Thanks, Luke.

Third quarter HIV sales grew by 8%, driven by the growth in the innovation portfolio and taking year-to-date growth to 4%.

In Q3 around 2% of the growth was driven by favourable wholesaler purchasing patterns in the US, and 2% by the growth of tenders in the international region.

Strong commercial execution is driving performance of the innovation products, which now represent 29% of our portfolio, delivering almost £1 billion of sales year-to-date.

*Dovato*, in particular, continues to grow strongly, building on the positive momentum that we saw in Q2. In the US and Europe, despite the depressed switch market, *Dovato* has gained further share, with 15.3% and 27.8% of the switch market respectively.

Turning to *Cabenuva*, the world's first long-acting injectable treatment for HIV. As with any new class of medicine *Cabenuva* will take time to build and the COVID environment continues to constrain switch activity, particularly where a patient needs to visit a physician's office. We have robust lead indicators with over 80% market access and strong brand recognition.

More than 2,000 people living with HIV are now taking *Cabenuva* and intent-to-prescribe levels are high. We are very excited about the potential approval and launch of two-monthly dosing in the US in early 2022.

This quarter we also made significant progress with cabotegravir long-acting for prevention. Last month the FDA confirmed that it had granted priority review status, which builds upon its prior identification as a breakthrough therapy. We believe this underscores the importance of this medicine, supported by the results of the HPTN studies, which demonstrated cabotegravir's superior efficacy over daily oral FTC TDF tablets.

In the United States, fewer than 25% of those who could benefit from PrEP are currently taking it, which points to the need for additional HIV prevention options. A final FDA regulatory decision is anticipated in January 2022.

As we said at the Investor Update in June, we expect our long-acting portfolio of *Cabenuva* and cabotegravir, a long-acting for prevention, to generate sales of around £2 billion by 2026.

We are also particularly proud to announce a new collaboration with our long-standing partner, Shionogi, on a third generation HIV integrase inhibitor with potential for ultra-long-acting dosing intervals. This agreement aims to build on the success of dolutegravir and cabotegravir, with the potential to anchor the next generation of innovative long-acting therapies beyond 2030.

I conclude by inviting all of you to attend an HIV Investor Event on 29 November in which we will share further details about the growth outlook and early-stage pipeline. There will, of course, be plenty of time for you to ask questions.

With that I will hand over to Brian. Please turn to slide 13.

### **Consumer Healthcare: Q3 2021 sales +10%**

#### **Good category performance reflecting strong execution**

**Brian McNamara:** Thanks, Deborah. Now turning to Consumer Healthcare in Q3.

We saw strong growth, with sales excluding brands divested and under review up 10% at constant exchange rates, reflecting good momentum and execution across the business.

Importantly, performance improved across all categories and regions helped by strong investment in the business. Emerging Markets performed well with continuing business of double digit, and with China, and Middle East, and Africa standout performers.

Let me provide some colour on our category performance.

In Oral Health sales increased 5%, reflecting continued good execution and successful innovation.

Pain Relief was up double digits, helped by easy comparators last year, and strong double-digit growth in brands including *Advil* and *Panadol*, more than offsetting a low single-digit decline in *Voltaren*. The *Voltaren* decline was expected, given the entry of private label into the category following a successful US RX to OTC switch last year.

Vitamins, Minerals and Supplements growth was up 19%, driven by strong growth in *Emergen-C* and good *Centrum* results, helped by increased capacity enabling a return to more normal retail stock levels.

Respiratory benefited from good growth in allergy and in cold and flu, as well as some help from favourable comparators in the prior year, resulting in sales up 16%. Digestive health and other sales are up 3% in the quarter.

Similar to consumer peers, we saw further pressure from cost inflation in the period, however our cost structure, combined with a continued focus on productivity, along with pricing across our categories and regions, enabled us to increase both gross margin and operating margin.

Innovation continued to be an important growth driver, and we had six first market launches in the quarter, taking this number up to 25 year-to-date, and 281 launches including market rollouts.

In e-Commerce year-to-date we grew in the mid-20% range, and it's now 7% of sales. Our ongoing investment in digital capabilities continues to position us well for growth in this key channel.

Year to date, seven of our nine power brands maintained or gained share. Our full year sales outlook remains unchanged, and demerger plans remain firmly on track. We are making good progress on standing up the functions and building the future processes needed to be a separate company.

Finally, I am looking forward to sharing more information with you on this incredible business as we move closer to separation, and at our Capital Markets Day in Q1 next year. Through the two largest Consumer Healthcare transactions in the last six years we have



created great business, the global leader in Consumer Healthcare with a fantastic portfolio of brands and strong capabilities to drive sustainable market out-performance.

With that, I will hand it over to Iain.

## **Q3 2021 Results**

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

### **Headline Results**

This is a summary of the Group's results for Q3 and the year-to-date. In Q3, turnover was £9.1 billion, up 10%, and adjusted operating profit was £2.9 billion, up 16%. Total earnings per share was 23.3 pence, up 3%, while adjusted earnings per share was 36.6 pence, up 10%.

In the year-to-date turnover was £24.6 billion, up 3%, and adjusted operating profit was £6.9 billion, up 8%. Total EPS was 72.7 pence, down 19%, and adjusted EPS was 87.7 pence, up 5%.

On currency, there was a headwind of 5% on sales, and 7% on adjusted earnings per share, in particular due to the strengthening of sterling against the US dollar relative to the third quarter of last year.

### **Results reconciliation**

#### **Q3 2021**

Slide 16 summarises the reconciliation of our total to adjusted sales. The adjusting items of note for the quarter were in intangible impairments, which primarily reflected the results and determination of the agreement with Merck KGaA on bintrafusp alfa.

My comments from here onwards are on adjusted results, unless stated otherwise.

### **Group sales and adjusted operating margins**

#### **Q3 2021**

The key drivers of revenues and profits for the Group in Q3 compared to the prior year are set out here. Revenues grew 10% overall. Excluding revenues from our COVID solutions, sales were up 8%. The positive operating leverage from higher sales in the quarter was bolstered by continued focus on cost control, and the benefits of restructuring across the group. This was alongside the expected 15% increase in R&D investment.

The resulting Q3 margin was 31.7%, and the year-to-date margin 28.1%. We now expect R&D to grow high single digits in the year, reflecting upscaled investment balanced by continued realisation of efficiencies with our approach to One R&D.

### **Adjusted operating profit to net income**

Moving to the bottom half of the P&L on Slide 18, I would highlight that the effective tax rate of 20.6% was higher than last year, and reflected the timing of settlements with the various tax authorities. We still expect the full year effective tax rate to be around 18%. We also still expect interest expense to be between £800 million and £850 million.

### **Free cash flow of £1.5 billion**

I will briefly cover free cash flow for the quarter before going into more detail on the financials of each business. In the year-to-date, we generated £1.5 billion of free cash flow. The main positive factors were increased adjusted operating profit at constant exchange rates, lower dividends to non-controlling interests, and lower tax payments, mainly in the US, versus the comparative period.

The primary factors more than offsetting this were increased purchases of intangible assets, including our collaborations with Alector and iTeos, adverse timing of returns and rebates compared to 2020, and adverse exchange impacts.

Improving cash flow performance continues to be a constant focus for the team, and pleasingly, we are ahead of expectations for the year; however, we do still expect this year to be a significant step down versus 2020.

## **Pharmaceuticals**

### **Q3 2021**

Turning to performance of the Pharma business, overall pharmaceutical revenues grew 10%, driven by strong growth in New and Specialty Medicines, favourable US return and rebate adjustments, and sales of *Xevudy* in the quarter, which contributed approximately three percentage points of growth.

In the year-to-date, overall revenues grew 5%, and we are raising our expectations for sales to increase low single digit in the full year, excluding *Xevudy* sales. Within this, we still expect Established Pharma sales to climb high single digits in 2021.

The Pharma operating margin was 29.4% in Q3, and 29.2% year-to-date. The increase in Q3 primarily reflected the positive operating leverage from increased sales as well as continued tight cost control and restructuring benefits.

These positive margin dynamics were delivered alongside our focus on increasing R&D investment, which grew 11% in the quarter. The prior period comparator included the recognition of pre-launch inventory for *Blenrep*, which was a credit of slightly over £540 million.

## **Vaccines**

Slide 21 is an overview of Vaccines performance, with overall sales growth of 13%. Excluding pandemic adjuvant revenues, sales growth was 8%, primarily driven by *Shingrix* in the quarter, which Luke described earlier.

In the year-to-date, total Vaccines revenues were up 5% and down 2%, excluding pandemic adjuvant sales. With sales year-to-date and a strong Q4 comparator, particularly for *Shingrix*, we now expect Vaccines sales to decline mid-single digits this year, excluding pandemic adjuvant. This has no impact on our mid-term expectations for the Vaccines business, for we continue to be very confident in the demand for our products and high single-digit growth outlook, notably with regard to *Shingrix*, where we have set the ambition of doubling sales by 2026.

The operating margin was 47.5%; the increase in operating profit and margin primarily reflected the positive operating leverage from sales growth with positive mix, as well as higher royalty income. Partly offsetting this was increased R&D investment of 46% as we progressed our RSV and meningitis development programmes and invested in our mRNA platform. The year-to-date operating margin was 37.3%.

## **Consumer Healthcare**

Q3 revenues in Consumer Healthcare increased 10%, excluding brands either divested or under review. Including those brands, turnover grew 8%, and Brian outlined the main drivers earlier.

In the year-to-date, revenues excluding brands either divested or under review, increased by 2%. The operating margin for Q3 was 25.9%, up 420 basis points at constant exchange rates versus last year. Year-to-date operating margin was 23.6%.

In Consumer in the full year, excluding brands divested or under review, we continue to expect low-to mid-single-digit percentage revenue growth.

## **2021 Outlook**

I'll close with considerations for our 2021 outlook. Following our strong performance in year-to-date, we are now confident that we can improve our full-year guidance. As a result of continued commercial execution, sustained delivery of tight cost control, and the

anticipated dynamics for Q4, we now expect adjusted earnings per share to be between -2% and -4% at constant exchange rates, excluding the impact of COVID solutions.

We also now expect COVID solutions to contribute approximately 7 to 9 percentage points of earnings growth in the full year, following better than expected progress on *Xevudy* contracting. It is worth noting that the outcome within that range is still dependent on pandemic adjuvant contracting for 2022 and the resulting potential charges within cost of goods sold as we continue to manufacture for this potential.

Key factors that influence Q4 and where we deliver in the full-year range, will continue to be the trend in adult vaccination rates within the context of the COVID environment, the relative phasing of launching investments to generate future growth, and the effective tax rate.

We will keep you informed of our progress in executing against our strategy, through events such as the HIV Update to which Deborah referred, and the upcoming Investor Science Event for daprodustat. We hope you will be able to join us for these events.

In summary, we believe that the business momentum from the excellent work of our teams has set us up for a step-change in growth in 2022, which is both an exciting and important year for the company. We will provide formal guidance for 2022 with our full-year 2021 results in February. Overall, an encouraging quarter with positive momentum.

With that, we are ready for Q & A.

### **Question & Answer Session**

**James Gordon (JP Morgan):** Thank you for taking my questions. My first question is on OPEX. I saw the reiterated comments about meaningful operating margin expansion next year, but also SG&A was 5% below in R&D and 8% below expectations today. The question is, how much is low OPEX about cost avoidance versus structural changes at the company? As we look into next year, from the higher base, when you talk about meaningful expansion, can New GSK have hundreds of basis points of EBIT margin expansion next year, or could there be a bit of catch-up if things get better with COVID and you have to start spending more? That is my first question.

My second question is about Consumer separation. A couple of weeks ago, Bloomberg was reporting that the Consumer division could attract bids from PE firms or other pharma or consumer companies. Have you had recent informal expressions of interest in the Consumer business and are discussions ongoing in parallel with the separation process that you have described? Or is that story inaccurate, or perhaps

something that happened historically, and is it definitively the separation process as described?

Finally, a clarification. I saw a comment about price rises in the US for Consumer. Are you able to tell us what the price rises are that you put through in October in Consumer, and how do you see the pricing power of the business going forward, please?

**Emma Walmsley:** Thank you very much for that, James. I will just comment on the separation first of all. As I outlined today, we are very committed to the demerger of at least 80% of our holding in Consumer. We are absolutely on the runway for that. We have had a tremendous amount of positive feedback from investors who are interested in owning this business, and really looking forward to sharing with you in Q1 with the Management team the prospects for that business and much more detail on its competitive advantage and the strength of the brand portfolio.

We have consistently said that we will seek to monetise in a timely and pragmatic manner the up to 20% remaining part of our shareholding in that business, and of course, the Board will always do its fiduciary duty, but we are really focused on the significant amount of work that delivering on this separation and the tremendous value unlock that's going to bring.

I will let Iain comment on the dynamics of OPEX, although I know his first answer is going to be we will guide into 2022, and then Brian can come back with some specifics on the price, because we do think we are a bit advantaged on that dynamic versus some other Consumer companies, but, Iain, over to you.

**Iain Mackay:** I hate being so predictable!

James, thanks for your questions. We will absolutely provide detailed outlooks for 2022 in early February '22 when we get there.

On your OPEX questions, I think one of the things that is really important to note, which is true across the business over the course of this year and last is just the very strong focus we have on tight cost control across, really, every line within the P&L. Whether it's within our costs of goods sold and great productivity, across the Pharma, Vaccines, and Consumer Healthcare businesses, really, from within the manufacturing sites through the logistics and to our main storage areas, also from an SG&A perspective, and then notably within R&D continue to keep moving our trials, moving along at pace, sometimes in quite a difficult operating environment, but also realising benefits through our approach to one R&D that Hal and his team have been leading.

There is another factor that has continued to play a part in 2021, and that is lower expense in line items, for example, in travel and related expenses, where, frankly, our levels of such activities are continuing to be fairly constrained in the current pandemic environment.

In terms of how we see this moving through the rest of the year, we will, as I mentioned in my comments here, continue to invest behind launches with a focus on driving growth and good momentum going into 2022.

We continue to grow investment in R&D, as you've seen this quarter, and we will continue to grow investment in R&D through the fourth quarter and into 2022 as well, but as I say, we will provide more detail on that when we offer 2022 guidance in February next year.

**Emma Walmsley:** Thanks, Iain, and Brian, on pricing and cost dynamics.

**Brian McNamara:** Yes, thanks, James. First, I just reinforce, I feel very good about the top-line growth in the business and the fact that we are seeing momentum across brands and categories from Q1 to Q2 to Q3.

On pricing, we have taken pricing across regions and categories. Most recently we took pricing in the US in October, and the US price increases were mid-to-high single digits on brands that represent about 50% of our sales, so brands like *Sensodyne*, *Parodontax*, *Emergen-C* and *Tums*.

While it is never easy to take pricing in the US environment, we had good acceptance on the pricing.

We are also taking pricing across Europe and have been successful in taking pricing in China also. Maybe for perspective, in the quarter, with our 10% growth, we saw about a quarter of that growth come from price, with about three-quarters coming from volume growth, and I am confident going forward we have the ability to take price. We have great brands, with great equity, strong innovation, and that puts us in a very good position.

**Emma Walmsley:** Yes, and the other aspect of that is we are less exposed on input costs, I think, than some other Consumer Goods companies, both from the size of our products and I think it is about 10%, or so, share of our sales comes from that too, so that's important to be aware of.

**Peter Welford (Jefferies):** Hi, yes, thanks for taking my questions.

Sticking to the two, firstly, I think one for Hal, I just wondered if you could comment a bit on DREAMM-5? We saw some headlines from your partners SpringWorks on this. I wondered if you could just comment in terms of what you have seen in the encouraging early data with the gamma secretase inhibitor, and what's prompted the expansion of this study, and what we should perhaps be thinking about in terms of next steps, and what you are looking for in that expansion cohort?

Then, secondly, just one, I guess, for Iain, just on the EPS outlook. Just to be clear, can you just outline in the band you have given for EPS, does that at the moment include any COGS write-downs for the pandemic adjuvant, or does that explain, if you like, the 7-to-9% delta, and perhaps you could just explain what the implied sales are of *Xevudy* and the pandemic adjuvant within that 7-to-9% range? Thank you.

**Emma Walmsley:** Okay, let's come to Hal first and then to Iain, please.

**Hal Barron:** Thank you for your question, Peter. I think, as you know, the functional genomic data that we generated was very suggestive that there would be synergy between a gamma secretase inhibitor and *Blenrep* due to its inhibition of the cleaving of BCMA protein from the surface of the plasma cells. That's what was being tested in the sub-study of the DREAMM-5, to see if a dose of *Blenrep*, which we studied at 0.92mg/kg, Q3 weeks, would be active on top of a GSI.

We know from the DREAMM-1 study, although limited numbers of patients, that such a dose would have limited, if any, activity, so we studied to see if the combination of gamma secretase plus *Blenrep* at this low dose would induce meaningful responses. As we said, the data, although preliminary, is very encouraging and has led to us un-gating the expansion phase of this programme. In that expansion we are going to be comparing in a randomised way, so that we can get more robust data, whether the 0.9mg/kg dose of *Blenrep* given Q3 weeks with a GSI, compares to the standard approved dose of 2.5mg/kg, Q3 weeks, as monotherapy in the refractory setting.

**Iain Mackay:** On EPS, and specifically any elements coming through COGS on adjuvant sales, no, we absolutely fulfilled the obligations and expectations for adjuvant sales for 2021, with no adverse impacts coming through cost of goods sold. As I mentioned in my comments, Peter, in terms of whether there will be any impact in the fourth quarter, or for that matter next year, is really very much about the antigen contribution based on the outcomes of the Phase 3 studies that we have going on with a number of partners, two of which – Sanofi and Medicago - we would expect to read out in the fourth quarter, and one in

the first part of next year from SK Bio. So, at this point, nothing adverse coming through cost of goods sold as it relates to that.

In terms of *Xevudy*, we have contracted more than 420,000 doses, and we have reserved, with agreements being negotiated presently, of more than 220,000 doses, those negotiations ongoing with a number of governments. You'll have noticed within the quarter we recognised £114 million of revenue from part of those 420,000 contracted – not all of that 420, obviously. Clearly, Luke and the team continue to pursue contracting opportunities for this important treatment for COVID-19 aggressively, because it clearly has a very beneficial effect conceivably on impacted patients; but that is really the dosage outlook that we have in terms of contracted and reserved at this point in time, Peter.

**Mark Purcell (Morgan Stanley):** Thank you very much for taking my questions. First one on RSV for older adults: the timeline has shifted forward from the second half of next year to the first half of next year, can you help us understand whether this is a function of speed of recruitment or higher implied infection rates at the trial sites, including competitive dynamics with two other players in pivotal trials.

Then secondly, there has been a lot of press recently around COVID vaccines and raised concerns around a relatively narrow neutralising antibody response versus only the S protein. With actual infection you're seeing much higher levels of N protein antibodies, for example, so when it comes to next generation approaches, are you considering with your partners developing COVID vaccines against a broader range of protein targets beyond just the S protein? Thank you.

**Hal Barron:** Thanks, Mark, for the great questions. First, to talk about RSV, very excited about the opportunity here, of course, because of the significant unmet medical need that RSV represents, with, I think as you know, more than 175,000 patients in the United States alone being hospitalised, and 14,000 deaths, something that compares in some respects worse than flu.

Our programme is progressing very well, the decreased movement forward in timelines is really completely driven by operational efficiencies and our ability to enroll more aggressively. Of course it's going to be an event-driven trial, so events will matter, but the timeline shift is simply due to better execution and acceleration.

I think the second question was about COVID and the impact of neutralising antibodies, whether they be from vaccines or endogenous infections, and I think it's an opportunity to highlight that the immune response generated from the various vaccines does



differ, and as variants start emerging the response in the neutralising titres to each of these sub-clones is different. This is why we're very excited about our protein with the adjuvant as a vaccine, and I think we'll have data for that in the coming months. We're very excited to see what neutralising antibody titres and how they compare to other vaccines that are available today, because there could be, as you say, an opportunity for a broader spectrum response.

With mRNA, as you know, we are pursuing a collaboration with CureVac, and we have a second generation approach, where we are using this so-called 'optimised five prime three prime to make sure the transcripts are more stable and therefore protein expression is higher. We're also exploring a version of that with both unmodified as well as modified, to see what the incremental contribution of modified is. Pending that data, of course, there is the opportunity to be able to explore creating transcripts to any of the variants that emerge, to be able to focus on neutralising titres on any variants. It is an exciting technology and we are excited to be playing a major role.

**Simon Mather (Exane):** Thank you for taking my questions – my first is for Deborah. Just looking at HIV, obviously *Dovato* is doing exceptionally well now, is driving new growth in the ViiV division overall. Do you have any thoughts about the future potential threat from Merck's islatravir, two days ago, I think we saw headline results that their ILLUMINATE SWITCH study seemed to be non-inferior to the current best-in-class treatment opportunity. If you could talk us through the opportunity that you still see in the two-drug regimen and the threats you see from Merck, that would be great.

My second question may be for Luke. Could you give us an update on your views around the commercial opportunity for daprodustat? Originally, I think there were very bullish expectations that HIF inhibition could offer an oral alternative that was safer than ESAs. Obviously, from the competitive data, it doesn't seem as though that is the case and I was wondering whether you could talk about the commercial opportunity for daprodustat. Thank you.

**Deborah Waterhouse:** When we think about our portfolio, you are right that *Dovato* has had a very good quarter. We are really proud of our innovation and leadership in the development of two-drug regimens in the long-acting therapies. You can see our competitors following us and, as you say, there were two studies out this week at a headline level for Merck in a two-drug regimen in the switch setting.

If you think about the label that *Dovato* has, basically we have the GEMINI studies in naïve out to three years, which showed non-inferiority versus a dolutegravir-based three-

drug regimen. Then you have the TANGO in the switch setting again, with data out to three years with no confirmed virological failures. Then we have recently published our SALSA study, which was a second switch study: this was similar to the Merck one, so it was an ARV versus *Dovato* study and, again, we saw no confirmed virological failures on *Dovato* through to 48 weeks. All that data has led to a great deal of confidence in *Dovato* by physicians, and we are now seeing that converting into prescribing. We see that *Dovato* is on all the major guidelines, recommended for both naïve and switch.

However, I think that having a competitor coming into the market, who is following on from us and is also, in the future, going to promote two-drug regimens, will help to move the market to two-drug regimens. If you think about the US, at the moment, less than 5% have converted over to *Dovato*. It is much higher than that in Europe but it is a journey that is moving at pace, albeit probably more slowly than we would like to see. That could be very helpful in reshaping the market and building even more confidence in two-drug regimens.

For me, the question we should ask ourselves every single day is, why should someone living with HIV take three medicines when two is all they need? On that basis, there is a huge potential for two-drug regimens, and I think *Dovato* has a very bright future. We will see what our competitors bring in, following on from us.

**Emma Walmsley:** Luke, on dapro?

**Luke Miels:** Thanks, Simon. If we all went back 18 months ago, I don't think many people would have expected that dapro would be one of one, or maybe one of two HIFs in the US. So, I think that has driven a reappraisal of the potential for that reagent in the US and also Europe. I think the potential is likely going to be driven by the type of label that we get overall, with safety being the key element there, particularly in the non-dialysis population, where a number of companies with EPOs, including long-acting EPOs, have tried to penetrate that area and it has been a bit of a challenge.

If you look at the numbers long-term, we estimate that by 2030, there will be about 8 million CKD patients who are anaemic – so less than 12 – and on the label that we expect initially, I would say that about three million of those would be eligible. You have about one-third of that with dialysis – and this is in the US and the EU5. The potential is certainly there, but I think it's going to depend on how the regulators treat it. I think also we are expecting publications around the ASN academic event, and I think the treatment through the editorials would also be very influential there. So, very positive but we just need to see how the frame lands. There is clearly a high demand for these products: EPOs have limitations, particularly in the non-dialysis setting, and we are very, very focused on ensuring that we make the maximum opportunity of this product.

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

**Graham Parry (Bank of America):** Thank you for taking my questions. Firstly, on *Shingrix*. In your commentary around 2022 in deferred sales, and you guided there to strong double-digit growth and record sales. If I look at the consensus at the moment, that's probably pointing to £2.5 billion or closer to 50% off where your current guide is. Does that fit within what you would define as a strong double-digit envelope?

Then, secondly, on RSV vaccine, if you are pulling forward to first half '22 just on enrolment, could higher RSV incidence see that data land as early as Q1? Perhaps just help us understand where you see a differentiation now you have started to see more data from the competitors in the clinic with data from Pfizer, J&J, and Moderna all out there now, particularly in terms of the implications of your adjuvant, but also not targeting RSV B with your vaccine. Thank you.

**Emma Walmsley:** Thanks, Graham. We are not going to outline specific guidance for *Shingrix* in '22 today, but, Luke, it may bear you just reiterating some of the underlying both consumer and commercial dynamics on that. Then let's hear both from Hal on the overall underpinning scientific differentiators, but also I think it would be good to hear from Roger on how we see the prospects of the RSV market playing out, but first to Luke, please.

**Luke Miels:** Sure, thanks, Emma. Thanks, Graham. If you look at demand for *Shingrix* in the second half of this year it has been clearly correlated with outbreaks of Delta, which I think is logical. People don't want to go into retail pharmacies if there is a Delta outbreak in their area, and we follow that at a state level each week and the pattern is very, very clear.

Now, what is interesting is when we look at leading indicators like, for example, Google searches are the highest level we have seen for shingles in the last couple of weeks. If you look at the script trends that we are now starting to see, these are also very encouraging. A key point on the script trends, and I mentioned in my commentary at the start, when we saw the impact of COVID vaccines and just the need for retail pharmacy to deploy infrastructure and staff to give those vaccines, we made the decision - and it was a risk at the time but it has played out - to promote *Shingrix* in the second slot on the *Trelegy* team, targeting HCPs in their offices, and normally that's about a third of shots that are given are HCPs and about two-thirds to retail. What we are seeing right now that's more 50/50, which means that you are seeing an under-reporting of the TRx levels because they are more efficiently captured in retail.

So these are all encouraging. Emma mentioned the market research that says when we ask people who have been vaccinated for COVID, so they tend to be motivated adults, they list *Shingrix* as their second vaccine they want to get after flu, so these are all pointing in the right direction.

I think if you look outside of the US, we will be in 17 markets at the year-end, with 35 added over the next three years.

We had a very strong start in Germany, that was disrupted by COVID vaccine and outbreaks; that is now returning. I predict Germany will be the second largest market next year.

These are all the elements that underly our confidence there. People may have questions around the inventory. The inventory is very much in the range that it has been historically. In the past we have seen it drop down to, say, 0.5, 0.7 million doses, but the range it normally stays in is just over a million, and we have a lot of heritage managing that very tightly because of the past supply problems, so right now it is very much within the million doses, very much under control, and our feedback from retail pharmacists and HCPs is continued demand.

So I think the hypothesis of deferred demand remains robust.

**Emma Walmsley:** Thanks, Luke, and Hal, and then Roger, please, on RSV.

**Hal Barron:** Yes, thanks, Graham. We are very excited about the RSV programme and the changes we have made in the development organisation to be able to speed this up from an operational efficiency perspective, but as you point out, there are other contributors to when you will be able to see the data, including event rates. That is one of the dependencies, to see how many events we have, and I should say the third aspect of when we will be able to see data is driven by being able to see the duration of the effects so making sure we have a broad section of the season, so that we can understand the effect over time. When all three of those things go into when we will see data, but we are confident it will be in the first half now.

As far as differentiators, we see this as a very important component of why we use the adjuvant. If you think about this disease, it is really prominent in those over 65 because, as you age, your immune system becomes somewhat less able to mount the appropriate B-cell response, the neutralising antibody titres, but also to mount an effect T-cell response, the cellular immunity. What we have seen over and over in vaccine development with other diseases and what was confirmed in our Phase 2 data is that the adjuvant that we are using is actually very effective at normalising, if you will, the T-cell response, and when you look at

some of the competitors that don't have that, it is not clear from the data generated whether the immune response that's generated in the elderly will be as effective as the one we can generate with an adjuvant, so we see that as a differentiating feature. It is not just true with this vaccine, but our whole adjuvant platform.

I think the other point is that we have looked very carefully at the neutralising antibody levels towards both RSV protein A and B, the different epitopes of the two viruses, and we see a very effective neutralising antibody to both by the pre-F protein, so we are expecting that will be very effective with both variants, and as I said, with the adjuvant being able to mount a T cell response, which we think will both have a broader antibody spectrum, as well as possibly greater duration of effect, leading to a differentiated vaccine on that.

So, pleased about the speed, pleased about the science, and hopefully we will see that translate into a very effective vaccine quite soon.

Roger, did you want to add a little more to that on the commercial side?

**Roger Connor:** Yes, just very quickly, Hal. I think you touched on the excitement – the market size here is really significant, one billion people more than 60 years old, we believe there is that major opportunity. I don't think people have really realised again that the hospitalisation burden on this is higher than flu, so we have a real opportunity, we believe, to come in and take a significant part of what is a big market as well.

A couple of points that we will be looking at to potentially drive differentiation: duration of protection, as Hal mentioned, linked to that adjuvant as well. I wouldn't underestimate the importance of our safety record on our ASO1 adjuvant as well. We have now given this to more than 25 million people, so again, building off the *Shingrix* history there. We know the older adult market through *Shingrix* as well, so that's another positive that we want to apply.

Just quickly on supply as well. We are investing at pace in advance to be ready for this vaccine as well. We obviously step-changed *Shingrix* capacity recently, this is the same technology platform. We had a double whammy benefit: by improving *Shingrix* we also get a step in our RSV capacity as well, which is great, which means that we're going to be ready for this launch as well.

**Seamus Fernandez (Guggenheim):** Thanks so much for the questions. I just wanted to go back to the gamma secretase, hoping you're going to help us understand when you might be sharing the combo data that you have so far, and how you see the combos

fitting in relative to some of the other Phase 2 expansions that you've started? I just note the DREAMM-14 study has a number of different doses and schedules with *Blenrep*.

My second question is really on the process of the demerger itself. There has been some speculation and questions around the value of potentially shifting gears to an IPO. Just wondering if you could either confirm or deny that possibility. It seems like you're quite far down the path with a straight demerger spin, and just hoping to get a little bit of clarity there, given some speculation in the market. Thanks so much.

**Emma Walmsley:** Seamus, I can be really quick on your second question and then hand back to Hal on *Blenrep*. Just to repeat what I've already said, we are very committed to the demerger of at least 80% of our holding. We've had very positive levels of interest from our shareholders, and then we are looking at a timely and pragmatic monetisation of the remaining up to 20%. We are on the runway and we are really focused on executing that brilliantly.

Hal, over to you on the various approaches to maximising BCMA.

**Hal Barron:** Thanks. When you look at the strategy we have for maximising the opportunity for *Blenrep* in patients, it's important to remember that the risk/benefit for myeloma patients changes according to the line of therapy that we're studying, so when we think about studying the second-, third-line patients, such as in DREAMM-3, we're going head to head with pomalidomide, in DREAMM7 and 8 we're going head-to-head with Velcade and Darzalex. We're doing a number of things.

First of all, we're trying to be superior to pretty effective standard of care, and in that setting we're really focusing on optimising efficacy. As we think about trying to reduce some of the ocular toxicity that we're seeing, we really have a four-pronged approach, of which gamma secretase plays one role. We're really looking to see if we can lower the dose, as we've seen in the ALGONGUIN study, to doses like 1.9mg/kg where when we give it with standard of care therapy such as Pomalidomide and other drugs that are approved, and we think that by lowering the dose we might be able to reduce ocular tox.

We also know that there's an opportunity – and we'll be seeing some of this data later this year – of the impact of changing the schedule, and by that I mean moving from a Q3 week to a Q4 week, maybe even a Q6week or even a Q8 week dosing regimen, where the peak trough ratio changes and exposure changes in a way that we hope might reduce ocular tox. Of course, we have the opportunity to think about how we alter the schedule as it relates to dose holding. Currently the approved regimen as demonstrated in the programme on DREAMM-2, we tend to hold the dose when patients develop – whether they're

symptomatic or not – Grade 3 keratopathy. There's an opportunity to alter that holding pattern to, say, Grade 2 keratopathy, to prevent the further development.

So we're exploring those three different levers, if you will, on how to optimise, in combination with this very intriguing concept of being able to lower the dose by inhibiting gamma secretase, which, as I mentioned earlier, is responsible for clipping the BCMA off the plasma cell, and by inhibiting that increasing expression and by doing so, maybe allowing equivalent efficacy at a lower dose.

Those are the four levers to reduce ocular tox, and of course at the same time designing trials to show superiority in head-to-head trials, as I mentioned, in DREAM-3, 7 and 8. So there are a number of different strategies, all being modular to some extent, and depending on the patient population, the concomitant medicines and, most importantly, the line of therapy. We are mixing and matching those to optimise the programme.

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

**Andrew Baum (Citi):** Thank you, I have a couple of questions. Emma, I listened very carefully to your comments at the beginning of the call. You described GSK as being 'agile' in terms of COVID opportunities. One of your existing partners in ViiV, a very longstanding one, has a novel non-boosted protease inhibitor for COVID. I am just intrigued if you would care to comment on the relative level of interest, given that Shionogi has talked to partnering the asset with a global partner. It is difficult to think of someone better equipped than GSK.

Secondly, and again listening to your answer about private equity and the story that was on Bloomberg last week, you have juxtaposed your response about timely monetisation of your stake, the IPO, or the sale of stock from GSK that you don't demerge, potentially creates an overhang until it is put into the market. Are there potential creative solutions one may think about - and I am particularly thinking about PE - by which the overhang could be taken away and yet GSK could have access to capital early in order to facilitate business development? Thank you.

**Emma Walmsley:** My reference to agility on COVID was less about – and I will not to comment on any of these specific potential additional partnership or not – but it was much more about how the environment around COVID vaccination continues to change as data emerges all of the time. Obviously, the first question is, how do you contribute to the pandemic? Then the question is, what is the shape of an endemic-specific market for COVID? And then the question is, how do we all learn, and how will GSK continue to lead

the way in terms of a broad technology platform? It is that kind of agility, to make sure we keep adjusting, and the thoughtfulness on how we are approaching mRNA as Hal outlined earlier, in terms of looking both at the proof of the platform within COVID. This is because you can't imagine a better global dataset than we have now, both on a modified and an unmodified basis, but also looking at potential combos. We have said that we are looking to be in the clinic around COVID and flu by next summer and then we have another six possibilities over the next four years. There is lots of learning continuing on mRNA opportunities, and that is where we want to bring our agility.

It would be fair to say that the global level of supply around pandemic vaccines – even if such low percentages of the developing world are vaccinated so far – has surged. I don't think that is so much the primary question, although obviously we will be thrilled to contribute, not least through COVAX, as our protein adjuvant read-outs come. There, we are dependent on our antigen partners in terms of their capacity to supply.

On your other question, one of the key reasons for retaining up to 20% was precisely as you referred to – the additional opportunity beyond the initial deleveraging, with the transfer of debt, and to further strengthen our balance sheet and be able to keep investing in our No. 1 priority. We said it will be in a timely and pragmatic manner, and it will be timely and pragmatic - about maximising value.

I have to say, in terms of the prospects of the Consumer business, we really do feel confident that this is going to be an appealing stock and hopefully we will bring much more visibility to it in Q1.

**Laura Sutcliffe (UBS):** Could you help us understand a little further how *Shingrix* is working in the real world, in the retail setting, at the moment? If a patient is receiving a flu vaccine, or a COVID vaccine, and makes it as far as the retail pharmacy, are they a person who is a likely candidate to get *Shingrix* at that time? Or someone who is avoiding getting *Shingrix* at that time?

Then, for Deborah on HIV, on your third-generation integrase inhibitor with Shionogi, could you tell us what routes of administration you think might be possible for that molecule? Thank you.

**Luke Miels:** Laura, that is a great question. If someone presents seeking a COVID-19 vaccine, I think the key parameter is their history of adult vaccinations in the past. If they are somebody who regularly came for a flu shot, then they are likely to be more receptive on the part of the pharmacist. It depends then on how much time that individual



has at that point, and also on how busy the pharmacist is. Of course, if there are 10 people lining up for a COVID shot, then the opportunity to discuss the benefits of being vaccinated for shingles is less. In that case, though, the retail pharmacists have incentives through the major changes in the US to rebook that patient to come back to the retail pharmacy on another date and receive that vaccination, or they can give those doses concomitantly, which ACIP have indicated they are comfortable with.

We are also running a study with Moderna's COVID vaccine that will read out in Q1 of 2022, just to build some more evidence around that co-administration. Then the other trend which I think is just encouraging, although we didn't mention it earlier, is around seven out of 10 shots right now are for *Shingrix* are their first shot, and we know 90% of people so far come back for the second shot, so is there a history of vaccination and how much time does the individual have and the pharmacist have, and then usually the aim is to rebook them to come back.

**Deborah Waterhouse:** Thanks, Laura. Our current and future portfolio has integrase inhibitors at the core and they really are the proven gold standard of therapy in the field today, and we believe in the future. They are supported by guidelines, by a significant amount of really strong data, and you have, I think, more than 18 million people living with HIV today taking a second generation integrase inhibitor, so our core belief is that if you are going to be successful it is very important to have a strong and a robust integrase inhibitor at the core of your regimen.

Then, if I think about what Shionogi offers, the Shionogi integrase inhibitor has the potential to be ultra-long-acting, and it will also have a unique resistance profile, so by the time we get to 2030, undoubtedly, some resistance will have emerged to the second generation integrases, such as dolutegravir and bictegravir, so this unique resistance profile is going to be very, very valuable.

We believe the opportunity to really harness the ultra-long-acting potential is to have it as a subcutaneous or an intramuscular, and so what we will do as we now start the development journey of that medicine is to explore both of those options, but we don't see it as an oral. We are very much looking at it as a subcut or an intramuscular injection.

**Emma Walmsley:** Thanks, Deborah. I think we have time for one last question today. Obviously we can do lots of follow-up with you afterwards, but time for one last question, please.

**Kerry Holford (Berenberg):** Thank you very much. Two questions, please. On *Zejula*. Luke, I think you said diagnosis rates vary, around 15% below pre-pandemic levels. Are you seeing any signs of improvement here now, and is this something that you expect to normalise this year, or are we going to move into next? Essentially, when do you expect a step-change in the *Zejula* sales growth trajectory?

Then, just on *Benlysta*, perhaps question for Hal, any thoughts of why the Phase 3 BLISS-BELIEVE study failed to show any incremental benefit over *Benlysta* mono alone? Thank you.

**Emma Walmsley:** Let's to go to Hal first and then finish with *Zejula*.

**Hal Barron:** Kerry, thanks for the question. I think the simplest answer is that *Benlysta* was a backbone for both arms, of course, and is a very effective therapy for these patients with lupus nephritis, and, essentially, rituximab in the single dose in the manner it was given just didn't add anything to *Benlysta*'s very effective management of these patients.

**Emma Walmsley:** Right, Luke?

**Luke Miels:** Thanks, Kerry. I think we were actually hoping to see a recovery by now, but then we saw the Delta version emerge, and on Slide 26 in the appendix we put the IQVIA data there just showing that relationship.

Now, surgery did go up in August. We expect a restatement, but you can see obviously we hadn't got through the peak of Delta in the US in August, so hopefully as we go into the northern hemisphere winter we see a reduction, and with the booster a reduction in the number of cases, and more of these women present to their GPs and then are diagnosed. Of course, ovarian is a very difficult tumour to diagnose because the symptoms are quite diffuse, so that's the challenge.

The downstream effect, then, of course, is typically they will have six to seven cycles of chemo, so from that initial debulking event it is going to take another six months before they present to maintenance.

What we don't know is are these women going to be, by virtue of being diagnosed later, more progressed in their disease, so likely to relapse faster, and therefore compress the total period at which they are treated with a maintenance therapy, so it very much remains unknown.

When we do look at the patients that are coming through and being diagnosed, as I said earlier, we are very, very competitive in those new and emerging patients, and continue to be so, and continue to make the argument for the benefits of *Zejula* over the alternatives.

## **Closing**

**Emma Walmsley:** Thank you.

In conclusion, it is a quarter where we've continued to deliver evidence that the hard work of the transformation programme over the last four years is generating results. We have strong business performance, double-digit sales growth in Pharma and Vaccines, and increased momentum in Consumer Health, and that's allowed us to upgrade the full-year guidance, and alongside the progress in strengthening our pipeline reinforces our confidence in the outlook for a step-change in growth and performance from 2022 and beyond. At the same time, we are very excited about the progress towards unlocking all the shareholder value with a successful demerger in mid-2022, which is going to be a landmark year for our company.

Thanks very much, everyone, and I look forward to following up with you in the coming days.

[Ends]