### GLAXOSMITHKLINE

# Q1 2018 Results

## 25 April 2018

**Sarah Elton-Farr:** Good morning and good afternoon, everyone. Thank you for joining us to discuss our Q1 2018 results which were issued earlier today. You should have received our press release and can view the presentation on GSK's website. For those not able to view the webcast, slides that accompany today's call are located on the investor section of the GSK website.

# Cautionary statement regarding forward-looking statements

Before we begin, please refer to slide two of our presentation for our cautionary statements.

### Agenda

Our speakers today are Chief Executive Officer Emma Walmsley; Luke Miels, President of Global Pharmaceuticals; David Redfern, Chief Strategy Officer and Chairman of ViiV, and Simon Dingemans, Chief Financial Officer.

Following our presentation, we will open the call to questions and answers. We request that you ask only a maximum of two questions so that everyone has a chance to participate.

Joining us for Q&A are Dr Hal Barron, Chief Scientific Officer and President of R&D; Brian McNamara, CEO of our Consumer Healthcare business, and Luc Debruyne, President of Global Vaccines.

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

### Q1 2018 Progress

**Emma Walmsley, CEO:** Thanks very much Sarah, and good morning and good afternoon to everybody.

#### Balanced business to deliver growth and returns to shareholders

As we have said previously, a strategic strength for GSK is our balanced business profile beyond Pharma, for sustainable growth, returns and cash flows. I am pleased to say that, in our first quarter 2018, we have continued to deliver growth across the business on a CER basis, with a strong focus on commercial execution. This performance represents encouraging progress and is in line with our expectations for the year.

## CER sales growth in all 3 businesses: improved Group operating margin

We delivered Group sales growth of 4% in CER terms in the first quarter.

In Pharma, our new Respiratory portfolio grew at 42%, including the first full quarter's contribution from *Trelegy*. So our new products are generating strong growth and we are increasing our share in the important US market.

In HIV, we continued to delivery double-digit growth, driven by continued increases in market share for *Tivicay* and *Triumeq*, as well as the first full quarter of sales of *Juluca*, the first of our new 2-drug regimens in HIV.

Vaccines was up 13%, with a strong and fast start from Shingrix.

In Consumer Healthcare, we delivered 2% growth, in line with our expectations.

This Group sales performance, combined with continued cost discipline, helped deliver a further improvement of 130 basis points in the Group Adjusted Operating Margin, at constant exchange rates. This has driven adjusted EPS growth of 11% and free cash flow of £324 million, impacted by the payment of a milestone to Novartis.

## Q1 progress made on our 3 long-term priorities

In July last year, I laid out my long-term priorities for the whole company: Innovation, Performance and Trust. These priorities are designed to support changes and the new focus we need to reach our goals, and to position us for stronger growth in the 2020s and beyond.

In 2018, we are particularly focused on three things, all underpinned by the start of a necessary shift in culture. First, there is excellence in commercial execution. Our new launches continue to perform well and we've seen encouraging starts for *Trelegy*, *Juluca* and *Shingrix*. Luke and then David will give you more of an update on these in just a moment, as well as on our growth in new Respiratory products and HIV.

The second, very important priority this year is strengthening R&D. Dr Hal Barron joined us at the beginning of the year and is set to give a first update on our R&D direction and priorities at Q2. In the meantime, we continue our portfolio review which, together with

changes we are making throughout the company, will allow us to invest more resources behind what we see as the assets with the highest potential for GSK, such as our multiple myeloma therapy BCMA.

Our third major focus in 2018 is cost, cash and capital discipline. We are allocating resources to those areas where we see the best returns. We are investing behind our new product launches, with a focus on priority markets. Funding is coming through savings made with changes to our supply chain and by restructuring our commercial ops to take cost out of the back office and invest it in customer-facing activities.

When it comes to capital allocation, we made significant progress this quarter with the announcement of the buy-out of the Novartis stake in the Consumer Healthcare joint venture. This will allow GSK shareholders to capture the full value of the business we believe is well-positioned to deliver future sales growth and continued operating margin improvements.

This transaction is expected to be accretive to earnings and it strengthens cash flows. Most importantly, it removes a long-term uncertainty for the group's capital planning, allowing us better to plan future capital allocation, in particular to strengthen our Pharma R&D pipeline which is our No.1 priority.

Finally, of course, underpinning all of this is cultural change. This is a long-term effort and making GSK fitter to compete in the future. We are committed to building a culture with greater performance focus and more accountability but without losing the values and long-term purpose that make our company special. We are making significant changes in our leadership teams, in our engagement with our employees and in our expectations for how we want our people to work. Our new incentive programme, which is an increased focus on performance was also launched this quarter.

I shall now hand you over to Luke and David who will give you an update on our progress within Pharma and also the *Shingrix* launch. Luke.

### Pharma Update

**Luke Miels (President, Global Pharmaceuticals):** Thanks, Emma. Good morning and good afternoon everyone.

# Increasing focus and prioritisation

At Q4 I shared our commercial priorities for the business and the key areas of focus, and I am pleased to say that we are making very good progress. You can see on the slide here a few examples. We have identified 20% of non-customer facing commercial spend that will be reinvested in frontline support for our key products. Our best commercial leaders have been put in charge of our key markets and through detailed business reviews, we have now identified additional growth opportunities in key markets, such as accelerating launch timelines in China, and targeted salesforce investment in India.

More broadly, our Emerging Markets business has been segmented into three models based on market characteristics and growth potential to ensure each market has the right level of resource to optimise their performance. We have also clarified accountabilities between the above-country and in-market teams to ensure everyone in the commercial organisation is focused on where they can create the most value for the business. We are now strengthening the above-country teams to ensure a stronger, more effective commercial input into R&D with Hal's team.

These changes, together with a more decisive and, frankly, fast-pace culture, we believe will deliver long-term value for the business and our shareholders by maximising the potential of *Trelegy* and *Shingrix*, as well as accelerating *Nucala* and improving growth across the Emerging Markets.

## Trelegy - driving continued leadership

Moving to our Respiratory portfolio, I would like to give you an update on the launch of *Trelegy*, the first once-daily closed triple treatment for COPD in our innovative and easy-to-use *Ellipta* device.

We started our roll-out plans at the end of last year with a targeted launch to pulmonologists - if you recall, we had a relatively narrow label - and we have made steady progress on building coverage. This targeted approach, together with our strong clinical data and the clear demand for a closed triple therapy in COPD, has led to a strong uptake. The chart on the slide clearly shows how *Trelegy's* launch has surpassed that of our other *Ellipta* launches in recent years. I am also pleased to say that, to date, it is one of the best Respiratory launches in the past decade at this point post-launch.

The benefit to patients offered by *Trelegy* has now been demonstrated in both the FULFIL and IMPACT studies, which clearly show the superiority of triple therapy over duals in patients who are exacerbating. The landmark IMPACT study, which was just published in the *New England Journal of Medicine*, demonstrated significant reductions in exacerbations against ICS/LABA and LAMA/LABA combinations, as well as a range of other clinically important outcomes including lung function, health-related quality of life and some very interesting data on mortality in patients with a history of exacerbation, which will be further explored at ATS.

I believe it is fair to say that these data, which are, for the first time, answering important questions in COPD management, support the expanded label that was approved by the FDA, and they will now enable us to ramp up our promotional activities and expand our reach beyond the initial target universe to the primary care physician base. This really is the key to the longer-term success for *Trelegy*, which we believe raises the bar for the treatment of COPD, and we expect this over time to be reflected in the sales potential.

Taking the Inhaled Respiratory market more broadly, we continue to see market share and volume growth for our portfolio and, as we have previously said, the pricing and competitive outlook is challenging and we are seeing that impact on certain products specifically in the US. With these increased competitive pressures in the ICS/LABA market, we are now shifting resources from behind *Advair* to support our future: the new products such as *Trelegy* and *Breo* where we see a greater long-term value and we shall continue to prioritise and allocate resources to respond to the environment and new competitive dynamics.

### *Nucala*: a new respiratory biologic with significant growth opportunity

Let us now look at *Nucala*. We are confident that the long-term success in the severe EOS asthma space is strong and consistent efficacy, demonstrated with *Nucala* which is the best within the IL5 class when you look at the level and consistency of exacerbation reduction achieved in both pivotal studies, where even a relatively low EOS level of 150 delivered a reduction of 56%, ahead of our competitors. At a level of 300, *Nucala* is able to show a reduction of more than 60%. These effects are also very consistent across studies.

This quarter we presented data from the OSMO study at Quad AI, which showed that severe asthma patients who are uncontrolled, despite receiving Xolair, and who are eligible for treatment on *Nucala* received improved asthma control when switched onto *Nucala*. This is key because there is a sizeable overlap in patient population between Xolair and *Nucala*, and we believe around 20% of those patients on Xolair are suitable for treatment with *Nucala*.

Clearly the market for biologics in the treatment of severe eosinophilic asthma is increasing and, as the chart here on the right of the slide that you can see now shows, and we believe that this is a market that remains undertreated, with fewer than 25% of patients receiving a biologic agent to reduce the number of attacks they are suffering. There remains plenty of untapped opportunity, despite the entry of new competitors into this space, and we are confident that we have the data to continue to generate meaningful sales growth.

On top of the opportunity within asthma and EGPA, we have filed for use in the treatment of COPD – a market that has material potential – and we hope to gain US approval later this year. We are also continuing with our global roll-out, with launches in Italy and France during Q1, and more European launches expected later this year. Performance year-to-date in these markets, I am also pleased to say, is very encouraging.

### Shingrix: encouraging launch performance

Now for *Shingrix*. Moving to *Shingrix*, which was launched towards the end of 2017, as you all know, *Shingrix* represents a new standard of prevention, with more than 90% efficacy in the prevention of shingles. Last year we received a preferential recommendation from ACIP, giving us a target universe of over 100 million patients in the US.

Initial indications are also very good. We are rapidly building coverage, and now more than 90% of patients have access through both Medicare and Commercial channels.

We have also gained market share rapidly and in the last data I just saw recently, we have a share of 99% according to IMS. This is pharmacy sales, so it represents about 60% of the market.

The sales that you have seen reported today of £100 million are still heavily driven, however, by filling the pipeline, but take-up is growing, and we estimate that around one-third of the doses we have sold to date have now been used to vaccinate patients.

We would expect, therefore, on that basis, that the mix changes as the pipeline fill comes to an end, and the patient use builds. We are confident this is going to be a very significant product for GSK.

With that, I will now hand over to David.

#### Confident in HIV growth outlook

### David Redfern ( Chief Strategy Officer, Chairman of ViiV Healthcare):

Thank you, Luke.

Overall, we continue to see strong prescription growth for our HIV medicines. This includes in the US where, driven by both market growth and, importantly, increased share of the market for dolutegravir-based regimes, we are maintaining our leading position in the single tablet and core agent market, which has now grown to just over 28%.

Reported sales in the quarter were impacted by some wholesaler inventory effects, but overall, we are encouraged by the dynamic trends we are seeing so far. Dolutegravir continues to maintain its position as the preferred core agent, based on the extent of the data we have and the consistency of effect in all patient populations, including more difficult to treat patients, and those with a higher viral load.

We are also pleased with the introduction of the first of our two-drug regimes, *Juluca*, which now has a 3% share of new to brand prescriptions. Encouragingly, more than half of the source of business for *Juluca* so far is coming from non-dolutegravir based regimes, and particularly from those patients switching from older combinations. We recently received a positive opinion in the EU for *Juluca*, and we very much look forward to receiving 48-week data from the GEMINI study of dolutegravir plus lamivudine in naïve patients, the second of our two-drug regimes this summer, and that will form the basis of an FDA submission later in the year.

We are also expecting the Phase 3 data from the FLAIR and ATLAS studies for our long-acting injectable two-drug regime in the second half of 2018.

With this broad portfolio of assets, we believe we are very well-positioned to meet the changing and different needs of HIV patients, as lifespans and durations of therapy increase, and we remain confident in our growth outlook for our HIV business.

I will now hand you over to Simon to take you through the Q1 financials.

## Q1 2018 Financial Results

## Simon Dingemans (CFO): Thank you, David.

Overall, the results we have reported today keep us on track for the year. Our earnings release provides an extensive amount of information, so I am going to focus on the major points, our expectations for the rest of 2018, and important comparators to take note of for your modelling.

As usual, my comments today will be on adjusted results and on a constant exchange rate basis, except where I specify otherwise.

### Headline results

On the headline results, Group sales up 4% to £7.2 billion, total EPS, 11.2 pence, and adjusted EPS 24.6 pence, up 11%.

On currency, movements in sterling resulted in a headwind of 6% on sales, and 13% on adjusted EPS, and if exchange rates remain at the quarter end rates for the rest of the year, we would expect the headwind to sales from currency for the full year to be approximately 5% and 8% for adjusted EPS. The impact on Q2 would be similar.

#### **Results reconciliation**

### Q1 2018 results

Turning to total results, compared with Q1 2017, the two main differences in the items not included in adjusted results are firstly, transaction-related adjustments which were 9.0 pence per share this quarter, primarily to recognise the revaluation of the Put on the Consumer business to the consideration that has been agreed with Novartis to buy out their interest in the Consumer joint venture.

This transaction will give us 100% ownership and control of a strong business and one we know very well. Assuming shareholder approval in May, we now expect to complete the transaction on 1 June.

The second main difference with Q1 last year is the 2017 disposal of the anaesthesia business which gave us a net gain in the 'Disposals' column of 3.0 pence per share this time last year.

### **Sales Growth**

#### Q1 2018 Growth in all three businesses

On sales, Pharma sales up 2%, growth from HIV, our *Ellipta* products and *Nucala* offset declines in *Seretide/Advair* and the established products.

In our HIV business, *Tivicay* and *Triumeq* continued to gain share and deliver strong sales growth. We have also seen an encouraging start from *Juluca*. I continue to expect this business to deliver good growth this year, albeit at a lower rate than 2017, reflecting the larger base of the business.

In Respiratory, our new *Ellipta* products grew 34%, including the first full quarter of *Trelegy. Nucala* delivered £104 million of sales, up <del>89</del> 87%\* with the US up 57%, despite some de-stocking in the quarter and a competitor launch. We remain confident *Nucala* will continue to be a significant contributor to the Respiratory business going forward, given its strong data, new indications and overall growth in the market.

### \*post transcript edit.

Seretide/Advair was down 20% overall. In the US, Advair was down 25% which was a bit worse than our original expectations, driven by continued pricing and contracting pressures ahead of a possible generic. Now that we have better visibility on our full contract position for the remainder of 2018, we expect that we will see a bigger decline in Advair this year before any generic of around 30% for the full year.

*Breo* delivered US volume growth of 44% in the quarter but reported revenue was up only 1%, mainly impacted by negative RAR true-ups for prior periods and a tough prior year comparison on this front. *Breo* will have another tough comparator on RAR in Q2 but they get easier in the second half of the year and we are still expecting good growth in net sales for the full year, despite the broader pressures in US Respiratory. Global growth will also contribute. Total sales for *Relvar/Breo* in this quarter were £219 million, up 14% as we continue the global rollout of the product.

Vaccines sales were up 13%, and as Luke has already said, *Shingrix* is off to a strong start and it contributed most of that growth. At this stage the majority of sales in the quarter are still stocking into the channel. End-patient uptake should contribute more significantly over the next couple of quarters but with the mix between patient-uptake and pipeline shifting over the balance of the year you should expect a similar run rate in sales for the remaining quarters of this year as we saw in Q1.

Remember though that Vaccines sales overall will continue to be lumpy due to tenders and the impact of CDC stockpile movements.

Consumer reported 2% growth after a drag of 2% from the combined impact of TDS generics and the GST in India which will also impact Q2 growth.

The global power brands again delivered high single digit growth and for the business overall we saw about 2% volume growth with price contributing about 1%, although this was offset by the impact of GST. For the year, we continue to expect a low single digit percentage top line growth for the Consumer business overall.

### Adjusted operating margin

### Continued margin progression in Q1 2018

Turning to operating margins, we delivered an improvement of 130 basis points in the Group adjusted operating margin. COGS as a percentage of sales improved 90 basis points, mainly due to the benefits of mix and cost savings offsetting the pricing pressure that we are seeing in the inhaled respiratory market.

SG&A was up 2% but as a percentage of sales improved 60 basis points, primarily reflecting benefits from sales leverage as well as ongoing cost discipline that partly offset new launch investments.

R&D was up 2% reflecting investments in advancing our priority programmes, partly offset by savings from the refocusing in R&D that we began last year. We will see additional benefits from the exit of a number of programmes but we intend to reallocate most of that spend elsewhere in R&D over the balance of the year. However, the expected phasing of

that investment will likely impact the second half more than Q2 which will also benefit as in Q1 from the comparison to investments last year as well as for Q2 specifically the PRV that we used in the HIV business.

Our royalties were £53 million versus £82 million in Q1 last year as payments from sales of Cialis ended in Q4. We continue to expect total royalties to be around £200 million in 2018.

The margin picture is slightly different for each of the businesses but the mix between them is allowing us to invest and drive top line and operating leverage at a Group level.

The Pharma margin was down 60 basis points in constant exchange rates, reflecting our targeted investments behind the new launches at the same time as we are seeing sales impacted by the decline in *Advair* and lower royalty income.

Vaccines was up 1.5%, mainly reflecting the benefits of leverage from top line growth, product mix and cost control offsetting the investments behind the launch of *Shingrix* and expansion of capacity. Remember, when you are modelling the Q2 margin, that there were one-off benefits last year, including a settlement with a third party, worth in total about £45 million.

The Consumer margin had a particularly strong quarter, up 270 basis points, driven by sales leverage, product mix and the phasing of some promotional spend that will impact Q2 progression, where we are also up against a tough comparator.

### Operating profit to net income

On the bottom half of the P&L, we continue to manage our funding costs carefully and have already re-financed ahead of upcoming maturities, to lock in lower rates. We continue to expect funding costs for the year to be broadly similar to 2017, before the additional costs of the Novartis buy-out come in after 1 June. We continue to expect that the overall funding costs for the Novartis transaction will be between 2% and 3%.

On tax, due to some phasing of settlements, the adjusted rate was 20.2% in Q1, but we continue to expect a rate of 19% to 20% for the full year.

The charge for minorities in Q1 was £224 million, compared to £199 million a year ago, primarily reflecting the progress in both the HIV and Consumer businesses. Clearly, after the Novartis transaction has closed, this charge will go down substantially.

### Free cash flow analysis

Turning to cash generation and net debt, we remain focused on driving greater cash discipline across the Group. Free cash flow is down £326 million versus Q1 last year, mainly

as a result of the impact of the £317 million payment to Novartis in relation to the Vaccines business. Cash flow was also impacted by currency, with a drag of around £200 million in the quarter as sterling strengthened. We have offset this headwind through improved cash generation from tighter working capital control, reduced restructuring spend and lower capex.

Similar to last year, we expect our 2018 cash flows to be weighted to the second half of the year, even before the expected accretion from the Novartis buy-out.

Net debt was up  $\pounds 0.2$  billion to  $\pounds 13.2$  billion compared with the year end 2017, reflecting primarily the free cash flow and a favourable translation benefit of  $\pounds 0.3$  billion offset by dividend payments to our shareholders of  $\pounds 0.9$  billion.

We are comfortable with our credit profile and we have now received confirmation from both S&P and Moody's that the Novartis transaction will not result in any change to our current debt ratings. We continue to have capacity to invest in the business consistent with the capital allocation priorities we have laid out.

### 2018 guidance and 2020 outlook expectations

Looking at the full year, we have made an encouraging start but it is still early days in 2018 and we have to navigate a competitive respiratory environment and a possible *Advair* generic. Our eventual performance in 2018 continues to rely heavily on how that plays out. As a result, we are maintaining our previously published guidance for 2018 and will update this when we have more visibility on *Advair*.

With that, I will hand you back to Emma.

### Summary

Emma Walmsley: Thank you, Simon.

### Confide3nt in 2020 outlook

In conclusion, it is a positive start to the year. Our new product launches are going well, particularly *Shingrix*.

It's early days for the increased competition we are seeing within HIV in the US, but initial indications are encouraging and we continue to gain share. We remain confident for our HIV business.

We are working hard to drive cost discipline across the company and strengthen our Pharma business. All of these factors mean that we are confident of delivery of our 2018 guidance and our 2020 outlooks. Now, the team is ready for your questions. Hal has joined us here today, but I am sure you will understand that he is still making an assessment of our R&D portfolio and strategy and he will save his more detailed commentary for July.

Operator, would you open the line please for Q&A.

## **Question & Answer Session**

**Graham Parry (Bank of America Merrill Lynch):** Thank you. My question is on *Shingrix* and the stocking, and I just wanted to clarify the comment where you said that one-third was used to vaccinate, so can we assume that that £70 million was stocking?

On your full year comments, you said we should expect similar quarterly run-rates for the rest of the year, so does that mean that you are looking at about £440 million for the full year?

Secondly, on *Breo* and *Advair*, what has really changed in the quarter? Presumably, you are rebating and your contracting position here was well known when you gave your guidance at the beginning of the year. It seems odd that you have had a bit of a shift, just in the process of the first quarter. Perhaps we could just have an update on what has changed.

Thirdly, looking at the impact of the Biktarvy launch, on MBRX data it looks as though *Tivicay* and *Triumeq* have lost about six points of new-to-brand share in the third agent market; Genvoya has lost six, and Biktarvy has jumped to about 19% already. Could you perhaps give us a feel for whether you think that that is being driven by Genvoya switching skewing the data and pushing up Biktarvy new-to-brand prescriptions? What is the timeframe over which you think new-to-brand translates into total prescriptions in this market, given that there has been very little impact on the total prescription data to date.

**Emma Walmsley:** Thanks very much, Graham. I will come in a moment to David, to answer your detailed questions on HIV. First, perhaps I will go to Simon to complement the commentaries given today on *Shingrix* and a little more detail on the pricing pressure in the ICS/LABA market.

**Simon Dingemans:** Graham, yes, you heard right: about 30% of the doses supplied into the market so far have gone to end use patient vaccinations where it is still expecting some stocking to go into the channel during the course of Q2 but over Q2 and Q3 you should see that process complete. That is why we are signalling that, at this stage, we

expect the run rate to be pretty consistent over the next four quarters over the balance of 2018, even though the mix is changing underneath that, so, yes, 4x110 gets you to the number that you just said.

On *Advair*, as we said at the year end and Q3 and Q2, we have been expecting for some time a tough environment in 2018 around the Respiratory marketplace more broadly but particularly *Advair*, as people anticipate a generic. Clearly, there is no particular update on that front in terms of timing when, how, and how much they might have, but contracting is anticipating it. We had a number of significant contracts to complete and those have come in a bit worse, as I said in my commentary, than we had originally expected, so I believe we now have enough visibility to confirm the outlook.

As Luke also said, we are much more focused, frankly, on making sure that we have the right access, the right support and the right backing for *Trelegy* and our newer *Ellipta* products, and we shall be shifting resource and continuing to resource *Trelegy* to make sure that we can now take full advantage of our expanded label. With that, I shall hand you over to David.

**David Redfern:** Graham, I think overall the headline is that our underlying trends on HIV, and dolutegravir specifically, remain very consistent. If you look at it in weekly TRx terms, dolutegravir has grown now to somewhere around 36,000 scrips a week, which, as I said in my remarks, translates to a TRx market share of core and SDR market of just over 28%, up about 1% from the end of 2017.

When you get into NBRx, as you asked, you have to dissect it a little bit. In the naïve part of new patients, our share has held very steady in the early 30s - 33%-34% - coming from both *Tivicay* and *Triumeq*. In the switch part of the market, what we are seeing is more switches going on and a lot of that is from the older regime, so from Atripla, from the older proteases and so forth, probably into Biktarvy to some degree. Our percentage of the switch market has gone down a little but the overall volume of switch is very stable or, if anything, has gone up.

Overall, while I would say that these are obviously very early days, at this point we have seen very little impact, if anything at all, on the dolutegravir franchise from the competitive launch. That is reinforced by the qualitative feedback we get from physicians, which is very consistent around continuing to be impressed by the very broad range of clinical data, the five superiority studies and obviously the contrast with the competitor products. Therefore, at this point, the trends are very consistent and the landscape and competitor environment has not really impacted us at all.

**Keyur Parekh (Goldman Sachs):** I have two questions, please. One is for Hal - and, Hal, welcome to Glaxo! I would love your thoughts on how you are thinking about developing the BCMA antibody, obviously there is lots of competition and lots of other stuff happening in the multiple myeloma landscape. Can you give us your initial assessment of where you see the BCMA product development? That would be great. Linked with that, what do you see as the big differences in culture across the two organisations where you have worked - that would be awesome.

Secondly, for Simon or Luke, can you help us understand the context around the pricing for the Respiratory products. How much of that is a mix issue between the different payor types versus actual pricing on a like-for-like basis, versus what your expectations were at the end of last year or early this year?

**Emma Walmsley:** Shall we go to Luke first on the pricing and competitor dynamics in ICS/LABA and then we can come to Hal?

**Luke Miels:** Keyur, we have always flagged that they are intense and, as Simon has indicated, it is a little more intense than we were expecting. It is primarily felt on *Breo.* If you look at *Incruse* and *Anoro*, you did not see that same type of dynamic at play, so it is very much an ICS LABA dimension. I think there are two aspects here: one you have a competitor which is quite aggressive with discounting and access, and as well the market is prime for an *Advair* generic, even though we don't know when that is going to enter.

As Simon has also said, I think this will be different in the second half specifically for *Breo*, and again we are very focussed on driving that volume growth, and you can see for *Breo* we had very strong growth, 44% on volume.

Emma Walmsley: Thanks, Luke. Hal – some first comments?

Hal Barron: Okay. Hi, Keyur, thanks for the question. I think, as you know and probably most people know, despite the number of therapies that are in development, multiple myeloma is a very terrible malignancy of plasma cells, and usually incurable, so I am excited that there are new therapies that might be available for patients. Our BCMA, or B-cell maturation antigen antibody is an antibody drug conjugate, so the antibody binds to this protein that is highly expressed on these myeloma cells, and we are excited, both because of its mechanism of action which is three-fold first of all, the antibody itself binds to the protein and delivers by internalisation this auristatin-F cytotoxic agent, so a very potent antibody drug conjugate.

In addition, we have preclinical data to suggest that the FC portion of the antibody is very effective at inducing antibody cell dependent cytotoxicity, so-called ADCC, so both those mechanisms are probably contributing to its efficacy as well as some data we have suggesting that it is also probably engaging the immune system in a way that we are not fully appreciative of yet, but seems to have a component of its pretty profound efficacy.

You have probably seen the data. The response rate in our Phase 1 clinical trials that were presented at ASH at the end of 2017 in December were very impressive – twice the response rate of that seen with Darzalex in a similar setting. These patients in that study were very sick; they had very limited treatment options and we were pleased to see the response rate in the so-called DREAM 1 trial.

As we have mentioned before, we are targeting a 2020 launch based on the clinical development programmes that we have outlined in previous calls in December. This includes starting a pivotal monotherapy programme later this year that we are excited about. We are also looking forward to advancing studies with combinations in earlier lines of therapy ideally in the second-line and eventually combinations that can enable a front-line indication and we are aggressively pursuing these as well.

Very excited about the science behind this antibody drug conjugate and particularly the unmet medical need.

You also asked about culture, and I will cover this in much more detail in Q2, but some preliminary observations from experiences that other companies as well as having been here for about three or four months. First of all, I think the thing that is most striking about the company, and I think what is well appreciated both internally and externally is that there is really a very deep commitment by the scientists and essentially all the employees, not just in R&D, but throughout the company, to really focus on doing what is best for patients, and that is not something to be taken lightly – that is a very important component on ensuring you have a world-class company, world-class R&D organisation and I am very proud to be able to at a place that considers this such a high priority.

I have also been very impressed with the scientific advances that have been made in many of the DPUs that we have, these Discovery Performance Units. I think we have some work to do in terms of how to translate that efficiently into drugs, but there is some great science underpinning what is coming out. We also have a very skilled what we call PTS organisation, which is where the technology is being driven. I think many of these technologies are going to transform how we both discover drugs and potentially even develop them. We will be talking a lot more about that at the Q2 call.

**Emma Walmsley:** Thanks, Hal. More to come, and we are looking forward to having many more discussions with you on these topics. Next question, please.

**Emmanuel Papadakis (Barclays):** I will assume so, and if so there is one quick follow-up on HIV. Unless I misheard there was a reference to wholesaler inventory movements in the call earlier; I don't think they were quantified. If you could do that, that would be extremely helpful.

The second quick one was on *Shingrix* capacity. Perhaps you could just remind us, in light of the better than expected start in the US, where do you expect that to provide any constraint in the US or outside it in terms of the trajectory, both for this year and beyond? Many thanks.

**Emma Walmsley:** David, if you could very briefly comment on the wholesale thing?

**David Redfern:** Very briefly, typically the wholesalers in the US tend to have between 14 and 17 days stock with them. At the end of Q4 it was at the upper range of that. At the end of Q1 it was probably closer to 15 days, so there was a couple of days destocking in the quarter.

**Emma Walmsley:** Thanks. In terms of *Shingrix*, we have obviously had an early, strong and very fast adoption of the overall CDC recommendation. We are already in the high 90s in terms of market share, so we have very high demand. As Luke said we have only one-third of these shipments being passed on directly to patients, so we need to see how that washes through over the next quarter, and we genuinely have visibility of the shape of the consumer demand.

Nonetheless, manufacturing is going very well. We have been accelerating our supply chain and are actively managing inventory and working with customers and all relevant parties to make sure we are maximising patient access. It is likely we may see some low inventory levels, but we are very focussed on minimising this and are prioritising all the access to supply the vaccine. Our focus is on the US. That's where this vaccine was approved first, and then we will plan for rollout over the years ahead. This is a very important vaccine, paradigm-shifting in terms of prevention and it's important for patients and for GSK's long-term growth.

The next question, please.

**James Gordon (JP Morgan):** Hello, thanks for taking the two questions. The first question was on *Shingrix*, so extra stocking and the different number of doses, the retail prescription data suggests there has been some expansion in market demand rather than it just being a share battle, so if that is right where is the demand expected to come from? Is it younger patients or re-vaccination or is it just that there was a bolus that built up of patients waiting for the drug or for the vaccine?

And then the second question, the Kevin Sin hire, how should we interpret that? Could we interpret it that there is a firm focus on Oncology for development and also that R&D might be expanding more in San Fran versus Philadelphia?

**Emma Walmsley:** I shall let Hal come in on the Kevin appointment in a second, but just on *Shingrix* it's a bit early for us to see, James, in terms of what the consumer shape is but what we are seeing is a very strong focus on the retail environment, so I think it's around 70% of sales stake being in retail. And it's a reminder that this is in many ways a Consumer launch, so that's as much shape as we can give at the moment, but we expect to be able to give you more detail in the quarters ahead.

Hal, obviously we are thrilled with Kevin's appointment. Would you like to comment a bit more on that?

Hal Barron: Yes. Absolutely, we are very excited Kevin has decided to join us. He is a very, very thoughtful and experienced business development professional as well as a fantastic leader and I'm personally very excited that I will be working closely with him.

His expertise is of course both in oncology and also technology and we will be able to take advantage of that expertise over the coming years and more to follow on that in Q2.

He will be based in San Francisco and that will just enable him to tap into much of the really innovative science and opportunities that exist not just on the West Coast but throughout the United States and in the global world as well. So we are very excited about him joining, but more to follow in Q2 on that.

**Emma Walmsley:** Right, thanks Hal. Next question, please.

Andrew Baum (Citi): A couple of questions. Firstly, just to go back to Kevin Sin's recent appointment and his background in oncology, given your commitment to improving GSK's R&D delivery and your existing position in rebuilding your Oncology franchise, perhaps Hal might like to talk about and characterise the type of potential BD opportunity you are looking at in oncology in terms of size, whether in market products are important, platform technologies and so on.

And second, a comment to Luke. One of the initiatives being proposed by HHS is the pass through of rebate to consumers. Could you talk about how that could impact your business model, particularly to what extent it could drive or not the closing of a list versus net price gap which has been highlighted by the administration? Many thanks.

**Emma Walmsley:** Okay, so we'll come to Luke in a minute but first of all Hal, is there anything else that you want to add, if anything, on the Oncology BD question?

Hal Barron: Andrew, thanks for the question. Kevin does have a lot of business development experience in oncology, although he has a lot of experience in other areas including technology. I think the areas that we are most likely to be excited about are more early stage development and potentially late stage research opportunities as well as, as I said, opportunities that we can identify that would be cutting edge technologies that could help us leverage existing projects that we have in house at this time.

**Emma Walmsley:** Yes, I think that's as far as we are going to go at this stage. Luke.

**Luke Miels:** Yes, I think it's a really difficult question to answer, Andrew, because as you know a lot of this rebate structure drives certain dynamics which ultimately have effects on pricing and subsequently the co-pay felt by patients.

There are some experiments. Aetna and United are talking about these changes and we are actually in discussions and observing that, but I think it's very difficult to answer in terms of the scale, how quickly it would be adopted but clearly there would be some change in the market. The gap between those two would likely to be more likely to converge over time, but I guess always in our industry the question is the time and ultimately if it was adopted, in what form.

**Emma Walmsley:** Okay, the next question, please.

**Michael Leutchen(UBS):** Thank you. Two questions, please. One, going back to your guidance, I am just trying to understand the moving parts here. I hear what you are saying on the rebating in terms of *Advair* and maybe *Breo*, but you do get accretion from the Consumer joint venture – it had a very strong margin in Q1 in pharmaceuticals - and *Shingrix* is growing very strongly, yet you haven't changed your full year guidance. In underlying terms, it seems you are assuming more headwinds than just the *Advair* rebating, or maybe I am over-interpreting that. If I could get you to comment that would be great?

Secondly, and you did say in your opening remarks there is a new incentive programme in place now that just kicked off; I wondered if you could elaborate on the details here? Thank you.

**Emma Walmsley:** Sure. Let me take both of those. First of all, there is no rebalancing of headwinds as you might suggest, or you might misinterpret. We are pleased with the start to the year for the reasons you have laid out. We pleased with the start to our new launches; it is early days – for sure early days in HIV, momentum is good, and we are pleased with the deal in Consumer, although we will have to complete that with a shareholder vote.

There is a bit of incremental pricing pressure in ICS LABA which we have laid out, but we are very focussed on the new launches ahead of an *Advair* generic that we are expecting. The reason that we are not updating guidance is that we are at Q1 and the big variable for 2018 is when and how an *Advair* generic turns up. As you know we have quite a spread of guidance at the moment and we will update when we have more clarity on this and more visibility on other puts and takes, but again, we are feeling encouraged by the start to the year.

In terms of the incentive programme, I think this is a key lever as part of culture where I suppose there are three main changes that we are making to the incentive programme. First of all, it is, in all cases across the company, aligned to three businesses that we have. We used to have very separate functional incentives, which obviously has an impact in terms of alignment and executional focus and can drive more internal negotiation than external competitive focus.

The second thing is that we have moved the organisation from being 60% on more personal qualitative and individual assessment to being 100% focussed on outputs, so therefore we break up that 100% into four buckets of specific numbers around delivery. The third thing is that we are, for the first time, putting cash flow – the four segments for the commercial organisations are around sales growth, innovation, sales profit and cash, so that is the first time that we are putting cash flow across the whole business as an incentive. Then, with R&D, where part of our diagnosis, and again, this is something that Hal can talk more about in Q2, which will be the first of several updates, by the way – in R&D we have been thinking very carefully about how we incent the right kind of behaviours around building the value of the pipeline and progressing not just as many things as possible, but progressing the right scale medicines that are going to have an impact not just for patients, but for shareholder returns, so those are the main changes I would comment on on the incentive programme. Next question, please.

**Jo Walton (Credit Suisse):** Thank you. Two questions, please. On the price pressure in Respiratory, can you confirm whether the pressure is really in the older products, or whether you think this will also bleed into the newer products over time? I am just wondering how sustainable a premium for products like *Trelegy* will be over the cheaper ingredients with this price pressure?

My second question would be on the Consumer business. If you could tell us a little bit more about that? You are showing 2% local currency growth, but you have some one-offs against that which would suggest that, excluding the Indian tax and the genericisation of the transdermal product you would be at about 4% growth. If you could just give us a bit of your view on the background, and specifically if you could tell us what proportion of the division is made up by your power brands, please?

**Emma Walmsley:** Okay, Jo. I will hand to Luke to comment on pricing, which has he said is in mainly in ICS LABA and has some impact on *Breo*, but he can talk a bit about your question specifically on *Trelegy* as well.

On Consumer, you are right, the reported growth is 2; the underlying, as Simon said, is closer to 4 because of both GST in India and the *Transderm Scop*, which we expect to impact this year, so our reported growth this year will be low single digit.

Fundamentally the health of the business, precisely as you have said, and that is part of what has driven the margin progression, is good because our power brands are growing at high single digits; in fact, all of them are winning market share in the first quarter again, all seven of them. That is, in part, why we have also been able as we take hold of the full business, subject to completion of the Novartis buy-out, to not only reiterate our confidence in the margin outlook for 2020 but indeed give a new margin outlook for 2022.

Luke, would you like to make any additional comment?

**Luke Miels:** Jo, I think it is very specifically an ICS/LABA dynamic. If you look at *Incruse*, we had some pricing there but we have excellent access. With *Anoro* we had positive price and I believe it is fair to say that with *Anoro*, we have established ourselves as the class leader against the two other comparators which are material. This dynamic around pricing is largely driven by market share and we took the decision with a couple of plans that essentially we didn't want that market share: it was not attractive for us to sign up under those terms. Therefore, we are trying to be disciplined here for exactly the reason that we have discussed as far as the products.

When we look at *Trelegy*, this is an extremely competitive product. I believe there will be some indirect pricing aspects but, fundamentally, this product does offer something that is not accessible in a single device. As you know, we have priced it at a 20% discount to the components and our focus is really on growing that. The positive news of the SNDA and the IMPACT data will further propel that, and I believe it is something that we are going to exhaust for success.

Interestingly, if you take a typical segment of patients on *Trelegy* today out of 100, 43 of those patients have been put on there by the physician, not promoted by us. They have been proactively placed on there by a physician, with no prior maintenance treatment in the last six months. For the other 57 patients, there is a series of combinations of which only eight are *Breo* and only six are *Breo* + *Incruse*. That gives you a sense of the interest and the demand for the product at this early stage, and I believe that our focus will be on competitively growing the volume.

**Richard Park (Deutsche Bank):** Thanks for taking my questions and congratulations on a great *Shingrix* launch. First, I have to clarify the answer to Michael's question on the guidance. I suppose my question is: does the current guidance reflect potential accretion from the Novartis transaction or not? My second question: in terms of the trends regarding dolutegravir franchise new starts, if we look at share of NBRx it is complicated by switching within the class given the Biktarvy launch. If we look at the absolute NBRx for the dolutegravir franchise, it seems to have been declining since that launch. I want to understand whether that is what you have been seeing in terms of absolute new patient starts, or whether there is some seasonality there.

**Emma Walmsley:** Simon, I don't know if you want to add any incremental commentary on the guidance and then we'll come to David?

**Simon Dingemans:** As we have said in the press release, we are factoring the increase in our stake in the Consumer joint venture into the overall pluses and minuses we have playing out over the balance of the year but, as Emma said, it is Q1 and there is still a long way to go in the rest of the year and the biggest single factor is *Advair*. Until we have better visibility on that, we are not going to update our guidance until we can land that with a bit more precision, and we have to see how that plays out.

**David Redfern:** As I believe I said earlier, overall our NBRx share has come down a little bit, that is entirely driven by the switch market. Our naïve shares, as I said, have remained very consistent. However, to explain that, I believe there are more switches

going on in the market and our percentage of those is less but a lot of them are Gilead-to-Gilead switches, so Atripla into Biktarvy, or Genvoya, Odefsey or Complera into Biktarvy.

On a volume basis, our NBRx numbers if anything have gone slightly up. We started the year at around 1,700-1,800 new-to-brand prescriptions per week, and we are about 100 or so more than that now. While the percentage has gone down because there is more switching going on, our volume has gone up and, as I said, so far, while it is early days, we have seen very little impact on our business from the competitor.

**Emma Walmsley:** Thanks, David, and I believe we are now going to the last question please.

Laura Sutcliffe (Berenberg): Thank you for taking my questions and I have two please. First, on HIV for injectable cabotegravir/rilpivirine, if the ATLAS and FLAIR trials are successful, would you look to file that data immediately for approval for a once-monthly product, or is there a possibility that you would wait for the every two months data before you file? Secondly, one of your stated priorities for capital allocation is increasing your capacity to produce vaccines. Could you just give us an idea of where you are in that process and how much more work you think there is to do? Thank you.

**Emma Walmsley:** Simon, do you want to give an update on vaccines investment?

**Simon Dingemans:** We have talked about one of the priorities which is *Shingrix* and we have already been putting in quite a lot of investment behind that and will continue to build that capacity during the course of the year. The other is *Bexsero* where, as we have discussed before, we inherited a supply chain with only a very few million doses in it and we have been ramping that up and see very good growth ahead of us. The third leg is the improvement in yield and consistency that we have seen in some of our older vaccines which is really driving some of the growth you've seen in the established vaccines portfolio over the last couple of years, so we are pretty much complete with the majority of that third leg and are already seeing the benefit, so that is where the focus is between the different product groups.

Emma Walmsley: Thanks, Simon. David?

**David Redfern:** Laura, as you say we are expecting the ATLAS and the FLAIR studies towards the latter half of this year. They are four-week studies. If that data is positive then we will file that and we will add the eight-week data to the file when we get that in due course.

I think as you have seen from LATTE-2, there's a good reason to be very confident about eight weeks but that will come later and we will add that as we go.

**Emma Walmsley:** Thanks, David. Thank you all for your questions. It has, as we have said, been a good start to the year and we look forward to speaking with you in Q2 where we will both update on R&D and also provide more on our launch progress. Thanks very much.

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