Q1 2018 Earnings Call

Company Participants

- David Simon Redfern, Chief Strategy Officer
- Emma Walmsley, CEO & Director
- Hal V. Barron, Chief Scientific Officer, President of R&D and Director
- Luke V. Miels, President of Global Pharmaceuticals
- Sarah Elton-Farr, Unknown
- Simon P. Dingemans, CFO & Executive Director
- Unidentified Speaker, Unknown

Other Participants

- Emmanuel Papadakis, MD
- Graham Glyn Charles Parry, MD and Head of Healthcare Equity Research
- James Daniel Gordon, Senior Analyst
- Jo Walton, MD
- Keyur Parekh, Equity Analyst
- Laura Sutcliffe, Analyst
- Michael Leuchten, Co
- Richard J. Parkes, Director
- Unidentified Participant, Analyst

Presentation

Operator

Good day, ladies and gentlemen. Welcome to the GSK Q1 2018 Results Analyst Call. My name's Iachi. And I'll be your conference operator for today. (Operator Instructions)

I will now hand the call over to Sarah Elton-Farr, GSK Investor Relations. Please go ahead.

Sarah Elton-Farr, Unknown

Thank you.

Good morning. 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 Investors section of the GSK website.

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

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. (Operator Instructions)

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

And with that, I will hand the call over to Emma.

Emma Walmsley, CEO & Director

Thanks very much, Sarah. Good morning. Good afternoon to everybody.

As we've said previously, a strategic strength for GSK is our balanced business profile beyond pharma for sustainable growth, returns and cash flows. And I'm pleased to say that in our First Quarter 2018, we've 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.

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're increasing our share in the important U.S. market.

In HIV, we continue to deliver 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. And this has driven adjusted EPS growth of 11% and free cash flow of GBP 324 million, impacted by the payment of a milestone to Novartis.

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 3 things, all underpinned by the start of a necessary shift in culture. First is excellence in commercial execution. Our new launches continued 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 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're making throughout the company, is going to 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're allocating resources to those areas where we see the best returns. We're 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 buyout of the Novartis stake in the Consumer Healthcare joint venture. This will allow GSK shareholders to capture the full value of a business we believe is well positioned to deliver futures 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 to better plan future capital allocation in

particular to strengthen our pharma R&D pipeline, which is our #1 priority.

And finally, of course, underpinning all of this is cultural change. This is a long-term effort in making GSK fitter to compete in the future. We're 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're making significant changes in our leadership teams, in our engagement with employees and in our expectations for how we want our people to work. Our new incentive program, which is an increased focus on performance, was also launched this quarter.

So I'm now going to hand you over to Luke and David, who will give you an update on our progress within pharma and also the Shingrix launch. Luke?

Luke V. Miels, President of Global Pharmaceuticals

Thanks, Emma. Good morning. Good afternoon, everyone.

So at Q4, I shared our commercial priorities for the business and the key areas of focus. And I'm pleased to say that we're making very good progress and you can see on this slide here a few examples.

So we've identified 20% of noncustomer-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've now identified additional growth opportunities in key markets such as accelerating launch time lines in China and targeted sales force investment in India.

More broadly, our emerging markets business has been segmented into 3 models based on market characteristics and growth potential to ensure each market has the right level of resource to optimize their performance. And we've also clarified accountabilities between the above country and in-market teams to ensure everyone in the commercial organization is focused on where they can create the most value for the business. And we're 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-paced culture, we believe, will deliver long-term value for the business and our shareholders by maximizing the potential of Trelegy, Shingrix as well as accelerating Nucala and improving growth across the emerging markets.

Next slide. Moving to our Respiratory portfolio, I'd 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.

So we started our rollout plans at the end of last year with a targeted launch to pulmonologists. If you'll recall, we had a relatively narrow label. And we've made steady progress on building coverage. This targeted approach, together with our strong clinical data and a clear demand for closed triple therapy in COPD, has led to a strong uptake. And the chart on the slide clearly shows how Trelegy's launch has surpassed that of our other Ellipta launches in recent years. And I'm also pleased to say today it is one of the best Respiratory launches in the past decade at this point postlaunch. The benefit to patients offered by Trelegy has now been demonstrated in both the FULFIL and the 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 think it's fair to say this data, which is answering for the first time important questions in COPD management, supports the expanded label that was approved by the FDA and 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. And 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. But as we've previously said, the pricing and competitive outlook is challenging. And we're seeing that impact on certain products in the U.S. specifically.

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'll continue to prioritize and allocate resources to respond to the environment and new competitive dynamics.

Next slide, please. So if we now look at Nucala, we're 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 IL-5 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 delivers a reduction of 56%, ahead of our competitors. And 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 AAAAI 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 on to Nucala. And this is key because there's a (sizable) 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 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, reduce the number of attacks they're suffering. There remains plenty of untapped opportunity despite the entry of new competitors into this space. And we're confident that we have the data to continue to generate meaningful sales growth.

On top of the opportunity within asthma and EGPA, we filed for use in the treatment of COPD, a market that has material potential. And we hope to gain U.S. approval later this year. And we're also continuing with our global rollout with launches in Italy and France during Q1. And more European launches expected later this year. Performance year-to-date in these markets, I'm also pleased to say, is very encouraging.

Now for Shingrix. So 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. And last year, we received a preferential recommendation from ACIP, giving us a target universe over 100 million patients in the U.S. Initial indications are also very good. We're 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; in the last data actually I just saw recently, we've got a share of 99%, according to IMS. Now this is pharmacy sales that represents about 60% of the market. The sales that you've seen reported today of GBP 110 million are still heavily driven, however, by filling the pipeline. The takeup is growing. And we estimate that around 1/3 of the doses we've 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're confident this is going to be a very significant product for GSK.

And so with that, I'll now hand over to David.

David Simon Redfern, Chief Strategy Officer

Thank you, Luke.

So overall, we continue to see strong prescription growth for our HIV medicines. This includes in the U.S. were driven by both market growth and, importantly, increased share of the market, the 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 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 2 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 naive patients, second of our 2 drug regimes, this summer. And that will form the basis of an FDA submission later in the year. We are also expecting the Phase III data from the FLAIR and ATLAS studies for our long-acting injectable 2-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.

Simon P. Dingemans, CFO & Executive Director

Thank you, David.

Overall, the results we've reported today keep us on track for the year. Our earnings release provides an extensive amount of information. So I'm going to focus on the major points, our expectations for the rest of 2018 and important comparisons to take note of for your modeling. As usual, my comments today will be on adjusted results and on a constant exchange rate basis, except where I specify otherwise.

On the headline results, group sales up 4% to GBP 7.2 billion; total EPS, 11.2p; and adjusted EPS, 24.6p, 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'd 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.

Turning to total results. Compared with Q1 2017, the 2 main differences in the items not included in adjusted results are, firstly, transaction-related adjustments, which were 9p per share this quarter, primarily to recognize the revaluation of the put on the consumer business to the consideration that's 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 June 1.

The second main difference with Q1 last year is the 2017 disposal of the anesthesia business, which gave us a net gain in the disposals column of 3p per share this time last year.

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've 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 GBP 104 million of sales, up 89%, with the U.S. up 57%, despite some destocking 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.

Seretide/Advair was down 20% overall. In the U.S., 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've better visibility on all full contract position for the remainder of 2018, we expect that we'll see a bigger decline in Advair this

year, before any generic, of around 30% for the full year.

Breo delivered U.S. 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're still expecting good growth in net sales for the full year despite the broader pressures in U.S. Respiratory. Global growth will also contribute. Total sales for Relvar/Breo in this quarter were GBP 219 million, up 14% as we continue the global rollout of the product.

Vaccine sales were up 13%. And as Luke has already said, Shingrix is off to a strong start. And it contribute most of that -- 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 Vaccine 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 to GST. For the year, we continue to expect a low single-digit percentage top line growth for the consumer business overall.

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're 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 programs, 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 programs. 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 GBP 53 million versus GBP 82 million in Q1 last year as payments from sales of Cialis ended in Q4. We continue to expect total royalties to be around GBP 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 the 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're 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're modeling the Q2 margin that there were one-off benefits last year, including a settlement with a third party worth in total about GBP 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.

On the bottom half of the P&L, we continue to manage our funding costs carefully. And we're already refinanced ahead of upcoming maturities to lock in lower rates. And we continue to expect funding costs for the year to be broadly similar to 2017 before the additional costs of the Novartis buyout come in after June 1. We continue to expect that the overall funding cost 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 GBP 224 million compared to GBP 199 million a year ago, primarily reflecting the progress in both the HIV and consumer businesses. Clearly, after the Novartis transaction is closed, this charge will go down substantially.

Turning to cash generation and net debt. We remain focused on driving greater cash discipline across the group. Free cash flow is down at GBP 326 million versus Q1 last year mainly as a result of the impact of the GBP 317 million payment to Novartis in relation to the Vaccines business. Cash flow

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to 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 buyout.

Net debt was up GBP 0.2 billion to GBP 13.2 billion compared with the year-end 2017, reflecting primarily the free cash flow on a favorable translation benefit of GBP 0.3 billion, offset by dividend payments to our shareholders of GBP 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've laid out.

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

And with that, I'll hand you back to Emma.

Emma Walmsley, CEO & Director

So in conclusion, it's a positive start to the year. Our new product launches are going well, particularly Shingrix. It's early days for the increased competition we're seeing within HIV in the U.S.. But initial indications are encouraging. And we continue to gain share. So we remain confident for our HIV business.

We're working hard to drive cost discipline across the company and strengthen our pharma business. And all of these factors mean that we are confident of delivery of our 2018 guidance and our 2020 outlooks.

And so now that team is ready for your questions. Hal, again, has joined us here today. But I'm sure you'll understand that he's still making an assessment of our R&D portfolio and strategy. And he will save small detailed commentary for July.

So operator, if you'd like to open the line, please, for Q&A.

Questions And Answers

Operator

(Operator Instructions) And our first question comes from Graham Parry.

Graham Glyn Charles Parry, MD and Head of Healthcare Equity Research

So firstly, on Shingrix and the stocking. I just wanted to clarify the comment. Now you said 1/3 was used to vaccinate. So commission, about GBP 70 million, was stock-in. And on your full year comments, you said to expect run rate -- similar quarterly run rates for the rest of the year. So does that mean you're looking at GBP 440 million-ish for the full year? Secondly, on Breo and Advair, what's really changed in the quarter? I mean, presumably, you're rebating, you're contracting position. It was well known when you gave your guidance for the beginning of the year it seems odd that you've had a bit of a shift just in the process of the First Quarter. So perhaps just an update on what changed. Then thirdly, looking at the impact for the Biktarvy launch. On NBRx data, it looks like Tivicay and Triumeq have lost about 6 points in new-to-brand share in the third agent market. Genvoya has lost 6 and Biktarvy has jumped to that 19% already. Now could you just perhaps give us a feel for do you think that, that is being driven by Genvoya switching, skewing the data and pushing up Biktarvy in new-to-brand prescriptions. And the time frame over which you think new-to-brand translation to total prescriptions in this market given that there's been very little impact on the total prescription data to date?

Emma Walmsley, CEO & Director

Thanks very much, Graham. So I'll come to a moment to David to answer your detailed questions on HIV. Then first, maybe to Simon to complement the commentaries given today on Shingrix and a bit more detail on the pricing pressure in the ICS/LABA market.

Simon P. Dingemans, CFO & Executive Director

So Graham, yes, you heard right. We've got about 30% of the doses supplied into the market so far have gone to end-use patient vaccinations. We're 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. And that's why we're signaling that at this stage, we expect the run rate to be pretty consistent over the next 4 quarters or over the balance of 2018 even though the mix is changing underneath that. So yes, 4 times 110 gets you to the number that you just said. And on Advair, I think that as we said at the year-end and Q3 and Q2, we've 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's no particular update on that front in terms of timing, when, how, how much they might have. But contracting is anticipating it and 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 originally expected. And so I think we've now got enough visibility to confirm the outlook. But as Luke also said, we are much more focused, frankly, on making sure that we've got the right access, the right support and the right backing for Trelegy and our newer Ellipta products. And we will be shifting resource and continuing to resource Trelegy to make sure that now our expanded label, we can take full advantage of. And with that, I'll hand you over to David.

David Simon Redfern, Chief Strategy Officer

Yes. So Graham, I think overall, the headline is our underlying trends on HIV and with dolutegravir specifically remain very consistent. If you look at it in weekly TRx terms, dolutegravir has grown now to somewhere around 36,000 scripts a week, which, as I said in my remarks, translates to a TRx market share of core and SDR market of just over 28%. So that's up about 1% from the end of 2017. When you get into NBRx, as you asked, you have to dissect it a little bit. So in the naive parts of new patients, our share actually has held very steady in the early 30s, 33%, 34%. That's coming from both Tivicay and Triumeq. In the switch part of the market, what we're seeing is more switches going on. And a lot of that is from the older regimes. So from Atripla, from the protease or the proteases and so forth probably into Biktarvy to some degree. So our % -- percentage of the switch market has gone down a bit. But the overall volume of switches actually is very stable or, if anything, has gone up. So overall, I would say whilst it's very -- obviously very early days, at this point we've really seen very little impact, if anything at all on the dolutegravir franchise from the

competitive launch. And that's really reinforced by the qualitative feedback we get from physicians actually, which is very consistent. And I'm continuing to be impressed by the very broad range of the clinical data, the 5 superiority studies. And obviously the contrast with the competitor product. So at this point, we don't -- the trends are very consistent and the landscape has not, on the competitor environment, has not really impacted us at all.

Emma Walmsley, CEO & Director

Thanks, David.

Operator

Next question comes from Keyur Parekh from Goldman Sachs.

Emma Walmsley, CEO & Director

Keyur, are you there? Another question. Can we have another question, please? We lost Keyur.

Unidentified Speaker, Unknown

We'll come back to him.

Emma Walmsley, CEO & Director

Yes. We'll come back to Keyur in a second. Hello?

Keyur Parekh, Equity Analyst

Hello? Can you guys hear me okay?

Emma Walmsley, CEO & Director

Keyur, we've got you. Great. Thank you. Welcome back.

Keyur Parekh, Equity Analyst

Okay. Two questions, please. One for Hal. Hal, welcome to Glaxo. Would love your thoughts on how you're thinking about developing the BCMA kind of antibody. Obviously, lots of competition, lots of other stuff happening in the multiple myeloma landscape. So if you just give us your initial assessment of where you see the BCMA kind of product development, that would be great. And also, kind of linked with that, kind of what do you see as the big differences in culture across the organizations or the organizations that you have worked, that would be awesome. And secondly, for David or for Simon or Luke. Just help us understand through the context around the worse pricing for the Respiratory products. Is it a mix? Now how much of that is a mix issue between the different payer types versus actual pricing on a like-for-like basis getting worse versus what your expectations were at the end of last year or early this year?

Emma Walmsley, CEO & Director

Okay. Great. So should we go to Luke first then on the pricing and competitor dynamics in ICS/LABA? Then we'll come to Hal.

Luke V. Miels, President of Global Pharmaceuticals

Yes. Yes. So Keyur, I think -- I mean, we've always flagged that they're intense. It's -- as Simon has indicated, it's a little bit more intense than we were expecting. It's primarily felt on Breo. If you look at Incruse and Anoro, you didn't see that same type of dynamic at play. So it's very much an ICS/LABA dimension. I think there's 2 aspects here. One, you've got 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's going to enter. As Simon also said, I think this will be different in the second half, specifically for Breo. And again, we're very focused on driving that volume growth. And you can see for Breo we had very strong growth at 44% on volume.

Emma Walmsley, CEO & Director

Thanks, Luke. So Hal, some first comments.

Hal V. Barron, Chief Scientific Officer, President of R&D and Director

Thanks for the question. I think, as you know and probably most people know, despite the number of therapies that are in development, myeloma -- multiple myeloma is a very terrible malignancy of plasma cells and usually incurable. So I'm excited that there's new therapies that might be available for patients. And our BCMA or B-cell maturation antigen antibody is an antibody-drug conjugate. So the antibody binds to this protein that's highly expressed on these myeloma cells. And we're excited both because of its mechanism of action, which is threefold, first of all. The antibody itself binds the protein and delivers by internalization 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. And so both those mechanisms are probably contributing to its efficacy, as well as some data we have suggesting that it also is probably engaging the immune system in a way that we're not fully appreciative of yet but seems to have a component of its really pretty profound efficacy. You've probably seen the data. The response rate in our Phase I clinical trials that were presented at ASH in the end of 2017, in December, were very impressive, twice the response rate of that seen with Deralex (sic) (Darzalex) in a similar setting. And 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 DREAMM-1 trial. As we've mentioned before, we're targeting a 2020 launch based on the clinical development programs that we've outlined in previous calls in December. And this includes starting a pivotal monitor preprogram later this year that we're excited about. And we're 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're aggressively pursuing these as well. So very excited about the science behind this antibody-drug conjugate and particularly the unmet medical need.

You also asked about culture. And I'll cover this in much more detail, I think, in Q2. But some preliminary observations from experiences at other companies as well as having been here for about 3 or four months. First of all, I think the thing that's most striking about the company. And I think this 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's best for patients. And that's not something to be taken lightly. It's a very important component of ensuring you have a world-class company, world-class R&D organization. And I'm very proud to be at a place that considers this as such a high priority. I've also very impressed with the scientific advances that have been made in many of the DPUs that we have, the discovery performance units. I think we have some work to do in terms of how to translate that efficiently into drugs. But there's some great science underpinning what's coming out. We also have a very, very skilled what we call PTS organization, which is where the technology is being driven. And I think many of these technologies are going to transform how we both discover drugs

and potentially even develop them. We'll again be talking a lot more about that at the Q2 call.

Emma Walmsley, CEO & Director

Thanks, Hal. So more to come. And we're looking forward to having many more discussions with you on these topics.

Operator

Our next question comes from (Emil).

Emmanuel Papadakis, MD

Papadakis from Barclays, I assume. So. And if so, just one quick follow-up on HIV. Unless I misheard, there was a reference to some wholesaler inventory movement on 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 U.S., whether you expect that to provide any constraint either in the U.S. or outside it in terms of the trajectory both for this year and beyond?

Emma Walmsley, CEO & Director

So Dave, just very briefly, if you can comment on the wholesale thing. And then I...

David Simon Redfern, Chief Strategy Officer

Yes. So very quickly, I mean, typically, the wholesalers in the U.S. 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, CEO & Director

Thanks. So in terms of Shingrix, we've obviously had an early strong and very fast adoption of the overall CTC -- CDC recommendation. We're already in the high 90s in terms of market share. And so we have got very high demand. As Luke said, we have only 1/3 of the -- these shipments being then 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're maximizing patient access. So -- and it is likely we may see some low inventory levels. But we're very focused on minimizing this and on prioritizing all the actions to supply the vaccine. Our focus is on the U.S. That's where this vaccine was approved first. 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.

Operator

Next question comes from James Gordon from JPMorgan.

James Daniel Gordon, Senior Analyst

James Gordon from JPMorgan. First question was on Shingrix. So extra stocking and the different number of doses, the retail prescription data suggests there has some expansion in market demand, broadly just being a share battle. So what -- if -- where is the demand expansion coming from? Is it younger patients or revaccination? Or is it just that there was a bolus or buildup of patients waiting for the drug or the vaccine? Then the second question, Kevin Sin hire, how should we interpret that? Could we interpret it as a firm focused on oncology for development? And also, the R&D might be expanded more in San Fran versus Philadelphia?

Emma Walmsley, CEO & Director

So I should let Hal comment 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, say, being in retail. And just as a reminder, this is, in many ways, a consumer, a 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're thrilled with Kevin's appointment. Would you like to comment a bit more on that?

Hal V. Barron, Chief Scientific Officer, President of R&D and Director

Yes. Absolutely, we're very excited Kevin has decided to join us. He's a very, very thoughtful and experienced business development professional as well as a fantastic leader. And I'm personally very excited that I'll be working closely with him. His expertise is, of course, in both oncology and also technology. And we'll 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 the global world as well. So we're very excited with him joining. And more to follow in Q2 on that.

Emma Walmsley, CEO & Director

Great. Thanks, Hal.

Operator

The next question comes from Andrew.

Unidentified Participant, Analyst

(inaudible) Couple of questions. Firstly, just going 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 vision in rebuilding your oncology franchise, perhaps Hal might like to talk about and characterize the types of potential BD opportunity, looking in oncology in terms of size, whether in-market about some important platform technologies and so on. Then second, a comment to Luke. One of the initiatives being proposed by HHS is the pass-through of rebates to consumers. Could you talk about how that could impact your business model, particularly to what extent it could drive or not the closing off of this versus that price gap, which has been highlighted by the administration?

Emma Walmsley, CEO & Director

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 V. Barron, Chief Scientific Officer, President of R&D and Director

Well Andrew, thanks for the question. I think Kevin has got a lot of business development experience in oncology, although he's got a lot of experience in other areas, including technology. I think the areas that we're most likely to be excited about are more early-stage development and potentially late-stage with surg 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, CEO & Director

Yes, I think that's as far as we're going to go at this stage. So Luke?

Luke V. Miels, President of Global Pharmaceuticals

Yes, I think it's a really difficult question to answer, Andrew, because, I mean, as you know, a lot of this rebate structure drives certain dynamics, which ultimately have effects on pricing and subsequently the copay felt by patients. I mean, there are some experiments -- I mean, Aetna and United are talking about these changes. And we're 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 I think there would be -- clearly, there would be some change in the market. And I think the gap between those 2 would likely 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?

Operator

Next question comes from Michael Leuchten from UBS.

Michael Leuchten, Co

Two questions, please. One, going back to your guidance, I'm just trying to understand the moving parts here. I hear what you're saying on the rebating in terms of Advair and maybe Breo. But you do get accretion from the consumer joint venture. You had a very strong margin in Q1 in Pharmaceuticals and Shingrix is growing very strongly, yet you haven't changed your full year guidance. So in underlying terms, it seems you're assuming more headwinds than maybe just the Advair rebating, or maybe I'm overinterpreting that. So if I could get you to comment on that, that'd be great. Then secondly, Emma, you did say in your opening remarks there's a new incentive program in place now that just kicked off. So I just wondered if you could elaborate on the details here.

Emma Walmsley, CEO & Director

Sure. So let me take both of those. First of all, there is no rebalancing of headwinds, as you might suggest. We are -- or you might misinterpret. We are pleased with the start to the year for the reasons that you've laid out. We're pleased with the start to our new launches. It's early days. For sure, early days in HIV. Momentum is good. And we're pleased with the deal in consumer, though, obviously, we still have to complete that with a shareholder vote. There is a bit of incremental pricing pressure in ICS/LABA, which we've laid out. But we're very focused on the new launches ahead of an Advair generic that we're expecting. The reason that we are not updating guidance is 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 starts to the year. In terms of the incentive program, I think this is a key lever as part of culture where I suppose there are 3 main changes that we're making to the incentive program. First of all, it is, in all

cases across the company, aligned to the 3 businesses that we have. We used to have very separate kind of functional incentives, which obviously has an impact in terms of alignment and executional focus and can drive more internal negotiation than external kind of competitive focus. The second thing is that we have moved the organization from being 60% on more kind of personal, qualitative and individual assessment to being 100% focused on output. And so we say -- well, therefore, we break up that 100% into 4 buckets of specific numbers around delivery. And the third thing is that we are, for the first time, putting cash flow -- I mean, the 4 segments for the commercial organizations are around sales growth, innovation, sales profit and cash. So that's the first time we're 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've been thinking very carefully about how we incent the right kind of behaviors 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 that I would comment on the incentive program.

Operator

Next question comes from Jo Walton from CrÃ©dit Suisse.

Jo Walton, MD

Two questions, please. On the price pressure in Respiratory, can you confirm whether the pressure is really in the older product or whether you think that this will also bleed into the newer products over time? Just wondering whether -- how sustainable a premium for products like Trelegy will be over the cheaper ingredients with this price pressure. And my second question would be on the consumer business, if you could tell us a little bit more about that. You're showing about 2% local currency growth. But you've got some one-offs against that, which would suggest that excluding the Indian tax and the genericization of the transdermal product, you'd be at about a 4% growth. So if you can just give us a little 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, CEO & Director

Okay, Jo. So just I'll hand a minute to Luke to comment on pricing, which, as you said, is mainly on ICS/LABA and has had some impact on Breo. But he can talk a bit about your question specifically on Trelegy as well. On consumer, you're 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. And that's why we've said that our reported growth this year will be low single digits. Fundamentally, the health of the business precisely, as you've said. And that's part of what's 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 7 of them. So that's in part why we've also been able, as we take hold of the full business, subject to completion of Novartis buyout, to not only reiterate our confidence in the margin outlook for 2020 but indeed give a new margin outlook for 2022. So Luke, would you like to make any additional comments on...

Luke V. Miels, President of Global Pharmaceuticals

Yes. So Jo, I think it is very specifically an ICS/LABA dynamic. I mean, if you look at Incruse, we had some pricing there. But we've got excellent access with Anoro. We actually had positive price. And I think it's fair to say with Anoro, we've established ourselves as the class leader both really against the 2 other comparatives, which are material. So -- and this dynamic around pricing is really 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. And so we're trying to be disciplined here for exactly the reason that we've discussed in terms of the products today. When we

look at Trelegy, I mean, this is an extremely competitive product. I think 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've priced it at a 20% discount to the components. And our focus is really on growing that. I think the positive news of the sNDA and the IMPACT data will further propel that. And I think it's something that we are going to exhaust for success. I mean, interestingly, if we look at -- if you took 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, that have been proactively placed on there by the physician -- a physician with no prior maintenance treatment in the last six months. Then the other 57 patients, there are a series of combinations of which only 8 of them are Breo and only 6 of them are Breo plus Incruse. So I think that gives you a sense of the interest and the demand for the product at this early stage. I think our focus is going to be competitively growing the volume.

Emma Walmsley, CEO & Director

Thanks, Luke.

Operator

Next question comes from Richard Parkes from Deutsche Bank.

Richard J. Parkes, Director

Congratulations on a great Shingrix launch. Firstly, I think I have to just clarify the answer to Michael's question on the guidance. So I suppose my question is, does the current guidance reflect potential accretion from the Novartis transaction or not? And that's, I think that becomes more straightforward. Then my second question. Just in terms of the trends in terms of dolutegravir franchise new starts, obviously, when -- if we look at share of NBRx, it's complicated by switching within the class given the Biktarvy launch. But if we look at the absolute NBRx for the dolutegravir franchise, it seems to have been declining since that launch. And I just want to understand whether that's what you've been seeing in terms of absolute new patient starts or whether there's just some seasonality there. So just understand that a little bit better.

Emma Walmsley, CEO & Director

Okay. Thanks. So Simon, I don't know if you want to add any incremental commentary on guidance. Then we'll come to David.

Simon P. Dingemans, CFO & Executive Director

Yes. I mean, I think as we've said in the press release, that we are factoring in the increase in our stake in the consumer joint venture into the overall pluses and minuses that we have playing out over the balance of the year. But as Emma said, it's Q1. There's still a long way to go in the rest of the year. And the biggest single factor is Advair. And until we have better visibility on that, then we're 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.

Emma Walmsley, CEO & Director

Thanks. David, on HIV?

David Simon Redfern, Chief Strategy Officer

Yes. So as I think I said earlier, I mean, overall, our NBRx share has come down a little bit. That's entirely driven by the switch market. And naive shares have, as I said, remained very consistent. But just to explain that, I think there are more switches going on in the market. And our % of those is less. But a lot of them are Gilead-to-Gilead switches. So Atripla into Biktarvy or Genvoya or Odefsey or Complera into Biktarvy. On a volume basis, our NBRx numbers, if anything, have gone slightly up. So we started the year around 1,700, 1,800 new-to-brand prescriptions per week. And we're about 100-or-so more than that now. So whilst the percentage has gone down because there's more switching going on, our volume has gone up. And as I've said. So far, it was -- it's early days. We've have really seen very little impact on our business from the competitor.

Emma Walmsley, CEO & Director

Thanks, David.

Operator

The last question come from Laura Sutcliffe from Berenberg.

Laura Sutcliffe, Analyst

Laura Sutcliffe at Berenberg. Two, please. Firstly, on HIV, for injectable cabotegravir, rilpivirine, if the ATLAS and FLAIR trials are successful, would you be looking to file that data immediately for approval for a once-monthly product? Or is there a possibility you wait for the every-2-month data before you file? And secondly, one of your stated priorities for capital allocation is increasing your capacity to produce vaccines. Could you just give us some idea of where you think you are in that process and how much more work you think there is to do?

Emma Walmsley, CEO & Director

Okay. So Simon, you want to update on Vaccines investment?

Simon P. Dingemans, CFO & Executive Director

Well I think we've talked about one of the priorities, which is Shingrix. And we've obviously already been putting in quite a lot of investment behind that. And we'll continue to build that capacity during the course of the year. The other is Bexsero where, as we've discussed before, we inherited a supply chain with only a very few million doses in it. And we've been ramping that up. And we see very good growth ahead of us. Then I think the third leg is really the improvement in yield and consistency that we've 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's where the focus is between the different product groups.

Emma Walmsley, CEO & Director

Thanks, Simon. David?

David Simon Redfern, Chief Strategy Officer

So Laura, as you say, we're expecting the ATLAS and the FLAIR studies towards the latter half of this year. They are 4-week studies. If that data is positive, then we will file that. And we will add the 8-week data to the file when we get that in due course. I think as you've seen from LATTE 2, there's a good reason to be very confident about 8 weeks. But that will come later. And we're at that as we go.

Emma Walmsley, CEO & Director

Thanks, David.

So thank you all for your questions. It's, as we've said, been a good start to the year. And we look forward to speaking with you in Q2 where we'll both update on R&D and also provide more on our launch progress. Thanks very much.