GLAXOSMITHKLINE FIRST QUARTER 2019 RESULTS PRESENTATION TO ANALYSTS Wednesday, 1 May 2019

Sarah Elton-Farr (Head of Global Investor Relations): Good morning and

good afternoon. Thank you for joining us for our Q1 2019 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. Before we begin, please refer to slide 2

of our presentation for our cautionary statements.

Our speakers today are Chief Executive Officer, Emma Walmsley; Iain Mackay, Chief

Financial Officer: Luke Miels, President of Global Pharmaceuticals, and David Redfern,

Chief Strategy Officer and Chairman of ViiV. We have a broader team available for Q&A.

We request that you ask only a maximum of two questions so that everyone has a chance to

participate and, with that, I shall hand the call over to Emma.

Emma Walmsley (CEO): Thank you, Sarah, and hello everyone.

Strong start to an important year of execution

2019 is an important year of execution for GSK and I am pleased that we have made

good progress this quarter, with growth in sales in constant exchange rates across the

Group and an improved Group margin. Group sales growth of 5% in CER terms reflected an

increase in sales in all three of our global businesses, with a particularly strong performance

in Vaccines. The Pharma business continues to shift its portfolio shape well with strong

growth in new launches and, although Consumer had a slow quarter, we remain confident

and excited about the outlook for this business.

Group adjusted operating margin this quarter was up 1 percentage point on a CER

basis. On a total basis, earnings per share were up 42% to 16.8p and adjusted earnings per

share increased 18% to 30.1p. Included within operating margin and EPS there are a

number of matters of note that benefited the quarter and lain will address these in just a

moment. Nonetheless, it is a strong start to the year and we reaffirm our full-year guidance.

Our free cashflow this quarter was in line with our expectations with £165 million,

impacted, as you know, by the launch of generic Advair, the phasing of rebates and higher

restructuring charges, all as anticipated.

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Q1 progress made on our 3 priorities

Two years ago this summer, I laid out my long-term priorities for the whole company: Innovation, Performance and Trust, all to be powered by a necessary culture change. We have made a strong start to the focus areas for 2019. We continue to execute on our new product launches and have demonstrated strong growth with *Nucala* and *Trelegy* in Respiratory, and most notably in Vaccines with *Shingrix*.

Strengthening our pipeline is critical to our long-term success and we have made good progress here too. In HIV we have already had good uptake for the first of our two-drug regimens - *Juluca* - and we are now seeing the next wave of important innovation come through. Last month, we received US approval for the second of our two-drug regimens in HIV for *Dovato* and we are delighted to make this new treatment option available to treatment-naïve patients. Just earlier this week, we filed for the US approval of the first long-acting, injectable HIV treatment, cabotegravir + rilpivirine, and we are planning for a potential launch in 2020.

We are generating data to support three upcoming Oncology filings for BCMA in multiple myeloma, for *Zejula* in the first line maintenance therapy of ovarian cancer, and for dostarlimab in endometrial cancer.

We were pleased to close the transactions with Merck KGaA as well as Tesaro, further strengthening our Oncology pipeline.

In Performance, we have continued to drive growth in sales and improvements in our profitability, and we have been working hard on the creation of the Consumer Health joint venture with Pfizer and expect this transaction to close in the second half of the year.

Integration planning is well under way and we have recently announced the new leadership team for the JV, bringing key talent from both companies into the joint venture, including Brian's counterpart, Chris Slager, the President of Pfizer Consumer Healthcare, who will be leading our new combined Americas business.

Lastly, on Trust we want GSK to continue to lead with a broader contribution to society. The best way to build trust is to innovate and we are committed to giving you regular and transparent updates on our innovation progress. We shall hear from Hal again on our progress at Q2 this year. We also remain committed to our global health agenda where we are embedding our more focused approach to achieve maximum impact.

Last week, the World Health Organisation initiated its first pilot of our RTS,S malaria vaccine in Malawi. We have also dosed the first patient in a Phase II study for GSK's 656 in patients with drug sensitive pulmonary tuberculosis.

In summary, we have had a strong start to an important year of execution with all of our priorities firmly on track. I will now hand you over to lain, who is going to give you more detail on our Q1 financial performance.

Q1 2019 financial results

lain Mackay (CFO): Thanks, Emma, and it is a pleasure for me to be speaking to you in my first quarter as CFO of GSK. All the comments I will make today will be in a constant currency basis, except for where I specify otherwise, and I will cover both total and adjusted results.

Headline results

On Slide 8 you will a summary of the group's results for Q1, which was a strong quarter with 5% revenue growth driven by all three businesses. Group total operating profit is up 10% with total earnings per share up 42% and on an adjusted basis operating profit was up 9% and adjusted earnings per share up 18%.

There are a number of factors benefiting the first quarter operating profit, notably strong growth from *Shingrix* and the introduction of authorised generics, favourable inventory adjustments in vaccines and phasing of our R&D investments. I will go through these in more detail in a moment.

We delivered £165 million of free cash flow in the quarter in line with expectations, and please bear in mind that cash flow generation is expected to be weighted towards the second half of the year. Net debt at the end of Q1 was £27.1 billion. The increase from the end of the year was primarily driven by the £4 billion acquisition of Tesaro, along with the adjustment arising from implementation of IFRS 16 of £1.3 billion.

On currency, a weaker sterling, particularly against the US dollar and Japanese Yen results in a tailwind of 1% of sales and 4% to an adjusted EPS.

Results reconciliation

Slide 9 summarises the reconciliation of our total to adjusted results. The main adjusting items in the quarter were charges relating to intangibles resulting from the Tesaro acquisition; major restructuring focused on the supply chain, representing non-cash charges relating to the ramp up of the programme we announced in July 2018, and the revaluation of the embedded derivative in respect of GSK's exposure to movements in Hindustan Unilever's share price.

My comments from here onwards are unadjusted results unless stated otherwise.

On the next few slides we have listed some of the key drivers of each business' performance, and I will also talk you through how we think they will evolve through the balance of the year.

Pharmaceuticals

Slide 10 summarises the pharmaceutical business where revenues were up 2%. Luke and David will take you through the performance of some of our key products shortly, so I will just point out a couple of important considerations. The Dolutegravir franchise delivered a growth of 7%, while the established HIV products represented a decrease in the quarter.

Dolutegravir in Europe showed a decline due to price erosion despite strong underlying volume growth, as well as a release of government call back payments in the comparative period.

Looking ahead we continue to have confidence in the growth outlook of our HIV business. Our two-drug regimen portfolio is important to our future growth, and we anticipate *Dovato* will become a key contributor, though it will take several quarters as we generate more data, gain broad reimbursement, and as physicians gain experience with the product.

Respiratory sales were up 25% reflecting the growth of the *Ellipta* portfolio with *Trelegy* delivering a strong performance as well as our injectable therapy, *Nucala*.

I want to remind you that from this quarter we are reporting the *Ellipta* portfolio and *Nucala* within the Respiratory category and all other respiratory products, including *Advair/Seretide* under established products.

Relvar/Breo declined 5% globally and 27% in the US despite good volume growth, reflecting the impact of generic Advair on pricing in the ICS/LABA class, which we have been signalling for some time now.

We continue to expect *Breo* to see a decline in the US in 2019, which will result in a slight global decline for *Relvar/Breo* despite good growth expectations outside the US.

Our Established Pharmaceuticals portfolio declined 6% with US *Advair* sales down 27% as expected following the approval of a generic competitor in February. As we said at Q4, it will take time for inventory levels in the market to adjust and respond to Mylan's supply. There continues to be a number of moving factors including the successful launch of our authorised generic, which is providing a boost to Q1, but the full impact of the Mylan launch has yet to be felt. Keeping these factors in mind, our outlook for *Advair* remains unchanged.

Ventolin performance was very strong in Q1, also driven by the launch of an authorised generic in January and reflecting a one-time benefit from the initial inventory build.

Informed by these factors, we still expect the Pharmaceutical business revenues to see a slight decline in 2019, before returning to growth in 2020, driven by our new products including *Zejula*, *Dovato*, *Juluca*, *Trelegy* and *Nucala*.

Turning to the operating margin, we saw a decline in the quarter, mainly driven by an unfavourable product mix due to the impact of generic *Advair*, by Tesaro dilution which, in line with previous guidance, we expect to have a sustained impact over the balance of 2019, and R&D spend, where we are increasing spending behind priority assets which will accelerate through 2019.

Vaccines

Slide 11 gives you a quick overview of Vaccines performance in Q1, with sales up 20%, driven mainly by *Shingrix* with continued strong demand in the United States. We remain on track to deliver doses in line with guidance previously given, with good progress made this quarter.

Q1 revenues of £357 million is a good indicator of our current expectations of revenue run rate for the remainder of the year.

The momentum in the Vaccines business continues to give us confidence in the midto high-single digit outlook for sales compound annual growth, out to 2020.

In Q1, we saw strong improvement in the operating margin, driven by enhanced operating leverage, particularly from *Shingrix* in the US. It is, however, worth noting that there was a favourable inventory adjustment in the quarter. As a result, we expect to see Q2 Vaccines operating margins more in line with our medium-term guidance of mid-30s per cent, which we continue to expect for 2020.

Consumer Healthcare

Turning to slide 12, Consumer sales grew 1%, despite a drag of around 1% from the combined impact of divestments and the phasing out of low margin contract manufacturing. This was a lower growth quarter, as we signalled at Q4, mainly due to a more competitive environment in Europe. We are seeing an improvement in performance, driven by our inmarket response, and expect growth to pick up in Q2.

For 2019, we continue to expect reported growth to be impacted by the loss of around £100 million of revenue from the smaller divestments completed at the end of last

year, and the phasing out of contract manufacturing as we restructure the Consumer supply chain.

Operating profit improved in Q1, resulting in an operating margin of 21.7%. It is worth remembering that Q1 is typically a higher margin quarter, due to pre-allergy season sell-in. Margin improvements were driven by continued manufacturing simplification, as well as ongoing strong cost control. We are focused on ensuring that we reinvest in the business to drive innovation and better growth and we expect to see this come through in the remainder of the year.

Overall, we remain confident in the prospects for the business and we are on track to complete the transaction with Pfizer in the second half of the year and the sale of *Horlicks* to Unilever by the end of the year, subject to regulatory approvals.

Sales and adjusted operating margins

On this next slide we summarise the sales and adjusted operating margin for the group, which I have already covered in some detail.

Adjusted operating profit to net income

Moving to the bottom half of the P&L, there are a couple of things I want to draw to your attention. Interest expense increased, reflecting higher debt levels, driven mainly by the Tesaro acquisition, although there is also an adverse comparison to Q1 2018, which had a one-off accounting adjustment of £20 million for amortisation of interest charges. The introduction of IFRS 16 in the quarter also resulted in an increase on the interest expense line of £11 million.

On associates, we had a one-time benefit of £51 million, reflecting our increased share of after-tax profits of Innoviva, as a result of a non-recurring tax benefit. Minorities declined, reflecting the comparison with Q1 2018, which was the last full quarter of distributions to Novartis for their share in the previous Consumer Healthcare joint venture.

Free cash flow of £0.2bn

On free cash flow, we remain focused on driving greater cash discipline across the Group and generated £165 million of free cash flow in Q1. The reduction from Q1 2018 mainly reflects the adverse timing of payments for returns and rebates, which we flagged to you at Q4, and an increase in trade receivables on the back of stronger sales, particularly in Vaccines. This was partly offset by improved operating profits and lower contingent consideration payments, which last year included a milestone payment to Novartis.

As previously noted, and seen in prior years, the generation of cash flow is expected to be weighted to the second half and we expect to see a step down as the impact of *Advair* generic flows through and rebate payments are made on pre-generic sales of *Advair*.

2019 Financial Priorities

For your reference, we have provided a slide in the appendix bringing together the key points I've made in our outlook for the year.

To summarise, our guidance for 2019, including that with respect to the dividend, remains unchanged. Our financial priorities are improving working capital management and cash generation, allocation of resources to key priorities including the pipeline and ensuring successful launch of new products, and the integration of Tesaro, completion of the consumer JV and disposal of the nutrition business.

With that, I will hand over to Luke.

Pharma Update

Luke Miels (President, Global Pharmaceuticals): Thanks lain, good morning and good afternoon. In Pharma and Vaccines our focus on improved commercial execution continues.

We've had a good start to the year, and overall our growth this year will clearly be impacted by the launch of generic *Advair*. We are seeing our new products perform strongly.

Respiratory sales are up 25% at constant exchange rates: pleasingly *Benlysta* continues to grow at double digit rates and *Bexsero* achieved sales of £156 million, up 14% at constant exchange rates.

Respiratory: continued strong growth from new products

I'll now go into more detail on some of our newer products. Starting in Respiratory, *Trelegy* continues to do well, with sales of £87 million in Q1. Globally, launches have had a good start and we now have the only once-daily triple therapy for COPD in 30 countries around the world.

2019 will be an important year for *Trelegy* as we are executing our launch strategy in Japan, and expect to have approval and launch in China later in the year. We are also looking forward to data from the CAPTAIN study, which if successful, could enable us to reach patients with asthma who struggle to breathe.

In asthma biologics, *Nucala* remains the market leader in total sales, and continues to grow, quarter over quarter. On past results calls we signalled that we needed to improve our commercial execution with *Nucala*. There is more work to do, but we are seeing some

encouraging signs. As you can see from this chart, it looks at an estimated new patient starts across both retail and non-retail segments, and we now have closed the gap with Fasenra in new patients and are now back to a one-to-one position versus our closest competitor.

We track several measures, but new patient starts remain a key target, because the IL5 class as whole can grow a lot more. We estimate that out of the 340,000 severe eos patient eligible for a biologic in the US, less than 25% have received one today.

Finally, we are excited about the opportunity to provide the convenience of home administration later this year.

Zejula continues to lead the PARP class in share of 2nd line maintenance ovarian cancer patients

I also wanted to highlight *Zejula*, our market-leading PARP inhibitor for recurrent maintenance therapy of ovarian cancer in the US. In Q1 GSK reported sales of £42 million, but when factoring in Q1 sales prior to the acquisition, sales were at £56 million.

Our share of the second line maintenance market for ovarian cancer is stable, and we are looking to improve our competitive focus as we integrate our commercial operations. *Zejula* is now approved in 35 countries globally, with an established presence in the US, Germany, the UK and Italy. Our teams are now establishing coverage in France and Spain, and we plan to launch with a partner in Hong Kong before the end of the year.

PARPS remain an important option for ovarian cancer patients and we continue to believe the class is under-appreciated. As we have mentioned before, evidence suggests that there is a significant opportunity to help many more patients than those with the gBRCA mutation, including those who are HRD positive, and potentially all comers in the first line maintenance setting. Linked to this, we look forward to getting the PRIMA data, which will give us more information about this opportunity by the end of the year.

Shingrix: US launch driving vaccines growth

Moving on, we are very pleased by the strong execution of *Shingrix*, as we continue to expand and accelerate capacity to deliver this significant step-up in doses in 2019 versus 2018 that we have previously indicated to you. In the US, where demand remains high, we are seeing more than 75% of individuals who receive their first dose of *Shingrix* complete the two-dose series.

In terms of who is getting vaccinated, it's consistent: we continue to see more than one third of individuals aged under 65, and also more than one third of those receiving *Shingrix* have previously been vaccinated with the competitor. Our capacity expansion plans remain on track.

Now I will hand over to David.

David Redfern (Chief Strategy Officer): Thanks, Luke. Good afternoon, good morning, everyone.

HIV growth of 4% CER with DTG portfolio growth at +7% CER

During Q1, HIV grew 4% CER to £1.1 billion, which comprised the dolutegravir portfolio of *Triumeq*, *Tivicay* and *Juluca* growing at 7% CER, offset by the anticipated continued decline of the mature portfolio. This was slightly slower growth than in previous quarters due to the significantly larger base of the overall business and the more competitive environment.

In the US we remain encouraged by the performance of *Juluca*, which continues to gain share with greater than 2,200 scrips per week and over 1,800 physicians now prescribing, giving sales of £70 million in the quarter. We have seen a pick-up in *Juluca* since the publication of the 96-week SWORD data in October of last year, and this has now been further endorsed by the positive 148-week data. Around 65% of the *Juluca* business continues to be sourced from non-dolutegravir combinations. We believe this is a good indicator of growing prescriber confidence in two-drug regimens, which will now be further reinforced by the launch in the US of *Dovato*.

The US business grew 3% CER with the dolutegravir portfolio growing by 4%, offset by the decline in the mature portfolio. In a continuation of a trend we have previously flagged, we have seen some switching at the margin, of the *Triumeq* business in particular, to both *Juluca* and competitor STRs. The overall market share of dolutegravir-based regimens in the STR and core agent market has declined slightly and is now around 26.6%.

Tivicay + Descovy remains a popular and broadly stable business and, through the second half of the quarter, we have seen *Tivicay* NBRx improve. Future growth in the US will come from our two-drug regimens, *Juluca* and now *Dovato* in 2019, with cabotegravir + rilpivirine long-acting providing further momentum, subject to FDA approval from 2020.

In Europe, the dolutegravir volume grew 8% driven by share growth in most markets but the overall HIV business declined 6% in the quarter. This was driven by three factors: first, price cuts over the last few months in France, Spain and Italy, all these price cuts being government mandated; secondly, a challenging 2018 comparator which included a one-off claw-back release on *Triumeq* in Q1 last year in Italy and, thirdly, the drag from the mature portfolio. We expect the impact from these factors to reduce to some degree as the year

goes on. In the International region, the business continued to grow strongly at 29% CER, including good contributions from Japan and Brazil.

Momentum building behind 2DR strategy with *Dovato* launch & further data flow through 2019

Turning to *Dovato*, we are very pleased with the approval by the FDA in April and the recent positive opinion granted by the CHIMP in Europe last week. We shall continue to invest in generating further clinical evidence to support *Dovato*, including in broader patient populations. This will include GEMINI 96 week data, which we expect to be available over the summer and, if positive, this should help to reinforce confidence in the durability and resistance barrier of *Dovato*; the TANGO and subsequently SALSA switch studies, which we anticipate will enable us to file for a switch indication in the US, and a number of Phase IIIB/IV studies.

Turning to our long-acting injectable cabotegravir + rilpivirine, we have now filed in the US, with the EU submission to come shortly. Later in the year, we shall report out the eight-week dosing study, which is important as it will enable patients to reduce their injections from 12 per year to just six. This is quite an amazing shift if successful from the current standard of daily oral care with 365 tablets taken per year.

Finally, fostemsavir, an important medicine for patients with few treatment options remaining, is on track and we continue to anticipate filing by the end of 2019.

Overall, therefore, we continue to have confidence in the growth profile of our HIV business. With that, I shall hand back to Emma.

Emma Walmsley: Thanks very much, David.

Focus on delivering business priorities

As a reminder, we have seen good progress this quarter on our priorities of Innovation, Performance and Trust, and we are firmly on track with our key areas of focus. It is important that we now build on this momentum for the year, so we are driving improvements in our operating performance, we are progressing our pipeline with a number of major read-outs to come and we are working towards a successful integration with Pfizer once the Consumer JV has completed.

Successfully delivering these priorities over the coming years will provide a clear pathway to the creation of two great businesses: one focused on Pharma and Vaccines, the other on Consumer Health.

We are now joined for our Q&A by Hal on the line and Brian and Roger. With that, operator, the team is now ready to take questions.

Question & Answer Session

Keyur Parekh (Goldman Sachs): I have two questions please, one for Hal and one for Iain. Hal, I notice that there is a slight delay on the timelines for the BCMA study in the second line myeloma setting. I wonder if you can give us some colour around that and what is causing the data to go from the first half to the second half? Secondly, for Iain, as I look at Q1 and at what is implied for your guidance for the rest of the year, it feels like you are implying margin degradation of somewhere in the region of 250-300 basis points across the company. I realise that there are several factors that will drag margin down but just help us to think if there is an upside to that margin number, where could there be potential for you to take guidance up as you feel more comfortable with the rest of the year? Thank you.

Emma Walmsley: Thank you very much and we shall go first to Hal and then come over to lain.

Hal Barron: Thanks for the question. As you know, we started a lot of studies to accelerate our anti BCMA ADC programme and I should point out that our timelines for the DREAMM-2 monotherapy study in fourth line remains on track. We are expecting to report on the data later this year and file by the end of the year as well.

As you point out, we have noted a delay in the pilot study in the second line, and that was really driven by discussions we were having with the FDA, and actually deciding to modify the protocol to enable us to have more patients and a more robust understanding of the dose response and dose exploration to enable us to design the DREAMM-7 and 8 studies optimally. That resulted in increasing the number of patients and so that is going to delay the read out, but importantly, this is not driven by any adverse safety signals in the study, just to remove any concern of that. I should also point out that we're aggressively exploring options to make up for this delay in the dose exploration, so that it will have hopefully less impact on the ultimate approval date.

Emma Walmsley: Thanks very much, Hal, and so, lain, following on from our strong start, what about any comments on Keyur's questions on the guidance.

lain Mackay: Thanks for your question. In terms of key influences on outlook for the whole year, really no significant change from the guidance we gave at the fourth quarter. Key influences on it, the full integration of Tesaro, and with that a significant

step up in R&D expenditure, specifically in that area, more broadly in R&D continuing to invest behind our priority programmes across the pipeline.

Another key feature, which we still haven't seen the full impact with playing through, in fact, really only the initial, is the *Advair* generizisation and the impact obviously of Mylan but also the introduction of our own generic *Advair* in that regard. Then one other feature which we have mentioned that sits within the first quarter, which is somewhat flattering to the operating margin, are a couple of inventory adjustments within the vaccines business specifically, which would most definitely have an impact on the vaccines operating margin but also more broadly for the group. More broadly within that range of down 5-9% notwithstanding a really strong performance from *Shingrix* in the quarter.

Guidance for the moment, early as the year is, very much as it is, and it goes without saying hopefully that as the year progresses we will keep you posted on how we see those margins developing.

Emma Walmsley: Thanks very much. Next question, please.

Jo Walton (Credit Suisse): My questions are along the same lines. I wonder as a new CFO coming in from another industry, whether you could give us your initial thoughts on particularly the cost structures that you see. You have highlighted tight cost control going forward. It is always interesting to hear another person's views of costs in this industry. The second question, going back to generic *Advair*, if we look at the prescription numbers, it does look as if there may be some capacity constraints with the generic because the generic isn't appearing to gain any more share, and the share is stabilising with yourself and your authorised generic. I wonder if you could just tell us what you think is happening in the market because maybe you have a better sense of that than we have.

Emma Walmsley: Firstly on the *Advair* generic, and then I will come back to lain to speak for his first impressions, but it is early days. I don't think it is for us to comment on the supply of Mylan but, at the moment, we think we are completely where we would expect and there is no change to the outlook that we have previously shared in terms of our expectations for *Advair* overall in 2020. Iain, would you like to comment on first impressions?

lain Mackay: First impressions; as you quite rightly point out, Jo, there are both dissimilarities and similarities across the two sectors, believe it or not. Initial observations; there are a number of important - I shan't call them restructurings but

refocusing of energy within the firm that I am seeing the early indications of, and that is the work that Luke and the team are doing across Pharma commercial, in terms of really orientating the commercial organisation to the key priorities around product launch and building revenues. Through that process seeing some reorganisation from that very effective cost control in that regard.

Equally, as we have talked about before, the work that Hal is doing in the R&D organisation which we talked about in some detail at the mid-point last year, is focused on improving the overall effectiveness but also the efficiency of the R&D organisation. What I see initially is a strong focus in cost management across the organisation, whether it is in the SG&A areas, whether it is specifically within R&D, whether it is within the supply chain across Vaccines, Pharma, and very notably, within the Consumer Healthcare space as well.

My first impression is there is a very strong focus on improving the overall efficiency, effectiveness and margins of the organisation, with a broad range of activities across really every line of cost category across the P&L, so in summary, favourable!

Emma Walmsley: Thanks, lain. Next question, please.

Graham Parry (Bank of America ML): Thanks for taking my questions. The first question is on HIV. We are starting to see some formularies such as express scrips, national formularies start to add HIV to its exclusion lists this year. GSK drugs are still on formulary, but can you run through whether GSK had to offer any increased rebate to keep the portfolio there and if you expect that to increase price pressure over time.

Secondly, on the vaccines margin of 40%, I think you have talked about what Q2 will look like but it would be helpful if you could just quantify and strip out both the rebate benefit to *Shingrix* and the phasing benefits across the portfolio, so we can understand what the right underlying and ongoing level for both *Shingrix* and the rest of the portfolio would be, as we are trying to calculate the rest of the year. Thank you.

Emma Walmsley: Thanks very much, Graham, so first to David, knowing that we have never given detailed updates on our commercial relationship, but first to David and then to lain, perhaps, on the Vaccines margin.

David Redfern: Thanks, Graham. As you say, we have very strong formulary access for *Tivicay, Triumeq* and *Juluca* – very strong coverage and, as I have said, it is pretty stable. We are in the discussions with *Dovato*, having been recently approved, with the payors in the US: the initial feedback that we have had is that the WAC

price, which is the lowest integrase STR in the market, has been favourably received and those discussions are going very well. There is no real significant change in the dynamic.

The one thing that is going on with the payors is that some of them, at least, are trying to much more actively manage their formularies to line up with the guidelines. HIV is very guideline-driven: the guidelines are updated regularly and so you see some formularies, like ESI and others, excluding some of the older Tenofovir-based regimens. That is going on but, overall, it is very stable and we have very strong coverage. We are very optimistic about the coverage we will have for *Dovato*.

lain Mackay: Graham, on the Vaccines margin point, taking broadly the influence of both rebating and inventory adjustments across that portfolio for the quarter, it has contributed positively about five points to the margin in the quarter, together. In total, in sterling terms, it represented about £70 million in total. When you think about the guidance we provided previously and looking out to 2020, that gives you a margin broadly consistent with where we would expect the Vaccines business to be in 2020. That is not to say that we would expect necessarily the Vaccines business to be at that level for the remainder of this year, but that is the impact, and that rebating was specific to *Shingrix*, and then inventory adjustments were across a broader range of products within the portfolio.

Emma Walmsley: Thanks, lain. Next question, please.

Tim Anderson (Wolfe Research): I have a question on consensus modelling for *Tivicay* and *Triumeq*. According to the data that you collect, consensus really has those two franchises as pretty much flat over a five-year window on a global basis. If I look at script trends, at least in the US, it shows some pretty stiff competition from Gilead. I am hoping you can give us some perspective on whether you think consensus modelling for *Tivicay* and *Triumeq* over something like a five-year window is right.

My second question is, could you disclose emerging market performance in the quarter, including China's performance. Thank you.

Emma Walmsley: Thanks very much, Tim. I will come to David in just a moment, to comment a little on shares and outlook in HIV, knowing that we never comment on the specifics of consensus.

In terms of emerging markets, we were up six. We don't explicitly disclose on China, although I am sure Luke will be happy to give some comments later if anyone wants to ask about what our plans are in our China business.

David, would you like to comment?

David Redfern: Yes. We will not comment specifically, as Emma says, on consensus, but I will just make a few remarks.

Firstly, HIV is obviously a competitive market place but, overall, we traded during Q1 very much in line with our expectations. There has been some switching at the margin, as I said in my remarks, particularly on *Triumeq*, but, overall, we are running – certainly through the guarter – at about 32,000 to 33,000 scrips, which is relatively stable.

What is true is that, going forward in the US, we see the vast majority of the growth coming now from our two-drug regimens – *Juluca* initially, but hopefully now also *Dovato* and then, from next year, subject to approval, cabotegravir. That is where the growth will come from and, to some degree, there will be some cannibalisation of *Tivicay* and *Triumeq* in the US, particularly probably *Triumeq*, into the two-drug regimes, and that will be fine. That is where the growth will come from. Outside the US, it will be more broadly based, including *Tivicay* and *Triumeq*.

Emma Walmsley: Thanks, David. Next question, please.

Peter Welford (Jefferies): I have my customary two questions, firstly on *Nucala*. I wonder whether you could just comment there, in regard to the trends that you are seeing now starting to evolve in the market place. Obviously, there is a new competitor entering and perhaps also a new at-home administration reaching the market for yours. How do you think about that product for the remainder of the year, given some prior more cautious commentary you have given perhaps ahead of this quarter.

Secondly, just on BCMA for Hal – just with regard to the multiple myeloma combo trial with Keytruda that you have initiated, I would love to hear the thinking behind that trial, given that obviously there have been a number of setbacks with the PD1s in this indication, and also whether or not you are confident that manufacturing for that is ready to be able to file by year-end when you get the data from the fourth-line trial. Thank you.

Emma Walmsley: Okay – first Luke, and then over to Hal.

Luke Miels: Thank you for the questions. With *Nucala*, it has been very much back to basics with us. We worked very hard to establish a clear positioning in the market. We have focused on productivity of the sales force and the medical teams and I think we are starting to see the benefits of that flowing through.

In terms of the broader dynamics, again, we are holding our own. Dupilumab seems to be taking the bulk of its business from Xolair and not from the IL-5 class, and there are no signs of that shifting at this point. Also, in our expansion beyond the US I think we are doing

quite well: we have a better understanding of the patient profile and the true size of the patient pool in countries in Europe and we are doing very well with around 70% market share in Japan.

In terms of the auto-injector, it is very interesting. If you look at perception mapping around *Nucala* historically, we were able to work on the efficacy profile and we were able to work on the mechanism – all of these components. Obviously, one of the challenges we had that was difficult to move with what we have available today, is this perception around dosing frequency. The opportunity for the auto-injector provides another option for patients and physicians so they have the choice as to whether they want to dose every four weeks in the office, or write a scrip to enable those patients subsequently to dose at home. It is an attractive option for us, we are very much focused on the launch and we expect approval in the second half of the year in the US and in Europe.

Emma Walmsley: Thanks, Luke. Hal?

Hal Barron: Thank you for the question. First, we will have the data to review by the end of the year and there won't be any concerns from a manufacturing perspective as far as filing the fourth line data, to the second part of your question.

Regarding the PD1 combination trial, it is important to point out that the BCMA ADC has multiple mechanisms. It not only inhibits the BCMA signalling, which is important for plasma cell survival, and the toxin conjugate, the ADC component, gives it enormous potential for destroying the plasma cells as well. The antibody is afucosylated which also gives an immune component, so a very enhanced ADCC. Lastly, what we observed preclinically is that there is a significant immune component to this therapy that may be due to the ADC or even to the ADCC but we see pre-clinically, a very interesting immune response that we believe will be synergistic with PD1.

You are right to point out that previous trials with pembro have not been successful and, in fact, I believe they taught us a lesson on how to think about PD1 inhibition in disease, in particular myeloma. We shall leverage that finding where there sometimes is an early hazard that one needs to progress past in order to see the full benefit, as you can see now with the longer-term follow-up. Based on the mechanism and based on some preclinical data, we believe that this is a smart risk to take and we shall see what the data show.

Emma Walmsley: Thank you, Hal. Next question please?

Steve Scala (Cowen & Co): In 2015 the company provided six or seven pieces of 2015-20 guidance. Iain, I wonder whether you have embraced all seven or if you

are revising any? Just briefly, if you will allow me: Pharma was low single digit ex-Vaccines; Vaccines was mid to high single digit but that now looks light; Respiratory at 2015 levels looks light; Consumer, low to mid single digit, that looks aggressive; total company low to mid single digit; EPS mid-single digit; tax rate increase two to three percentage points over the next three to five years and, if I have missed any, please reflect on those as well. Thank you.

lain Mackay: Steve, that's a fairly kick-ass question - thank you! From where I sit, someone who started my job 30 days ago, what I am particularly focused on is how we close out the remainder of 2019 and build on the progress that we made in the first quarter. In the fourth quarter, we talked about the 2019 guidance and how that took us through to 2020 and, in that regard, the guidance that we updated then and that we have reaffirmed today is, hopefully, suitable guidance for you to think about how the firm, as a whole, progresses through 2019 and then sets up for 2020. Clearly, the composition of the business is changing somewhat: we are going into a JV, subject to approvals, with Consumer Health later this year, which will obviously have an impact as far as how Brian and the team perform in that regard. We have also done the transaction with Tesaro, which changes the shape somewhat of Pharma and there are a couple of disposals going on as well. Therefore, the shape of the organisation is changing and, if I would dare to suggest a way of thinking about the guidance is how we have updated at the end of last year, how we have updated today or rather reaffirmed around that, with a strong focus on execution in 2019 and setting ourselves up for 2020.

Emma Walmsley: Thanks, lain. Next question please?

Laura Sutcliffe (UBS): Thank you for taking my questions. Obviously, Shingrix is doing very well. I notice, however, that you have killed your universal flu vaccine project, so could you perhaps talk a little about what you are excited about in the Vaccines pipeline, what might be coming up after Shingrix? Secondly, I am going to ask the question that Emma mentioned about your ambitions in China, so could you perhaps speak a little about that too, outside of Consumer Health?

Emma Walmsley: Of course, and we shall come to Luke in a moment on China. Since we have Roger Connor in the room, who has not only been working on the improvements in our supply in *Shingrix* but is also responsible for the R&D organisation - do you want to comment on the pipeline?

Roger Connor: Thank you very much for the question. You will notice that there were two assets in our Vaccines pipeline that we have removed this quarter. First of

all, this is not a concern as these are not priority assets but perhaps I can walk through the assets in particular. One was, as you mentioned, the universal flu asset which is a partnered asset in Phase I and II that we have stopped following an interim data analysis. Just to emphasise the point that we are very much committed to flu development and we are looking in the early stages of our pipeline at alternative approaches in the universal flu space.

For information, the other asset that we stopped is a next generation option for the prevention of pneumococcal disease, we are looking at new technologies there. Again, it is not viable to go forward. These are not priority assets for us and really allow us to stay focused on our priority assets in our pipeline and perhaps I can just mention two of these very quickly.

One is our RSV portfolio and I am very excited about this. We have in respiratory syncytial virus three different vaccines in development and, as I am sure you will know, RSV is the single biggest cause of hospitalisation in infants under the age of one. We have three vaccines in development: one for paediatric, one for maternal and one for older adult. When we look at that portfolio, we believe that there is a real potential for first and best-in-class vaccines within that portfolio. You may have seen already that our older adult and maternal vaccine in RSV have both received a prioritised fast-track designation from the FDA, so that is going on in RSV for us which is an exciting area.

As far as older adult, I should just emphasise as well. That vaccine will use the same adjuvant system as our *Shingrix* vaccine which proved very effective there. Just on another asset in the pipeline that we are looking at very closely and prioritising is COPD – chronic obstructive pulmonary disease. Again, this vaccine will use our adjuvant system. Again, it will be a therapeutic vaccine, and we are looking to see how do we exploit the adjuvant technology to go into this therapeutic space and on COPD in particular this is the first vaccine against COPD, which is looking to really address exacerbation rate and disease progression.

Exacerbations are associated with let's say bacterial presence and we feel that a vaccine addressing those bacteria could have a big impact, so exciting times in the pipeline, but those are just two of the priority assets we have.

Emma Walmsley: Thanks, Roger. Luke, China.

Luke Miels: Thanks, Laura. We remain very positive about China. I think in contrast to a number of fields, we have a very concentrated portfolio there, and so when we look at the opportunities in the immediate products that we have today, the first is *Seretide*. It is probably well known to everyone that COPD is significantly under-treated, even when it is

diagnosed in China, so we see that as a major opportunity to expand the usage of their product there. *Cervarix*; we still in the early days in the introduction there, we have around a third of the patients who are taking HPV or a vaccination with HPV. Then linked to that is the opportunity to broaden the vaccines portfolio within China. Underlying all of this is really just working very hard on our commercial and medical execution in country, and then ultimately working hard in partnership with Hal and his team to accelerate the introduction of pipeline assets such as BCMA and Hep B into China.

Emma Walmsley: Thanks, Luke. In the end, obviously we are starting, for the reasons you are all familiar with, from a lower base. That gives us opportunity for growth in arguably one of the most exciting markets at the moment, not least because of the deregulation that is going on around innovation, as Luke has alluded to. We are sat on slightly less exposure arguably in terms of the pricing around branded generics, so more to come there, and we will see where the *Shingrix* approval goes in due course.

Next question, please.

Richard Parks (Deutsche Bank): Hi, thank you very much for taking my questions. First one is for lain on free cash flow and the balance sheet; you called out, and you have done previously, a step down in free cash flow generation this year due to generic Advair. I wondered if you could give us some kind of steer on where that might fall out in terms of dividend cover this year, and how you are feeling about what flexibility there is still in the balance sheet to do business development? And maybe talk about what the path is to deleveraging the balance sheet and maybe getting more aggressive there in terms of business development. That is the first question.

Secondly, on the HIV franchise, obviously European sales saw a decline, and I think you flagged the price reductions. I am just wondering how you expect that to play out for the full year. Can HIV in Europe still grow this year and are you seeing any impact from the dolutegravir launches in that number? Thank you.

Emma Walmsley: David, why don't we go to you first, just to comment on HIV, and then we will come back to lain. We don't guide on cash flow in the year, but we will come back to lain on your other broader finance questions.

David Redfern: Thanks, Richard. HIV in Europe; the dolutegravir volume actually grew very strongly up 8%, with some very good performances in France, Spain and Italy, and we're actually particularly pleased about how *Juluca* has started in France but, as I said, there were some government mandated price cuts in a few markets. For example, in

France, the fifth anniversary from your launch you often have to take a price cut, and that was the case with *Tivicay*, so these won't happen every year but it is normal part of life in Europe which impacted the quarter and will obviously have an impact across the year, and then there was a one-off comparative in Italy. The impact will dissipate during the year, but it won't totally go, but overall, pretty pleased with the performance.

Emma Walmsley: Thanks, David, so over to lain, and in terms of the BD appetite point, I will say we are largely focused on digesting exactly the rather significant number of deals we haven't had, but lain, comments overall.

lain Mackay: Richard, thanks for the question. There is clearly strong focus in terms of working capital management, cash flow generation across the company with that embedded in everybody's goals and objectives. Just talking about the full year, obviously last year was a very good year from a cash flow perspective, with £5.7 billion for the full year.

What we talked about at the fourth quarter was a couple of things; one, lower profitability in line with the guidance for the full year. Other things kicking in are the full impact of *Advair*, which we would expect to see coming through over the next quarter or so, continuing to step up R&D and the investment behind our priorities in that pipeline, an important factor. Another thing is building on the announcement around the middle of 2000 in July with respect to restructuring we will see a bigger impact of restructuring in 2019. So those factors, as we said at the end of the year, we would expect to see cash generation somewhat lower than was the case in 2018, but nonetheless, a very, very strong focus in that area.

Guidance today in the dividend; absolutely no change, reaffirmed expectations around the 80p per share for the full year 2019. In terms of thinking about capital allocation more broadly, Emma talked about really focusing on implementing, executing the transactions that we have in the pipeline now and realising value from those transactions.

Clearly one of those, the disposition of the Nutrition business in India to Unilever, will generate significant cash flow as that deal closes and will go largely to improving overall balance sheet capacity. When we think about that capacity, it's around supporting the pipeline, returns to shareholders through the dividend and this continued aspect of looking for business development, that contributes to strengthening the long-term future of the firm. Subject, obviously, to pretty strict return criteria and structuring with those transactions. But it would not be an understatement to say that there is very, very sharp focus across the firm on cash generation.

Emma Walmsley: Yes, I certainly confirm that, and just in terms of what the pathway is, I would just remind everybody that we are obviously very excited about getting to the close, subject to the necessary approvals, of the Consumer deal. We are then going to be focused on successful integration, which we are confident we can deliver. Then up to three years after close, we intend to separate these companies, and that will create the reset of the capital structures for both businesses, which then creates a whole new level of capacity for that pharma and vaccines company focused on the science, immunology technology and genetics, to both invest in further growth – organically and inorganically – and deliver returns to shareholders.

Thank you – next question, please.

Simon Baker (Redburn): Thank you for taking my two questions. Firstly, just continuing on from Richard's question on free cash flow, perhaps I could broaden it out a little for lain, to get your perspectives at this admittedly early stage on where free cash flow conversion is, notwithstanding the one-off effects in the quarter, and where you think it could and should be in the coming years.

Secondly, a question for Hal. There was a report out from the IQVIA Institute last week suggesting the potential impact of various new technologies on R&D productivity; given that the history of R&D is littered with technologies which have over-priced and underdelivered, it would be very interesting to get your perspectives on what you think are the principal technological drivers of increased R&D productivity over the coming years. Thanks very much.

Emma Walmsley: Fantastic. We'll come to lain first, and then come over to Hal on the phone, knowing that again, he will be giving you an update on this, including that question, I think, at Q2. First of all, lain, any further comments you want to make on cash flow?

lain Mackay: Not a great deal, just to emphasise the focus around working capital management across the organisation as a whole, and looking broadly across the balance sheet and the wider portfolio in terms of opportunity to create monetisation opportunities where returns are presently below hurdle rates that we've set, and that's a piece of work that we do across each of the businesses on an ongoing basis. The focus is there, really nothing more precise on the guidance in that regard.

Emma Walmsley: Thanks lain. Hal – new technologies for productivity.

Hal Barron: Thanks for the question, Simon. I think there's no question that the R&D organisations across Pharma could benefit from improvements in productivity. I would say the focus for us has been driven by the observation that only about one in ten molecules that enter the clinic actually ends up becoming a medicine and helping patients, and we're pretty focused on seeing if we can increase that substantially.

The three technologies that we have identified, that we believe will improve this dramatically potentially, is human genetics. With the reduction in the cost of sequencing as well as the number of people and patients who have been signing up for various sequencing opportunities such as 23andMe, where we have now millions of patients who have donated their genetic information to help us understand and better target, we think is going to be a very important technology.

In addition, functional genomics, which is essentially taking that genetic data and being able to understand what does it really mean, what are the structural variants telling us about human disease, could also enable us to find much, much better targets. Given how massive these data sets can become when you do all these technologies, we really do believe that machine learning and artificial intelligence applied to these highly dimensional data sets can unravel the biology in a pretty profound way.

All three of these are growing in sophistication, and I'll be talking a lot more about this at Q2, but we've already started seeing some interesting targets that were never identified previously. We think that because they are driven really by using the human as the model organism, if you will, using human genetics and functional genomics, we think this could have a significant impact on our probability of success and therefore our productivity. More on that in Q2.

Emma Walmsley: Thanks very much, Hal, and with that I think we have come now to the end of the call, so I would like to say thank you to everybody for joining, good to hear your voices, and we look forward to catching up soon. Thanks, bye.

[Ends]