GLAXOSMITHKLINE
THIRD QUARTER 2019 RESULTS
PRESENTATION TO ANALYSTS
Wednesday, 30 October 2019

Sarah Elton-Farr (Head of Investor Relations): Good morning and good afternoon. Thank you for joining us on our Q3 2019 results which were issued earlier today. You should have received our press release and you 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 our website.

Cautionary statement regarding forward-looking statements

Before we begin, please refer to slide 2 of our presentation for our cautionary statement. Our speakers today are Chief Executive Officer Emma Walmsley, Iain Mackay, Chief Financial Officer, Luke Miels, President Global Pharmaceuticals and David Redfern, Chief Strategy Officer and Chairman of ViiV. Hal Barron, Brian McNamara and Roger Connor are joining us for the Q&A section of the call. We would request that you only ask a maximum of two questions so that everyone has a chance to participate and with that, I shall hand the call over to Emma.

Q3 2019 Progress

Emma Walmsley (Chief Executive Officer): Thank you, SEF.

Sales growth across all three businesses

2019 is an important year of execution for GSK and I am pleased that we have made continued good progress this quarter with growth in sales and constant exchange rates across the group. Group sales growth of 11% in CER terms, or 6% on a pro forma basis, 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 with strong growth from our newer Respiratory products and *Benlysta*.

Consumer benefited this quarter from the consolidation of the Pfizer Consumer Healthcare business powering sales growth of 25% and, on a pro forma basis, the Consumer business grew at 3% in line with our expectations.

Group adjusted operating margin this quarter was down 2 percentage points on a CER basis, primarily due to the impact of generic competition to *Advair* in the US, while also substantially increasing investment in R&D and support for new launches. This was partially offset by a strong contribution from Vaccines.

On a total basis, earnings per share declined 1% to 31.4 pence and adjusted earnings per share increased 1% to 38.6 pence, reflecting both our operating performance and a lower tax rate. Iain will give you more detail in a moment but, based on this delivery and our outlook, I am pleased that we are able again to update our 2019 earnings guidance.

Our free cash flow year to date was £2.5 billion in line with our expectations and, as guided previously, cash flows are weighted to the second half of the year.

Q3 progress made on our 3 priorities

This quarter, we have continued to make progress against our priorities for the whole company - Innovation, Performance and Trust - all to be powered by an ongoing culture change. We have continued to execute on new product launches and have demonstrated strong growth with *Nucala* and *Trelegy* in Respiratory and most notably in Vaccines with *Shingrix*, now expected to deliver high-teens millions of doses this year with continued improvements in supply.

This has been a very important quarter of progress against our top priority of strengthening our pipeline, including three positive readouts in three pivotal Oncology studies. In August, we reported positive headline results from our DREAMM-2 study of our BCMA antibody drug conjugate belantamab mafodotin in fourth line multiple myeloma. We are on track here with regulatory submissions supporting potential first launches next year to help patients who are refractory to daratumumab and are running out of treatment options.

In September, we presented positive data at ESMO supporting the use of *Zejula* monotherapy for women with ovarian cancer in the first line maintenance setting irrespective of biomarker status, and we are on track here to make regulatory submissions by the end of the year. Last week, we also received approval for *Zejula* in the later line treatment setting.

We also presented at ESMO encouraging data on our ICOS agonist, supporting a move into Phase III studies in head and neck cancer in combination with pembrolizumab by the end of the year, and we now have positive data in-house from our PD-1 inhibitor dostarlimab. We plan to make a US regulatory submission for use in second line endometrial cancer by the end of this year too.

Beyond Oncology, it has also been a busy pipeline quarter. In Respiratory, we recently made a US submission for *Trelegy* in the treatment of asthma and received European approval for *Nucala* self-administration.

In HIV we received positive data in the ATLAS 2-month study, looking at eight week dosing for our long-acting HIV treatment. This builds on what has already been a very strong year of data supporting the two-drug regimens in HIV.

We also recently started Phase III studies of our novel antibiotic, gepoditacin, the first in a new class of antibiotics in uncomplicated urinary tract infections and urogenital gonorrhoea.

Moving to performance, I'm pleased with our delivery on sales growth, on cost control and on strengthened cash flow. We completed the creation of the joint venture with Pfizer and have started work on integrating these two businesses under Brian's leadership, building a world leader in consumer health, with a strong and exciting portfolio of brands.

In Pharma, we continue to build our specialty capabilities, ready to support the three oncology launches we anticipate next year. We are hiring people with the right oncology experience in the key markets, and doing so at pace.

Finally, on Trust: we want GSK to continue to lead with a broader contribution to society, and this quarter I was delighted to see that ambition reflected in the Dow Jones Sustainability Index, where GSK was listed for the first time as the top-ranked company in the Pharma sector.

This week we were pleased to see the final results of our Phase II study for our candidate TB vaccine published in the *New England Journal of Medicine*, potentially providing the global health community with a new tool to help provide protection against TB.

In summary, Q3 represents another quarter of strategic progress, and good growth, with all our priorities remaining on track.

I will now hand you over to Iain, who is going to give you some more detail on our Q3 financial performance.

Q3 2019 financial results

Iain Mackay (Chief Financial Officer): Thanks, Emma. All the comments I make today will be on a constant currency basis except where I specify otherwise, and I will cover both total and adjusted results.

Headline Results

On Slide 8 is a summary of the Group's results for Q3, which was a strong quarter across all three businesses. Reported turnover growth was 11%, reflecting the closure of the consumer joint venture with Pfizer on 31 July, with total revenue growth as 6% on a *pro forma* basis.

Total operating profit is up 3%, with total EPS down 1%. On an adjusted basis, operating profit was up 3% reported and was down 1% *pro forma*, while adjusted EPS was up 1%. I will go through the drivers behind these in more detail in a moment.

We delivered £1.9 billion free cash flow in the quarter, in line with our expectations, reflecting higher operating cash flows and improvements in working capital. In currency, a weaker sterling, particularly against the US dollar and Japanese yen, resulted in a tail wind of 5% on sales and 8% to adjusted EPS.

Results reconciliation

Slide 9 summarises the reconciliation of our Total to Adjusted results. The main adjusting items in the quarter were major restructuring focused on the supply chain, with also some initial charges for the integration of the Consumer Healthcare JV with Pfizer. Within transaction-related, a re-measurement of the ViiV contingent consideration liability, primarily driven by changes in exchange rates, as well as the unwind of the fair value uplift on inventory taken on as part of the Consumer Healthcare JV. Within the disposals column, the main contributor is again from the revaluation of the embedded derivative in respect of GSK's exposure to movements in the Hindustan Unilever share price.

The comments from here onwards are now adjusted results, unless stated otherwise.

Pharmaceuticals

Slide 10 summarises the pharmaceutical business, where revenues were up 3%. 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.

Starting with Respiratory, sales were up 19%, with continued growth from *Trelegy* and *Nucala* across all regions. This was partly offset by *Relvar-Breo*, which declined 8% globally, driven by a 32% decline in the US, reflecting the impact of generic *Advair* on pricing in the ICS LABA class. We continue to have good growth expectations outside the US, and this quarter sales grew 19% in Europe and 22% in international.

Overall revenues in HIV were flat, with the dolutegravir franchise up 2% globally; the dynamics in this market reflect the impact of competition, as well as the shift within our portfolio towards our two-drug regimens, with growth in *Juluca* and *Dovato* offsetting declines in *Tivicay* and *Triumeq.*

At a regional level, dolutegravir grew in Europe and International and was flat in the US.

We have seen an encouraging start for *Dovato,* both in the US and in Europe, where we had our first launches this quarter. We continue to build momentum with the two-drug regimens but, as anticipated, it will take several quarters for them to become a significant contributor to growth.

Our Established Pharmaceuticals portfolio declined 5% overall, driven by US *Advair sales* which were down 64% as expected, given generic competition. This was offset by continued upside on *Ventolin* from the authorised generic launched in the US earlier in the year which, you will remember, is an in-year benefit ahead of the introduction of the substitutable generics expected in 2020.

We also saw favourable RAR true-ups in the US, primarily on *Flovent.*

Outside Respiratory, the remainder of the Established Pharma portfolio grew by 1% in the quarter, helped by the phasing of some tenders in Europe. Our expectation for the longer term for this part of our established products portfolio, excluding Respiratory, remains a mid- to high-single digit decline.

Overall, benefitting from some in-year upsides, we now expect to see Pharma sales broadly flat in 2019.

Turning to operating margins, we saw a decline in the quarter, mainly driven by an unfavourable product mix and price impacts including, notably, the impact of generic *Advair*. Tesaro dilution which, in line with previous guidance, we expect to have a sustained impact over 2019. In SG&A, some provisions for ongoing legal cases, as well as investments in promotional activity for new launches. And Pharma R&D, spend, which increased by 19%, reflecting our investment behind priority assets.

Vaccines

Slide 11 gives you an overview of Vaccines performance in Q3, with sales up 15%, driven mainly by *Shingrix* but also by meningitis and flu vaccines. *Shingrix* continues to benefit from our actions to increase our supply capacity, with revenues in the quarter of £535 million, driven by continued strong uptake in the US as well as in Germany and Canada. With our strength and supply position, we now expect to achieve high teens of millions of doses this year. We expect to be able to supply slightly more doses in 2020 than in 2019 but, as we have said before, we do not expect a significant step change in doses until we bring a new facility online.

In our meningitis portfolio, *Bexsero* continued to perform well, growing 19% in the quarter, with share gains in the US and strong demand across all regions. Flu was up 15%, which was helped by an earlier season compared with last year, but it also reflected share gains given our speed to market and a favourable impact from a prior year returns provision reversal. The phasing benefit will wash through in Q4, where we expect a decline in flu, given the higher comparator. Overall, I expect our full-year volumes to be slightly ahead of last year.

The Q3 operating margin of 50% reflects enhanced operating leverage from seasonality of the business, as well as product mix, including *Shingrix* and *Bexsero*, and higher royalties. Looking forward, Q4 is normally one of our lower margin quarters for Vaccines, given mix and seasonality trends throughout the year. While we expect to see a Vaccines margin this year above the mid-30s, in the longer-term we will increase investment in SG&A as we expand *Shingrix* geographically and in R&D as we invest behind priority assets.

Also note that, this quarter, we announced the divestment of travel vaccines, *Rabipur* and *Encepur*, reflecting actions to further simplify our supply chain and increase focus on and investment in innovation.

Consumer Healthcare

Turning to slide 12, Consumer now includes the Pfizer portfolio after the closure of the JV at the end of July, with sales of the new JV up 3% on a proforma basis, despite a drag of around 1% from the combined impact of divestments and the phasing of low margin contract manufacturing.

We saw a good performance from our power brands, particularly in the US and international. We also saw Europe return to growth this quarter.

In Oral Health, *Sensodyne* grew double-digits in the quarter while, in Wellness, *Panadol* continues to perform strongly and *Advil* was flat, reflecting a partial recovery from historical supply issues.

The integration has started well and we expect to have a revised external category reporting structure in place from Q1 2020, to appropriately reflect key drivers of the combined business and to take into account divestments.

The divestment of the Indian nutrition business to Hindustan Unilever is progressing, and we now expect closure in Q1 2020, subject to the receipt of regulatory approvals. We are also moving forward with other divestments which will continue through next year, proceeds of which will help to fund integration and restructuring activities.

Operating margin Q3 was 24%, higher as expected reflecting the benefit of sales of seasonal cold and flu products, as well as the strong on-going focus on cost control and benefits from restructuring and manufacturing.

It is worth bearing in mind that Q3 is usually our highest quarter, given this seasonality, and therefore in Q4 we expect higher costs and lower margins as we promote to drive consumption.

Sales and Adjusted operating margins

On slide 13 we have summarised sales and adjusted operating margins. At a group level SG&A increased, reflecting investments in Tesaro and new product launches alongside continued tight cost control.

While R&D increased as we invest in development for our pipeline, including the Tesaro assets. On Royalties, these were higher, driven by *Gardasil* and we now expect royalties for the year to be around £350 million.

Adjusted operating profit to net income

Moving to the bottom half of the P&L, I would highlight the following. In interest expense we continued to see the benefit of our refinancing activities, and also note that this quarter also included a fair value gain in interest rate swaps. We now expect an interest expense of between £850 million and £900 million for the year.

The effective tax rate in the quarter of 15.8% reflects our on-going progress in settling historic tax matters and key jurisdictions, and now have a rate of 16.9% year to date.

The changing shape for business and the transformational M&A we have undertaken, together with the progress in settling historic tax disputes means that we now expect an effective tax rate of around 17% for the full year. We continue to expect to see an average effective tax rate of 19% over the medium term.

On non-controlling interests we saw the initial impact of Pfizer's share of profits of the new Consumer Healthcare JV, and in Q4 we will see the first full quarter impact on this line.

9M 2019 free cash flow of £2.5bn

On free cash flow we remain focused on driving greater cash discipline across the group, and generated £2.4 billion of free cash flow in the first nine months of the year, very much in line with our expectations.

This was driven by improved operating profits and working capital management, as well as the benefit from FX so far this year, offset by the launch of generic *Advair*, and related phasing of rebates, and the upfront payment of €300 million to Merck KGaA.

We are pleased with the progress on cash flow. As previously noted, we do expect to see a step-down overall this year versus 2018, as the impact of *Advair* genericisation goes through.

2019 guidance

A number of the factors that we incorporated into our previous guidance are playing out very much as we expected. However, we are seeing better operational performance in Pharma and Vaccines businesses, and are benefiting from lower interest expense and a lower effective tax rate.

In the remainder of the year we will see continued impact from generic competition to *Advair,* higher non-controlling interests, increased targeted promotion in priority markets, and R&D spend continuing to grow.

Taking these factors into account, we now expect adjusted 2019 earnings per share to be around flat compared to 2018.

With that I will hand over to Luke.

Pharma and Vaccines update

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

Overall, our growth this year is clearly impacted by the launch of generic *Advair.* We are seeing a strong performance from our new products, and I am going to take you through a few examples of where we have made changes to refocus our resources and are seeing positive results.

Respiratory: new products continue to deliver strong sales

Starting with Respiratory on slide 18. *Trelegy*, I am pleased to tell you continues to do well with sales of £139 million in Q3. Globally, launches have had a good start, and we continue to drive uptake.

We have submitted the data from the CAPTAIN study in asthma to the FDA, and hope to get approval next year. Around 30% of asthma patients taking an ICS/LABA still experience symptoms, so this filing is an important step towards giving them an additional treatment option.

Trelegy is now launched in 38 markets around the world, including Japan and we are planning for a launch in China later this year.

In asthma biologics, *Nucala* remains the market leader in total sales in major markets around the world, and continues to grow quarter-over-quarter.

The launch of the at-home administration, combined with improved execution has increased our performance in the US retail segment, and assisted in our ability to remain the market leader, despite competition.

Also, this quarter we presented data from the real world evidence study at ERS, demonstrating highly positive results on reduction in exacerbations, and reduction in oral corticosteroid use. We are the first biologic agent to present this data, and further reinforcing our leading market position.

At this conference we were pleased to hear feedback that indicated that our monthly at-home dosing was seen by physicians as very positive as far as patient compliance, and the opportunity with biologics remains significant with slightly more than 25% of suitable patients receiving therapy today.

***Zejula* leads PARP class in share of 2nd line maintenance ovarian cancer; data supports opportunity to expand.**

I want to highlight that our PARP inhibitor *Zejula* remains an important treatment option for ovarian cancer patients in the second line maintenance setting. We are maintaining our leading position in this indication and are now focused on the opportunity to expand the reach of *Zejula* in women in the first line maintenance setting through our PRIMA data which we presented at ESMO last month.

The PRIMA data show a clear benefit in using *Zejula* across all biomarker subgroups, providing a unique opportunity to help patients in the first line setting regardless of HRD status. We believe that the PARP inhibitors are an under-utilised class: in the US only 31% of patients currently receive one in the second line maintenance setting falling to 12% in the first line setting.

With the data presented at ESMO, I am confident that this will change. We have now shown that *Zejula* is proven to be a better option than watch and wait, and we anticipate filing based on these data by the end of the year.

Finally, we are pleased to receive approval of our sNDA for *Zejula* in late stage ovarian cancer based on our QUADRA data. This approval allows us to address the unmet clinical need patients and demonstrates that *Zejula* is active as a late line therapy for women beyond those with BRCA mutation.

We are making rapid and material progress in building our Oncology commercial capabilities and the acquisition of TESARO has catalysed this process. We have also rebalanced our salesforce for therapeutics in the US and have been actively recruiting people with a great track record with success in Oncology into key markets. We are already seeing some of this benefit coming through and expect to see this reflected in our sales performance starting from the end of this year as our refocused approach flows through.

Benlysta: delivering growth with expansion potential

It is fair to say that *Benlysta* is a good example of how we are investing more broadly in specialty care and accelerating our growth. With the approval of the subcut formulation in 2017, increased support behind this product and a new team, we have driven strong performance this year. *Benlysta* remains the first and only medicine for SLE in over 50 years and yet this condition remains significantly undertreated.

We are also working hard to generate more data to support the increased use of *Benlysta*. On the back of an investigative sponsored pilot study, we are evaluating *Benlysta* with a single cycle of rituximab in the Phase III BLISS-BELIEVE study which started in March last year. Two agents have different but complementary mechanisms of action and early data suggest that a single priming co-administration of rituximab could enhance the treatment effect of *Benlysta* to provide sustained disease control and it could potentially also lead to remission. We shall have the headline results of this study by the end of 2020 and we expect to see data for lupus nephritis by the end of the year. If positive, these studies could become key contributors to future growth.

Vaccines: strong performance for _Shingrix_ and _Bexsero_

Moving on to Vaccines, we continue to be delighted with the performance of our business, particularly with the contribution to growth from our shingles vaccine *Shingrix* and our meningitis B vaccine *Bexsero*. We are pleased with the commercial execution of *Shingrix*, particularly in the US market where we have made good progress in accelerating our supply delivering sales of £535 million this quarter. We look forward to our phased launches in China and Japan next year.

Bexsero has also made a meaningful contribution to growth. We saw strong demand across the region with share gains in the US market where we are benefiting from the convenience of our dosing schedule relative to the competition. In Europe, where the disease burden is highest in infants, we are also differentiated by our label where we have the only meningitis B vaccine indicated for this age group. Now I will turn it over to David to take you through our performance in our HIV business.

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

HIV: momentum building in transition to two drug regimens

In Q3 sales of dolutegravir grew 2%, while declines in the mature products resulted in HIV sales overall being flat during the quarter. In the US total dolutegravir was flat, reflecting a slight year-on-year share decline as we transition to the new two-drug portfolio. However, *Juluca* and *Dovato* combined now account for approximately 3% of TRx and over 5.5% of NBRx with weekly scrips of approximately 2,700 and 900 respectively.

In particular, we are encouraged by the progress of *Dovato*, where NBRx is now approximately 3.5%, ahead of the *Juluca* launch trajectory and with positive feedback received from the early physician and patient adopters.

In Europe, we started the launch of *Dovato* during the quarter and saw dolutegravir up 3% with good volume growth and market share gains across all major markets offsetting some price cuts.

In International, we continue to see strong dolutegravir growth, which was up 9% although slightly lower than previous quarters due to the timing of certain tenders. The launch of *Dovato* and the strong flow of two-drug regimen clinical data will help to support the ongoing growth of the portfolio.

In addition to the important 96-week GEMINI data for *Dovato* and the TANGO switch study that we presented at IAS in July and which were very well received, during the quarter we also announced the very positive ATLAS eight-week data for cabotegravir, which show the potential of this medicine to be a once-every-two-month treatment.

We expect a regulatory decision on cabotegravir from the FDA by the end of this year. The fostemsavir filing with the FDA by the end of 2019 is also on track. Overall, we continue to be confident in the growth potential of our HIV portfolio.

With that, I will hand back to Emma.

Focus on delivering business priorities

Emma Walmsley: Thanks, David. So, as a reminder, we have seen good growth in all three businesses this quarter, and have made excellent progress on our three priorities of Innovation, Performance and Trust. We are on track with our key areas of focus. We are progressing our pipeline with a number of positive data readouts in hand, importantly

in our three pivotal oncology studies where we have regulatory submissions to come, but also in HIV with our long-acting HIV treatment, where we've filed for approval for four-week dosing and also have data in hand for eight-week. We have also filed for approval for *Trelegy* in asthma, and received European approval for *Nucala* self-administration.

We have progressed other assets too, with a Phase III study started in gepotidacin and plans to start pivotal studies with ICOS in head and neck also by year end. We are continuing to drive improvements in our operating performance and our specialty capability, and we are working toward a successful integration with Pfizer now that the consumer JV has completed.

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

We are now joined for Q&A by Hal on the phone and Brian and Roger, so with that, operator, the team also here in the room is ready to take your questions.

Question & Answer Session

Andrew Baum (Citibank): Thank you, a couple of questions, please. Firstly, to Luke: the Senate Finance Committee recently proposed a step-up in funding by the industry and PBMs for catastrophic coverage in part D, in exchange for a cap on out of pocket payments; thinking about *Zejula*, and more broadly, your oncology pipeline of small molecules, is this a proposal that GSK supports? I'm thinking about both the direct and indirect potential hit to net revenues, although offset by volumes. That's the first question.

Second question, much shorter: I didn't see any commentary on GSK Pharma in China, perhaps you could talk to that performance. Many thanks.

Emma Walmsley: Thanks, Andrew. I'll ask Luke to comment both on China and then add anything on what's happening in the pricing and regulatory environment in the US. Just to say, it's obviously extremely dynamic at the moment, there are a lot of different proposals potentially under review, as you know. We are monitoring all of them very carefully, and obviously also engaging with the administration on them.

Just in terms of big picture principles, what GSK supports is working towards addressing some of the real challenges in terms of patient out of pocket, that's why we were particularly supportive of rebate reform overall, and being able to pass through to patients some of the discounts that are there. In that sense, a cap on out of pocket is potentially a sensible idea. We also support transparency, and anything that simultaneously drives

access and innovation. We continue to monitor which bits will come through, in terms of direct impact overall for us.

Luke, I don't know if there's anything you want to add on that, but then specifically answer the China question.

Luke Miels: On China, Andrew, if you look <indiscernible>, Quarter 2 is the latest information we have, our growth is around 20%, so that is respectable, it's in the middle of the pack there. I think in terms of the future, the key thing is we are putting the building blocks in place now: we have the launch of *Trelegy* coming, where a key component of that will be to build acceptance on the part of Chinese physicians to treat COPD more aggressive. The background population is significant, it's enormous actually, and you have background things such as pollution and smoking, etc., which drive this. That's one product that we're very interested in.

I think with *Cervarix* things are starting to improve, it's been a bit bumpy but we are now getting about 120,000 in-arm shots per month, and the trend is upward there. If you look at *Benlysta*, which we are now in the process of launching in China, that again is something that will take some time to build, but again, it's an innovative product with limited direct competition. Also, we are increasingly competitive with Seretide, Flovent and Ventolin, so I think, again, off a smaller base than some of our competitors, the pieces are falling into place.

We then have the launch of *Shingrix* next year, which will be a very targeted initial launch because of the supply element that you know well. We are also looking right now, in terms of negotiations, around access for *Anoro* and *Relvar* in China, so hopefully over time we can get a few things lining up, and we will start to grow our base business in China.

Steve Scala (Cowen): Thank you, two questions. The first is a follow-up on reform, but in GSK's 19-year history, this could be the first time it raised guidance twice in one year, let alone in the first three quarters. This obviously shows the strength of the business, but, Emma, what does it tell us about your real concerns around US healthcare reforms and Brexit? It would seem that GSK would not want to show its full strength if it were truly concerned about upcoming changes, either in Washington or in London.

Secondly, on *Shingrix* the company continues to say that we should not expect a significant increase in doses produced in the near term, but the high-teens number of doses GSK will deliver this year was to have been achieved in two to three years, so some major

gains have been achieved, despite Management's cautions. Are you saying that a year from now the number of doses produced absolutely will not exceed 20 million? Thank you.

Emma Walmsley: Thanks, Steve, very much, and, actually, your two questions are linked, to a degree, in terms of what we have been able to over-deliver in terms of the initial expectations, in terms of operating performance, because, obviously, *Shingrix* is going extremely well. This is very much a supply-driven business for us, but it is a fantastic product, and we do expect it to be a material contributor to growth for the company for quite some years yet, but once we got the preferential recommendation and could see that demand was going to very swiftly outstrip supply, we did mobilise very materially across all of Roger's team to try and increase our supplies. It is very complicated to produce a vaccine, and I think whether it be through – all across that value chain we have been quite successful in making that progress, which is why we were allowed to bring forward that delivery to high teens.

I am not going to put an additional number specifically on the doses for next year, but if you listen to Iain's outline we said we would expect slightly more doses in 2020, but we don't expect a step-change until we have that new facility in place, which we have said externally we are talking about around 2024, so at this stage that is, I suppose, the overall commentary I can provide on *Shingrix*.

In terms of your point on guidance for this year, again, as I think Iain worked to step you through on his presentation, the upgrade this quarter is in part because of operating performance in both Vaccines and in Pharma, but also we are benefiting from a shift in our guidance around tax rate, which contributes again this quarter, but it is both aspects of it.

The links on that in terms of impact of Brexit and the US reform, obviously, in terms of materiality the UK is less than 4% of our global business and the US remains our biggest market and the most important market for innovation still at the moment.

Brexit we have been long prepared for operationally, and all of that has been in place, frankly, because we had to secure supply both in the UK and in Europe. What we are more focused on is securing, regardless of the new government, a life sciences-friendly environment for our heavy investment still in the UK beyond the upcoming election. I am quite confident about that on the basis that it is a strategic industry for this country, whether it is us or other large cap companies, or, indeed, the biotech and education environment here, but the US I see it – it is, as you all know, extremely dynamic. As we have already said, we are watching it carefully, but in some ways it is uncomplicated, because as long as we innovate differentially and price responsibly that will be our best opportunity for driving growth, and we will just monitor it live as it lands, and respond as impact comes through.

That was too long an answer to your two detailed questions. Perhaps we will move to the next one please, thank you.

Peter Welford (Jefferies): Hi, thanks for taking my questions. Firstly, I just wonder if you can talk a little bit about 2020? I appreciate it is early to give guidance for this year already, but can you just perhaps give us some broad terms what the potential pushes and pulls we should think of, I guess, aside from *Shingrix*, where obviously I think you have outlined that pretty clearly, but just in terms of both the top line, but also in terms of the earnings momentum?

Then, just secondly, for Hal, perhaps, on the pipeline, I noticed daprodustat looks as though it is slightly earlier than we had anticipated now we should get those reads. I was just wondering if there was anything we should read into that, and then also 772, the RIP1 K, if you could just perhaps give us some insights into why that's gone back into research phase, it will be much appreciated. Thank you.

Emma Walmsley: Okay, so I will come to Hal in a second on the dapro and the RIP 1 question, but the short answer on 2020 is we will tell you in February. There is no expected change, although there are puts and takes in the overall outlook for 2020 that we have guided to previously. We will give more detail on that in Feb.

Hal, would you like to pick up the other two questions, please?

Hal Barron: Yes, thank you for the questions. In the growth to dapro, you say we have moved up the interim analysis but I should say that that is an analysis that we are doing for internal purposes only. As you know, we have a very robust programme and, while we have very, very high confidence that the drug and probably the class is useful in terms of improving haematocrit, the real question is, compared to EPO, whether the cardiovascular profile will be equivalent or superior. We thought it prudent to do an interim analysis and, based on events, we thought that we could move up the timing of that but, again, that is internal and it is more of a safety look. That is what that is. As you know, the full data will be later, and that is event-driven and so we will put that out when we can.

The other question was about RIP 1 kinase. We have decided, based on an examination of the data generated in three different clinical trials – small Phase IIa type trials – to move the molecules back to research. We haven't killed the programme but we felt that, based on the data, there are a number of human research questions that need to be addressed, to understand why the effect was less than we had hoped for. We have a number of hypotheses that we are not willing to share at this time but we will be exploring

them either in research studies or even possibly check how some of those hypotheses bear out preclinically, potentially even moving it back to Phase I. However, that will be dependent on some research studies that we are going to undertake to understand why the molecule was unfortunately not as active as we had hoped.

Graham Parry (Bank of America, Merrill Lynch): Thank you for taking my questions. Firstly, on *Shingrix,* could you help us quantify 'slightly more in 2020' – is that slightly more each year out to 2024, when the capacity kicks in? For example, have you taken all the *Cervarix* capacity out of the glycoprotein e-bioreactors already, or is that still an improvement you've got to come? When you bring more capacity online in 2024, will you have the adjuvant capacity to match, or will that start to become a constraint at that time?

Secondly, on the ASO-HBV – I see you have data coming on that now at AASLD, the Phase II data. Is this a game-changer? I think, Hal, you called this out as one of the two most exciting assets with a proof of concept read-out at your first R&D day: do you still think that is the case? Thank you.

Emma Walmsley: Thank you, Graham. I will come to Hal on the second question. The short answer to your first question, I am afraid, is that we cannot give you any more detail than we have just outlined. We re-confirm slightly more in 2020 but, obviously, we are working on this continuously and it remains fluid. We would not commit to any step-change until 2024, with a new site. Obviously, we work on all aspects concurrently, to make sure that that step-change can be delivered.

Let me then come back to Hal, please, for HBV.

Hal Barron: Hello, Graham – thanks for your question. I think we remain excited about the potential for the ASO-HBV programme, for many reasons. First of all, it is an incredibly important medical problem, with somewhere over 200 million people chronically infected with HBV and probably over 1 million of those will die of hepatic failure cirrhosis or even hepatic cellular carcinoma. Available treatments are very limited in terms of their efficacy and they are certainly not without their toxicity, and so a novel therapy can be a significant advance for patients and a very important asset for GSK, should it work.

We have reported that the Phase IIa data showed significant activity with a reasonable, well-tolerated safety profile – that is the 836 molecule. We will be sharing that data within the next three to four weeks at the AASLD.

It is also important that it is a very novel approach using ASO, as I have mentioned, because that opens up an opportunity for us to think about that as a novel modality for

intervening, particularly in liver disease, and so we are excited about that. However, it is early days and we are working with the regulators, in multiple countries actually, to figure out how to move the asset forward into a Phase IIb study. As I have said, the data will be forthcoming at the liver meeting next month.

Emma Walmsley: The only other thing to add to that – whilst reiterating the early days point - is the relevance potentially of that asset, and the data making it worth progressing for the China market. This is really to reinforce what Luke was saying earlier, which is that that is a deregulated and increasingly innovation-focused market, where we are starting from a low base but we are thoughtful about the pipeline we may be able to bring, over the years ahead.

Richard Park (Deutsche Bank): Thank you for taking my questions. The first is a financial one, and then I have a pipeline one. I thought I would give another try to Peter's question on the outlook for 2020, and just more whether you could give us some kind of directional steer on the push and pulls on the margin in 2020. You have already highlighted the slight pressure on the Vaccines margins, so given the need to reinvest I wonder what the positives and negatives might be and, directionally, where R&D spend as a percentage of sales might be moving, so if you can give any detail there?

Secondly, I wonder if you can give us some clarity on when we might see the efficacy data from the PRIMA study by starting dose and if you can help us to understand how confident you are that you can get that individualised dosing in the label, given that only a third of patients in the PRIMA study were eligible for that revised starting dose? Thanks very much.

Emma Walmsley: We shall come to Hal in a minute on PRIMA and dosing. On 2020, I reiterate that we shall update you on 2020 in 2020. Iain may wish to add a couple of comments, repeating what he said in some of his introductory remarks around some of the dynamics between Vaccines and our choice to invest in R&D. The only thing that I would say quite firmly is that we do not believe in targeting a fixed percentage of R&D spend. We are very clear on our capital allocation priorities and right at the top of that list is strengthening our pipeline for future growth, which means investing behind new launches as we have been, their execution but also investing in R&D, which has been a big driver with increases this year. As data demand, we expect to continue to do so but certainly not as some kind of target because people can always spend money. The discipline that Hal is driving around that but, likewise, in Vaccines, as Iain also mentioned, over the next few years as proofs of concept come through for our next wave of Vaccines pipeline, should

those data merit it, we shall want to back those. Long may the *Shingrix* contribution continue but we are obviously very thoughtful about what may come in the longer life-cycle of Vaccines development. Iain, would you like to be any more generous on the insight into 2020?

Iain Mackay: I won't use up too much of the clock talking about things that we will do and talk about it when we do the full year results in 2020. However, if you reflect on what we talked about as we walked through the numbers and the priorities of the company from the standpoint of Innovation, Performance and Trust, it is clearly focused on growth. An important part of that is supporting launches of assets in priority markets and investing behind R&D. The broad shape of where we shall allocate capital, our energy and resources will not be significantly different to where we have invested those resources over the course of 2019. However, we shall give you guidance that you can sink your teeth into when we get the full year results out in February next year.

Emma Walmsley: We shall come back to Hal on PRIMA.

Hal Barron: Thank you for the question which I believe was related to the subgroup that received the "weights and plates" in a prospective manner. We are in the midst of evaluating those data right now and, as you said, it is a smaller subset so that is challenging to do both from the point of view of the analyses overall but, more importantly, in each of the subgroups. We are mostly through that and, once the data are analysed, we shall submit them to the regulatory authorities and publish them in a meeting although we do not have a date set for that.

I should point out two things. First, clinicians are very cognisant of the fact that using the "weights and plates" dosing regimen, where you adjust the dose down to 200mg when the body weight is in excess of 77kg or the platelet count is below 150, we are pretty confident that it does reduce the incidence of thrombocytopenia. The prospective analysis is looking at how similar the treatment effect is and, as I said, we shall have those data soon but most of the clinicians are already using that kind of dosing paradigm as they treat their patients today.

Geoff Porges (SCB Leerink): Thank you for taking the call. It's just a pipeline question if I may. Could you give us a sense of when we shall see the Phase II data on your pentavalent Men vaccine: you haven't given a timeline and what would be the criteria for proceeding to Phase III?

Roger Connor: Thanks for the question and from an ABCWY point of view, we are absolutely committed to developing that product. As you know, we are bringing together *Bexsero*, the world's leading meningitis B vaccine, with Menveo. We have just completed Phase II in terms of studies, we looked at 1,400 subjects in that study, and we expect to see the final Phase II data during the first half of next year, and, actually, at the moment we are engaged in regulatory discussions around the pathway and how we take it forward into Phase III, so it will be through the first half of next year that we will be looking at the data from the Phase II.

Emma Walmsley: Thanks, Roger.

Laura Sutcliffe (UBS): Hello, thank you. I have two questions, please, both on HIV. I think you have talked about the business transitioning to a new portfolio in terms of HIV drugs, and so whilst *Triumeq* obviously is still going to be an important drug for many patients, how should we be thinking about the resources you will be putting behind that versus other drugs in the portfolio in future? In other words, should we be looking at this as more of a legacy product from now on?

Also, you should, all being well, be able to launch your injectable product next year. Assuming it becomes a product that has a once-every-eight-week option further down the line, is that ultimately the optimal profile for that sort of product, or would you try to refine this or any other injectable any further? Thank you.

Emma Walmsley: Thanks. Both of those for David, please.

David Redfern: Yes, hi Laura. I think we have said several times that we really see the future growth of the HIV portfolio coming from the two-drug regimens, whether that's oral, or, as you say, hopefully, the first long-acting on the market next year.

In the cases of orals, and principally *Dovato*, that, of course, is powered by dolutegravir and our efforts to really promoting two-drug regimens, so that is where we are putting our resource, so this year behind *Dovato* and *Juluca*, and next year including cabotegravir.

As I said in my remarks, it is relatively early days, but we are pleased with the progress – sales of two-drug regimens of £119 million in the quarter, and hopefully more to come as we get the guidelines updated and the label updated in the US for the positive TANGO data, and I would also say that weight gain on the TAF side is becoming a growing issue. We saw a bit of that with the ADVANCE study at IAS, but more recently the full-set meta-analysis. I think there were about 5,700 patients from eight studies. Meta-analysis is

never perfect, as you know, but there is growing noise around that, so we will have to see how that plays out.

I think on cabotegravir we are excited about this great data, the FLAIR and ATLAS studies, and then we supplemented that with the eight-week data this quarter. It won't be for every patient. I think there will be a lot of patients happy to continue on oral therapy, but for those patients that are interested in moving they are very passionate about it.

Clearly, every eight weeks I think will be preferable to every month. Ultimately, if we could move it out to coincide with patient visits, which typically now are every six months, that would be better, but every eight weeks is a major step forward, and we are very excited to produce the first long-acting medicine on the market.

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

Keyur Parekh (Goldman Sachs): Hi, can you guys hear me okay now?

Emma Walmsley: Yes, just perfectly, Keyur!

Keyur Parekh: Thanks, two questions, please. One for Luke on *Zejula.* Luke, given the data we have seen at ESMO, would you expect *Zejula* to be on the NCCN Guidelines, and if so, can you help us think about the timelines associated with that pre the FDA approval?

Then, secondly on China, and I know you have made some comments about the growth rate, but, clearly, the base of business still remains to be very small. Merck has reported a 90% growth for Gardasil this quarter. When do you think China will become a relevant/substantive part of the business? Is it likely in 2020, or should we think of it as an opportunity beyond that? Thank you.

Emma Walmsley: Thanks, Keyur, so we will give both of those questions to Luke.

Luke Miels: I think in terms of China, beyond that, Keyur, I think we are going to need to see assets like Shingrix under full supply to materially shift our base business in China.

In *Cervarix,* again, our target right now, I think about 60% of our business from school-age girls, and that's a programme that we only launched a couple of quarters ago and it has been very successful, so, again, it is an interesting battle there. We do have some age advantages versus *Cervarix* and we are now concentrating on that.

We have also made some changes to the team in China, which, again, I think will become more visible in time, but material change to a significant scale is further out.

In terms of *Zejula*, we believe the NCCN Guidelines Committee is going to be meeting around 31st of October. I guess the question is we have published PRIMA in the *New England Journal*. We have yet to see a publication from the other study, and we have not filed the PRIMA data with the FDA, as you said at this point, so I guess the open question is going to be will the Committee move ahead and signal their support for PRIMA based on that scenario, or will they wait to either we filed or the second study is published, and it is hard to speculate. As you can imagine, we are certainly making our case that we believe the guidelines should change, and whether they change in October or whether they change in a couple of months' time, I still think the days of watch and wait are going to be increasingly difficult to justify. Again, when we announced the deal that was a key assumption of ours, that as Hal has said, the PARP class is under-utilised, so I think it's a matter of time, but we would like it to come sooner, obviously for the benefit of those patients, and we see that flow through for Zejula.

Emma Walmsley: Thanks very much, Luke. Next question please – I think we have one more, is that right? Yes, one more question.

Tim Anderson (Wolfe Research): Thank you. I have a Vaccines R&D question. With *Shingrix* you've shown that you can go into an existing market with a better product and do quite well, and I'm wondering if that is capable of being repeated in a couple of other areas where you already have a presence. So, with Gardasil for example with Merck, that can be a $7 or $8 billion product over time, you have a product in this space, didn't gain much traction, but what about trying to come up with a new version that is more competitive?

Same question in the Prevnar space, too, where you have *Synflorix* – should we assume that you will not try to re-enter these areas with new and improved products, or could this be a possibility?

Then second question on Consumer. Now that the transaction has closed with Pfizer, just an update on timing of the spin. I guess the real question is, why it really needs to take three years - could it be pulled forward, and is that guidance of three years overly conservative?

Emma Walmsley: Thanks very much Tim. I'll ask Roger to talk to you about the Vaccines pipeline and then I'll come back finally on the group demerger.

Roger Connor: Thanks very much for the question. I have to say, there's a high degree of excitement in Vaccines about the pipeline that we have. A couple of general comments first: obviously we're pleased with the breadth that we have, and the shift that we're making into therapeutics vaccination, treating disease rather than simply preventing.

I think a backbone of that strategy is our adjuvant technology actually, and our adjuvant platform. As many of you know, that adjuvant system is a key part of what made *Shingrix* so successful, and in our Vaccines pipeline we're really looking to maximise that. A couple of assets that I would draw out that I think we can really use to optimise that are COPD, vaccine for Chronic Obstructive Pulmonary Disease, an exciting year next year when in the second half we should see the proof of concept data that has ASO1 in it as well, that's the only vaccine really in development for COPD. A huge opportunity there, just given GSK's legacy in this space. And to take the US alone, where there are 16 million people suffering from COPD, we really believe that that vaccine could have a really significant impact to reduce acute exacerbation and disease progression, with such a proportion of exacerbation linked to infection that the vaccine will treat.

On RSV as well, I think we are looking to use our platform technology and our science again to differentiate. I've mentioned before we have three vaccines in the RSV space. Again, maternal, we think – just linking to your question around where can we exploit our knowledge and experience – we have maternal vaccination experience with *Boostrix*, for example, and we really feel with that experience we can drive our maternal vaccination in RSV.

Our older adult vaccine I'm excited about as well. Again, it builds off the adjuvant platform also – big opportunity there, again in the US, 70 million people over the age of 60. Then we have a paediatric vaccine in RSV too, which builds off another platform we have, which is our viral vector platform, too.

So, lots going on in the vaccine space, and other assets in the early stage, like our Hepatitis B vaccine, our *C diff.* vaccine, again, that is built off our adjuvant platform.

Emma Walmsley: Thanks, Roger. Then on the Consumer Health, there is no change to our declared intent to separate the Consumer Business around three years from close - that is not a rolling three years, we have already clocked down a quarter. The reason that we think that is around the right time is because we have the experience of doing this before. Both Brian and I, and the Board, believe and know how big a job it is to integrate two companies successfully, whilst continuing to perform competitively and extract the synergies that we are confident and committed to delivering, but also, at the same time as making sure that that business is set up for success, and a great start independently. It is during this

period that we are continuing to work to make progress on our pipeline, both in Pharma and in Vaccines, and the build of our specialty capability as well.

We think this is around the right timeline. Obviously, that is this time round a decision that GSK is in control of, up to five years, and should we ever change our view on the target date of that, we will update things, but for now there's certainly no change to that at all, and we think it's about right.

With that, thank you very much everybody for joining the call today, and we shall look forward to talking to you soon. Thank you.

[*Concluded*]