GLAXOSMITHKLINE
THIRD QUARTER 2018 RESULTS
ANALYSTS CALL
Wednesday, 31 October 2018 @ 14.30

Sarah Elton-Farr (Head of Investor Relations): Good morning and good afternoon everyone. Thank you for joining us to discuss our Q3 2018 results which were issued earlier today. You should have received our press release and can view the presentation on GSK's website. For those not able to view the webcast, slides that accompany today's call are located on the Investor section of our website.

Cautionary statement regarding forward-looking statements

Before we begin, please refer to slide 2 of our presentation for our cautionary statements.

Our speakers today are: Chief Executive Officer, Emma Walmsley; Luke Miels, President of Global Pharmaceuticals; David Redfern, Chief Strategy Officer & Chairman of ViiV, and Simon Dingemans, Chief Financial Officer. Following our presentation, we shall open the call to questions and answers, and we request that you ask only a maximum of two questions so that everyone has a chance to participate.

Joining us for Q&A are Dr Hal Barron, Chief Scientific Officer & President of R&D, and Brian McNamara, CEO of our Consumer Healthcare business. With that, I shall hand the call over to Emma.

Emma Walmsley (CEO): Thank you, SEF.

CER sales growth in all 3 businesses; improved Group operating margin

Overall, Q3 was another good quarter of progress for GSK with improvements in sales, the Group operating margin, earnings per share and cash flow. Group sales growth of 6% in CER terms reflected sales growth in all three of our global businesses. Our Pharma business grew at 3% CER during the quarter, driven by HIV and growth of new Respiratory products. Our new Respiratory portfolio grew at 40% CER, including a £42 million contribution from *Trelegy*, which continues to see good traction.

In HIV we also continued to deliver double digit growth, driven by sales of our dolutegravir portfolio including *Juluca*, the first of our new two-drug regimens.

Benlysta has also become a contributor to growth and grew at 31% CER.

Vaccines sales were up 17% CER with continued strong demand for *Shingrix* and for which sales are now expected to be £700-750 million for the full year, as well as growth of the meningitis vaccine *Bexsero*.

In Consumer Healthcare, we delivered 3% growth with growth in Wellness, Oral Health and Nutrition. We are making very good progress on margin improvements within our Consumer Healthcare business and this quarter operating margins reached 22%, an increase of 250 basis points in CER terms compared to this quarter last year, reflecting continued manufacturing restructuring and integration benefits and improved product mix as well as strong cost control.

Group operating margins this quarter were up 20 basis points on a CER basis, reflecting a more favourable mix of business and continued tight control of ongoing costs, which offset the investments we are making in the business.

Adjusted earnings were up 14% CER ahead of operating profit growth, primarily as a result of lower minority charges due to our acquisition of the Novartis stake in Consumer Health JV, as well as a reduced adjusted tax rate. On a total reported basis, EPS were up 23% CER to 28.8 pence.

Our free cash flow position also continues to improve and for the year to date it was almost £2.4 billion, up 42% versus the same period last year. We continue to expect to pay a dividend of 80 pence for the full year 2018 and, based on the results we have achieved to date, we are now tightening our guidance towards the upper end of the range for the full year, expecting adjusted EPS growth of 8-10% at constant exchange rates. We expect to maintain this guidance range in the event that a generic version of *Advair* is introduced before year end.

3 long-term priorities for all 3 businesses

As you know, I set out three long-term priorities for the business when I became CEO; Innovation, Performance and Trust, all to be underpinned with a necessary shift in our culture. And we have made some progress on each priority this quarter.

On innovation, Hal laid out his new approach to R&D at our Q2 results and he has made some really important changes to his organisation with a new governance framework in place, a new Head of Development, a dedicated Head of Research and end-to-end Oncology and Global Health R&D units.

We have also had some positive developments in our pipeline this quarter. We continue to progress our two drug regimens in HIV, making regulatory filings in the US and Europe on the back of the positive GEMINI data for the combination of dolutegravir and

lamivudine and now also have had positive results from the pivotal ATLAS and FLAIR studies for our long-acting injectable HIV therapy.

We've started the first study of BCMA in second line treatment of multiple myeloma, we have presented some encouraging Phase 2 data on our anti-GM-CSF compound at the ACR conference last week and we've seen the first results from an ICOS study which, although they are early and we need to see more evidence, showed some initial indications of activity.

We have clearly said we will be more decisive with our pipeline and this quarter we have also decided to terminate five development programmes. These decisions were data-driven, primarily based on interim analyses and will allow us to focus our efforts on other assets with greater chances of becoming important medicines. Strengthening the pipeline remains a clear priority for the group.

Moving to performance, we continue to make good progress across the business. Investments and prioritisation to improve our commercial performance are being reflected in new product sales growth and we are moving ahead with the restructuring programme we announced at Q2. In addition to the recently announced changes to our supply chain, we have already made some significant changes to our US operations.

And to be a high-performing company for the long-term, we also need to run our business in the right way, building trust with all our stakeholders.

This quarter we updated our policy on how we work with healthcare professionals, with the changes designed to help prescribers understand new data and clinical experience with our innovative products.

We also updated our approach to Global Health so that it is focussed for impact and we are pleased to report this quarter initial promising data for our candidate vaccine to prevent TB.

And turning lastly to culture, we've continued to build the right teams to lead and this quarter also announced the appointment of Iain Mackay as CFO who will join us in the New Year.

Now culture change of course will take time and energy, but we are making progress and we are working hard to build more focus, agility, accountability and when appropriate the courage to take smart risks.

So overall, I am pleased with our progress this quarter on our three long-term priorities and the beginning of a shift in culture and now I am going to hand over to Luke, David and Simon who are going to talk you through some of the details.

Luke, over to you first.

Pharma Update

Luke Miels: Great, thanks, Emma and hello, everyone and it really is a pleasure to report on another good quarter.

Increasing focus and prioritisation to support future growth

Driving this is a greater level of focus and prioritisation in the Commercial organisation in the form that you can see on slide seven.

On the products level, this means investing in key products that are differentiated and can profitably grow and win. For *Shingrix* we are on track with good momentum and this is a very large opportunity, but in the near-term our ability to grow sales will be limited by our supply.

Bexsero is another important growth driver for our Vaccines business and we continue to see demand and share gains in the US on the back of a new campaign and better tactics. We are also seeing good growth in private markets in the International region.

With *Trelegy* the launch is progressing well and we expect a continued strong launch trajectory as we launch into other markets. The product is now available in 16 countries and a further nine by the end of 2019 and we have also filed in Japan for the planned launch in 2019 and in China. The key drivers for *Trelegy* right now are the US, the UK and Germany.

On *Nucala* we are doing well internationally but we are seeing a more competitive market in the US with the launch of Fasenra and now Dupixent. In my mind this is about execution and we have changed some key members of the *Nucala* Team in the US. We have also increased the resources behind the product and we will be engaging in a more focussed way with doctors driving our message of long-lasting protection from exacerbations.

Following updates to our healthcare policy announced earlier this month we conducted our first paid external speaker event in the US for *Nucala* at the recent CHEST conference and additionally we are planning to launch an autoinjector for at-home use in 2019.

Benlysta I will cover shortly and David will speak about HIV and the opportunity for growth and the potential for the two-drug regimens in a moment.

The second column on slide 7 is markets and, in a shift, we are very focused on the top 10 markets where the bulk of our growth is. Within these, naturally the US is our biggest opportunity and we are investing more here behind our priority products.

China is also a focus and under-represented today, but we are investing more and planning to launch more innovative Pharma and Vaccines products, going forward.

The third big change is that we are investing in our specialty capabilities. In Oncology, where we aim to bring our pipeline to market in the relatively near term with BCMA, we are laying the foundations of our commercial infrastructure, which means hiring external people who know haematology and oncology. Hal and I are very passionate about ensuring strong linkages between R&D and Commercial, including the co-location of R&D and Commercial and Oncology. This is not rocket science but we all know that it works to create value.

Shingrix: continued strong launch execution

We are pleased to see another very strong quarter with *Shingrix*. We are expanding the market with about a third of those receiving the vaccine below 65 years and, overall, around two-thirds of people getting the vaccine were not previously vaccinated with Zostavax. Target sales for 2018 are now in the range of £700 to £750 million and this is clearly an opportunity for further growth in 2019. Working with Roger, we are in the process of building up our supply capacity. However – and this is a key point – as we saw with meningitis, it will take time to reach a point where we are demand rather than supply led.

Benlysta: maximising the growth opportunity

I would now like to take a minute on slide 9 to talk a little more about *Benlysta* as this is a good example of how and where we are investing more behind certain products and getting better at execution and accelerating their growth. With the approval of the subcut last year and increased investment, we see considerable potential for *Benlysta*, which remains the first and only product for SLE in over 50 years, and yet the fact is that this condition remains relatively under-treated. Currently we have around 12,000 patients in the US on the drug out of an eligible or in-label pool of patients of 100,000, so there is substantial scope for further upside. The potential trigger to unlock many of these patients is a study that we are very excited by. This is the combo study with rituximab, where there is potentially a synergistic mechanism of action based on early data, that could enhance the treatment effect to provide potentially a sustained disease control and also potentially, in an upside, remission. This is a study that is recruiting well and reads out in late 2020.

Now, David will take you through the performance in our HIV business.

HIV performance on track

David Redfern: Thank you, Luke. We have continued to see good performance this quarter in our HIV business, with growth of 12% at constant exchange

rates, and 17% growth for our dolutegravir portfolio, which is broadly consistent with the growth trends we have seen for the year to date.

We are continuing to hold our share in the US within the STR/Core market at approximately 28%. There has been some switching at the margin, particularly from *Triumeq*, some of which has gone to competitors, and some also to *Juluca* but, overall, the prescription trends in the US are very similar to the last quarter.

Juluca has had a positive impact and is now at 1500 scripts or more per week, with greater than 1500 physicians having prescribed this drug.

Pricing overall in the US remains stable, albeit there is a slight adverse mix impact. In particular, there is an increasing trend towards patients receiving the Medicaid price, and this will likely continue next year.

We have had some very good progress this quarter on the development of our further two-drug regimes. On the back of the positive GEMINI data, we filed for approval in October for dolutegravir plus 3TC and anticipate US approval in the second quarter of 2019.

We also now have positive data from both the FLAIR and ATLAS studies for cabotegravir plus rilpivirine in a long-acting, once-monthly formulation, which will enable us to file for approval in the first half of 2019 for what we believe will provide a highly differentiated treatment option for those patients seeking a long-lasting therapy for HIV, freeing them of the burden of daily oral therapy.

We continue to progress the eight-weekly dosing of cabotegravir plus rilpivirine and expect to have data on that next year.

We also presented 48-week data on fostemsavir at Glasgow this week. This showed fostemsavir effectively controls HIV in heavily treatment experienced patients. We would expect to file for approval of this medicine in the second half of next year.

With this broad portfolio of assets and positive clinical data we believe we are very well positioned to meet the changing and different needs of HIV patients as lifespans and durations of therapy increase, and although we expect it to take time for the two drug regimens to gain significant traction, we are definitely seeing awareness, interest and enthusiasm for 2DRs increasing significantly following the clinical results from GEMINI, ATLAS, and now FLAIR, and we therefore remain confident in our growth outlook for the HIV business going forward.

With that, I will hand you over to Simon.

Q3 2018 financial results

Simon Dingemans: Thank you, David. Overall, we believe the group's results for the quarter demonstrate consistent operational execution against our key strategic objectives, with strong delivery in all three businesses.

We continue to grow sales across the group and deliver operating margin improvements, while investing behind our recent launches and R&D.

Based on this momentum, we are confident in our delivery for the rest of the year and have tightened our guidance for constant currency adjusted earnings per share growth for 2018 towards the upper end of the range.

Our earnings release provides an extensive amount of information, so I am going to focus on major points, our expectations for the rest of 2018, and any important comparators to take note of within your modelling.

As usual, my comments today will be on a Constant Exchange Rate basis, except when I specify otherwise, and I will cover both Total and Adjusted results.

Headline results

Starting with the headline numbers, group sales up 6% to £8.1 billion, total EPS 28.8 pence, and adjusted EPS 35.5 pence, up 14%.

Total operating profit was £1.9 billion, up 7%.

Adjusted operating profit grew at 6%, with profit growth in Vaccines and Consumer Healthcare more than offsetting a slight decline in operating profit for Pharmaceuticals as we increased investment in R&D and behind our new products.

On currency, the strength of sterling compared with last year, particularly against the dollar, resulted in a headwind of 3% on sales, and 4% of adjusted EPS. If exchange rates were to remain in line with the rates at the end of the third quarter, we would expect the full year headwind from currency to be approximately 3% on sales and 6% to adjusted EPS.

Results reconciliation

Total results for the quarter showed strong progression on Q3 2017, despite higher charges for the revaluation of acquisition-related liabilities principally the ViiV CCL - helped by disposal profits on *Tapinarof*, as well as stronger operating profits and lower minority interests after the buyout of Novartis' interest in the Consumer joint venture. A number of adjusting item provision releases also led to a lower total tax rate.

The rest of my comments will be on our adjusted results.

Sales growth

Turning to the top line, this quarter's growth of 6% was driven by momentum in all three businesses and within that, strong contributions from HIV and Vaccines in particular.

Sales within the Pharma business were up 3%, driven by the HIV portfolio, which grew 12% in the quarter.

Within HIV, our brands continue to perform well within a highly competitive marketplace and we continue to expect HIV to be an important growth driver for the Pharma business going forward, while remembering that in the short term Q4 is up against a tougher comparator than Q3.

Respiratory sales grew 5%, with growth from the *Ellipta* portfolio and *Nucala* more than offsetting the decline of *Seretide*/*Advair*.

Trelegy continued to perform strongly, benefiting from share gains after an expanded US label and we expect its momentum will be increasingly important as one of the key growth drivers of the *Ellipta* portfolio and Respiratory overall.

Nucala growth was driven by international launches and market expansion in the US. The competitive environment for *Nucala* is picking up, and as a result, we are expecting growth for the next few quarters to be a bit more challenging as we respond to these new conditions, as Luke set out.

Longer term, we remain confident that the strength of our data around *Nucala* and the 4.5 years of usage history in patients will allow us to build a significant product for the group.

Seretide/Advair declined more slowly this quarter with less volume and price decline than in the first half as we begin to annualise the step-up in pricing pressures that we saw in the second half of last year. Volume also benefited from some inventory phasing. I continue to expect an overall decline in *Advair* before any generic entry for the year of around 30% in line with the year-to-date performance.

Breo returned to stronger growth in the quarter, up 16% globally with good growth in Europe and International. The US was more challenging with sales up 11% despite volume growth of 27%, and the pricing benefit of lower RAR adjustments compared to last year partly offsetting an increasingly competitive pricing environment. We continue to expect that *Breo* will be the most affected of the *Ellipta* products as *Advair* goes generic.

Established pharmaceuticals declined 9% in the quarter and 6% over the nine months. I continue to expect that the full-year decline will be in the mid to high single digits.

Despite the competitive and pricing pressures we are experiencing in Pharma, the momentum we have from our new products means we remain confident that we shall deliver overall sales growth for Pharma in the low single digits for the full year.

Moving to Vaccines, sales up 17% primarily driven by *Shingrix*, as well as an improvement in *Bexsero*. We are very pleased with the execution of our *Shingrix* launch and, in particular, how we have been able to accelerate our production plans. By the end of Q3, approaching seven million doses have been administered globally since launch, and we now expect to be able to deliver enough doses in 2018 to take *Shingrix* revenues for this year to between £700-750 million.

Looking forward, *Shingrix* should be an important growth driver for a number of years as we continue to expand capacity. More specifically, over the next two to three years, we plan to increase our annual capacity to levels of doses in the high teens millions and build further from there but please keep in mind the ramp-up is very unlikely to be linear.

The Meningitis franchise returned to growth in the quarter with *Bexsero* driving market expansion and gaining share in the US. Europe continued to be impacted by the completion of cohort catch-up vaccination programmes.

Flu sales in terms of doses are broadly in line with last year, although we did see some price erosion largely due to channel mix in the US. Overall, I expect our full-year volumes to be similar to last year.

The momentum in the Vaccines business continues to give us confidence in the mid to high single digit outlook for sales CAGR over the medium term, although 2018 will show higher growth than this as a result of the *Shingrix* launch.

Turning to Consumer, sales grew 3% despite a drag of around one percentage point from the combined impact of the divestment of non-strategic brands and the final quarter's impact of GST in India. The drag is a bit less than we had originally expected as we are seeing supply shortages for the TDS generic that will probably last into 2019.

Oral Health had a slower quarter than usual, largely due to a step-up of competitive pressures in Europe and some destocking in International but consumption remains robust and we expect Oral Health to return to stronger growth in Q4.

The business continued to achieve both price and volume growth with volume up around 2% and pricing up 1%. We saw very strong margin progression for Consumer in the quarter. Keep in mind though that in Q3 we benefit from the selling of seasonal cold and flu products and, like last year, we expect higher costs in Q4 and a lower margin as we promote behind those sales to drive consumption. We remain confident of delivering low single digit

reported sales growth for Consumer for the year, and we are on track with our margin objectives.

Adjusted operating margin

Turning to operating profit, our adjusted margin of 31.2% was down 30 basis points as actual rates were up 20 basis points on a constant currency basis.

COGS as a percentage of sales was 30 basis points lower at constant currency, driven by improvements in Vaccines and Consumer, the mix benefits in supply chain efficiencies which more than offset the pricing pressures we are seeing in Pharma, and increased input costs.

SG&A increased by 4% in the quarter as we invested significantly behind driving our recent launches in Vaccines, Respiratory and HIV, as well as supporting seasonal products. This was partly offset by further reductions in the back office and other non-customer-facing resources.

R&D costs were up 8% with around a third of that growth driven by a provision for payments due to a third party on the PRV we were recently granted. While we continue to step up investment behind key R&D projects, overall R&D spend growth also continues to benefit from the savings from the portfolio prioritisation decisions outlined earlier in the year. We continue to expect growth rates in R&D spend to pick up next year.

Royalties were £94 million in the quarter, lifted by higher sales of *Gardisil* and I now expect royalties in the range of £250-270 million for the full year.

Moving to the bottom half of the P&L, we continue to manage our funding costs carefully. Net financing costs in the quarter were £221 million, reflecting the higher debt following the acquisition from Novartis of their stake in the Consumer joint venture, as well as around £23 million of one-off interest charges on historic tax settlements. I continue to expect net financing costs for the year to be around £725 million.

Restructuring is progressing well with changes announced in the quarter for the US Pharma business, the Sligo manufacturing site and the streamlining of our Cephs business.

On tax, the adjusted rate was 18.6% in the quarter, 19.5% for the nine months in line with the range we expect for the full year of 19-20%. Charge for minorities was £141 million, down from £228 million last year following the Novartis buy-in.

Improved cash generation

Turning to cash flow, we remain focused on driving greater cash discipline across the Group and improving cash conversion. Free cash flow for the Group during the first nine

months of the year was £2.4 billion, up £0.7 billion and 42% in actual terms compared with last year. This increase was principally driven by improved operating profit, tighter control of capital expenditures, lower restructuring costs and higher proceeds from divestments. This was partly offset by the Vaccines milestone payment to Novartis at the beginning of this year, some foreign currency movements and a larger increase in working capital. The working capital increase was primarily driven by increased receivables, largely *Shingrix*, partly offset by inventory reductions.

Net debt now stands at £23.8 billion, primarily reflecting the impact of the Novartis buy-in. Given our improving cash generation, we remain comfortable with our balance sheet capacity to support future investment requirements.

Updated 2018 guidance

Moving on to expectations for 2018, based on an encouraging nine months, I am pleased to be able to tighten the range of our guidance for the year towards the upper end of our previous expectations and we are now looking at adjusted EPS growth of 8% to 10% on a constant currency basis. Exactly where we land within this range will be dependent upon a number of factors but particularly the final deliveries of *Shingrix* and the timing and scale of any generic competition to US *Advair*.

5-year outlook to 2020 reconfirmed at group level

For the longer-term, while the mix of business and product contributions may have changed as the Group has evolved over the last few years, we remain confident in delivering the financial outlook for the group we published back in 2015 and reiterated in 2017 of mid to high single digit adjusted EPS CAGR over the five-year period to 2020.

With the business growth we see in Vaccines, including the positive momentum from *Shingrix*, we anticipate we will achieve stronger margins than originally expected and we are now targeting a Vaccines operating margin in 2020 of around mid-30s percentages at 2015 exchange rates.

This upside, together with the progress made in Consumer, offsets the increased investment we are making behind our new products and R&D which will impact the Pharma margin which we now expect to be around 30% in 2020, again at 2015 rates.

Overall, the progress we are making, the momentum we have in each of our businesses and the increased cost and cash focus that we are building across the Group gives us confidence that we can make the investments we need in R&D and behind our new products and still deliver our original expectations for the Group for the period to 2020.

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

Emma Walmsley: Thanks, Simon.

Confident in 2020 outlook

So in conclusion, we have had a strong first nine months of the year and we are confident of delivery for 2018. Our new product launches are going well, particularly *Shingrix.* We are working hard to drive cost discipline across the company and remain very focussed on improving the performance of our Pharma business and strengthening our pipeline.

And finally, looking more broadly, we remain confident in our ability to deliver the outlooks for sales and earnings growth previously set for the five-year period to 2020.

And now the team is ready for your questions. Operator, if you could open the line, please for Q&A.

Questions & Answers

Michael Leuchten (UBS): Thank you. Two questions on ViiV for David, please. One, just your comment about the trajectory of dual or the ramp of dual being maybe a little bit slower and the need to build over time, how do we think about the trajectory for ViiV into 2019? Does that mean we are going to see a transition year before momentum can pick up again or is ViiV actually going to be able to continue to grow whilst the dual strategy is building momentum?

And then the second question on ViiV just around pricing; historically the HIV market in the US has not been one where we've seen pricing being a component. Is there any evidence going into 2019 we are going to see any changes? What I am thinking about is, is Gilead really a player that could use the older part of the portfolio to try and position their integrase inhibitor more preferably? Thank you.

Emma Walmsley: Thanks, Michael. David, straight to you.

David Redfern: Okay, thanks, Michael. The first thing I would say is we remain very confident about our two-drug regimens, and particularly dolutegravir and lamivudine. It has been interesting actually since the IAS in July when we published the GEMINI data in detail we have had an awful lot of interest and very positive engagement around the world around that data with all stakeholders, but particularly physicians. I think the vast majority see it as a major innovation and there is clearly a debate going on with us and with the medical community of exactly which patients could benefit from that, so our

enthusiasm around two-drug regimes is as great, if not greater, than it ever was and clearly that has been supplemented by the positive ATLAS and FLAIR data on cabotegravir.

Inevitably, as we've said, we expect to get a regulatory decision in Q2 of next year. It always takes a little bit of time to build reimbursement coverage and so forth and that will be the case here. It's much faster than in respiratory but it still takes a bit of time, so that was really what the remark was referring to, but as we've said, we definitely see HIV and ViiV has an important part of the growth story of GSK going forward.

On pricing, Michael, as I have said, pricing for the ViiV products remains very stable with really nothing to say: nothing has changed either this year, or going into next year. The only thing is that at the margin there is a slight increase in the Medicaid book of business, principally from the increased use of 340B, which obviously has a slight impact on the mix. Overall, however, for our portfolio, pricing is very stable.

Kerry Holford (Exane BNP Paribas): I have two questions please, firstly on *Shingrix.* You have raised the guidance for this year, and that still leaves an implied Q4 sales figure below Q3 and I guess this still relates to demand. Can you just talk a little more about doses that you expect to deliver this year?

Simon, you mentioned moving forward to doses into the high-teens over the next two to three years. Should we expect that you are aiming for high-teens by, let's say, 2021? Or is that an average over that period?

Secondly, on the pipeline, it is good to see continued prioritisation here but, as the clear-out continues, I guess investors will increasing ask the question, what will replace these and fill the pipeline over time? I wonder whether you could talk about your willingness and ability to look at external collaborations in light of opportunities to bolster this slimmer but more focused internal Pharma pipeline. Thank you.

Emma Walmsley: Thanks very much, Kerry. Hal, we will come to you in just a moment, to talk about how you think about BD, because we have clearly said, in terms of our capital allocation priorities that strength in the pipeline matters. Obviously, we are stopping some of these things so that we can focus on the priorities we have organically but we also want to do – and have appointed a new leader to think about BD.

Just in terms of *Shingrix*, Simon may want to add to this, but in Q4 there is some seasonal demand but this is also supply-driven. We have obviously been absolutely delighted with the power of the launch of this vaccine, ahead of expectations, and we have mobilised very hard to increase supply. As Simon has said, we expect to reach high-teens

over the next two to three years, but it will not be linear and so we will not give you precise guidance either in doses by year for this year, or for 2019, but that is the shape of what you should expect. Then, as we look further to global roll-out, to further expansion beyond that, I don't know whether Simon would like to comment.

Simon Dingemans: As you would expect, Kerry, as we build up capacity, it comes in modules as you put in additional vessels and secondary capacity. It will not go up smoothly but we are moving as quickly as we can. We are really pleased with how the Vaccines team has performed this year, to pull forward some of the plans we have previously had. I hope that gives you a sense of where we are headed, after a very rapid ramp-up this year: we are now digesting that and we will move forward into '19, '20 and beyond. I would remind you, as I said in my remarks, we are not stopping at high-teens but we see much more potential as we go global on this product from there on. Clearly, we have to get on top of the short-term demand that we have, particularly in the US.

Emma Walmsley: Thanks, Simon. Hal, is there anything else you would like to add on BD?

Hal Barron: Yes, just to follow up. Strengthening our pipeline is clearly critical and inorganic growth through business development will definitely play an important role to achieve this. I think most of you are aware, my first hire, reflecting the importance of BD, was Kevin Sin, who is now with me in San Francisco and is very focused on exploring all the different opportunities.

As we said in July, the focus of BD, the strategy, is to explore opportunities that will facilitate us realising the strategy which, to remind you, is to focus on immunology, especially immuno-oncology, but also to explore human genetics, functional genomics and machine learning. Those efforts are ongoing and looking promising.

Our first deal was with 23andMe and I just want to point out that that is going extremely well. We have already identified 13 targets that we are exploring to see whether any of those would be candidates, and we will continue to look for other opportunities, but keeping an appropriately high bar.

Emma Walmsley: Thanks, Hal. Just to reiterate, we very much care about the discipline that we put in place around the terms on BD. Thanks, Kerry. Next question, please.

Graham Parry (Bank of America Merrill Lynch): Thank you for taking my questions. Firstly, in HIV and just coming back to the pricing question, I think Shionogi on

their call said that some price pressure was being driven by generic Atripla. Also, we see some payers now starting voucher programmes, to use *Tivicay* in combination with generic backbones. Is that pushing more of your mix towards monotherapy *Tivicay* and is there a negative price mix effect from that? Do you see, over time, that perhaps having generics in the market could just bring down pricing overall?

Secondly, on *Shingrix*, do you have a sense of how much of what you are getting in terms of vaccinations now is bolus patients, patients previously immunised, and do you have a sense of how far into that bolus pool you are versus a sustainable new patient pool, and is the intent to match capacity to the latter, or are you effectively producing capacity that ultimately one day will become redundant because you have run out of patients to immunise? Thank you.

Emma Walmsley: Thanks very much, Graham, for both questions. David, we will start with you on HIV, and then Luke, I know you made some comments already in terms of the profile of the patients, but perhaps you can pick up on the shape of the *Shingrix*, based on the US, obviously, at the moment?

David Redfern: Okay, thanks, Graham. On HIV pricing I think the dynamics vary a little bit across the world, but in the United States there is no doubt that today what matters more than anything is the medical profile of the medicines, and the data behind the medicines, and the differentiation between the medicines. Whilst it's true that today most HIV medicines are pretty potent and pretty efficacious, the potency does vary between them, and what particularly varies is tolerability and side-effect profile, and there's quite significant differences in the way patients feel and the way they tolerate their medicines.

We have seen over the last few years that, certainly in our case, the support for second generation integrases, generally, has really grown to become the standard of care, and within that *Dolutegravir,* where we now have five superiority studies, a whole raft of data from Phase 3 before, and over 6 – probably most important, actually, over 600,000 patients on the medicine. What really matters is the differentiation of that medicine, and that overrides, really, anything else, and we, as I've said to Michael's question, we see very strong access, very strong reimbursement. Nothing has changed. What happens in the generic backbones, and so forth, we will see, but I think it is pretty stable from where we are right now.

I would also say we will see where it goes in the medium term. I do think we are in quite a good position, because we have a bit more flexibility than most, given that *Tivicay* is the only second generation integrase single agent medicine, so it can be combined with all sorts of different combinations.

Emma Walmsley: Thanks, David. Luke –

Luke Miels: Sure, so, Graham, probably the best way to answer your question is just to give you some of the numbers and a sense of where these patients are coming from.

If you look in the US, people of 50-plus, there's around 115 million people, and then if you cut that by people who have had a recent adult vaccination, that's around 67 million. Within that population there's 22 million people who've previously had *Zostavax*, and so far we have had around 4.5 million people be vaccinated for *Shingrix*.

If you then split that 4.5 million out and ask, "okay, who's had a *Zostavax* vaccination before that?", it's around one third of those. Therefore, two-thirds are actually naïve.

If you look at this *Zostavax* population and say, "okay, what was their age split?" then around 40% of them were 65-plus; a third of them are 60 to 64; and, interestingly, about 10% of them are 50 to 59.

If you look at who's being vaccinated by age now with *Shingrix,* we have in the 50-to-59 cohort around 16% of our vaccines going to that group; 60 to 64 is around 18%, so that's 34% below 65 years; and then if you look at the 65-year-plus population, we are getting around 66% of vaccines going into that group.

Therefore, I think the short answer to your question on top of all those numbers, we are expanding the market, and there's a fair amount left to do, because if *Zostavax* is 22 million, and we've already got to a quarter of that, this is before we have even started DTC and on the back of tight supply, so the key question and the point that Simon's made and I've made is, really, we need to get the supply expanded as fast as possible because we can pretty much sell anything that we make now in the US.

Emma Walmsley: Thanks, Luke.

Tim Anderson (Wolfe Research): Hello, thank you. I have a question on HIV. My understanding is that one of the four measures being considered is to remove the protected drug class status from certain categories that relate out back a little over a decade ago, and HIV is one of those.

Therefore, that protected class designation has essentially made it so that companies in the US don't have to compete on price.

My question to you is do you think that that could happen as a reform measure in the coming months as a potential proposal, and if that protected class designation is removed, does that change the outlook for pricing that you articulated earlier in the call?

Then, the second question is just in general in US pricing, given the political environment, how you are looking at your ability to take net price increases in 2019 relative to 2018, and is there any diminution, or will it be like Pfizer, who just claim that it is business as usual?

Emma Walmsley: Yes, thank you for those. I will make a general comment. Obviously, we are not going to be specific about our pricing outlook looking into next year for competitive reasons, and GSK has long taken a very responsible position on pricing and we report our net pricing, which has been slightly down over the last five years, and this quarter was -3% [pharma business]. From the beginning of the year, we have reiterated that continued price pressure in Respiratory and obviously the genericisation of *Advair* will have an impact particularly on ICS/LABA but there is no new news there.

We watch very carefully at the broadest level and engage very seriously with the administration around all the discussions on blueprint. The latest communication on it is mainly focused on Part B, as you know, to which, relatively speaking, GSK has less exposure. In fact it is a part of both the *Nucala* and *Benlysta* businesses but, relatively speaking to other companies we have less exposure. If it takes five years to implement, it will take some time for meaningful impact but we shall be watching it closely, not least because of the prospects of our portfolio moving a bit more into specialty.

David, perhaps you would like to comment particularly on the protected class question, which was a very live question some while ago but a bit less discussed more recently?

David Redfern: Thanks, Tim. As you say, HIV is a protected class in Medicare, which is about 20% of our business in the US. It was obviously mentioned by the Health Secretary when blueprint came out a couple of months ago or so, and we have to say that it is a risk; I don't believe we can completely eliminate it.

That said, there are a couple of important factors. First, of all the protected classes - and you would probably expect me to say this - I would argue there is a very strong rationale why HIV should be a protected class for a highly infectious virus like this. The access to modern medicines remains critical and, clearly, in HIV there is a very powerful patient lobby and stakeholder group that will be extremely interested in retaining it as a protected class and keeping access to it.

Secondly, we shall have to see how things play through in the US, and you are probably more expert on it than I, but it is very unclear exactly what the process is by which protected classes could be removed. Does it have to go through Senate, can it be done by executive order and so forth? That then plays into all the other dynamics of the mid-term and so forth. I don't think that it is an immediate threat but it is certainly something that we shall watch.

Andrew Baum (Citi): Following up on the previous HIV-related questions, given United Healthcare's move to introduce their cost-centric HIV plan today, what is the risk that more aggressive narrowing of formularies in commercial plans increases the probability that a protected class removal under Medicare is more palatable? We know that the President's HIV and Aids Committee disbanded shortly after his administration began, suggesting that there is not significant interest within that community. I am guessing that, looking at the way the commercial outlook is evolving, if it is good enough for commercial plans to have a more narrow formulary, then why should a government cover a broader unrestricted range?

Secondly, could you clarify the opt-in rights? I am thinking about your BCMA molecule. Novartis is a leader in haematological medicines with the exception of having a key position in myeloma, so I imagine there may be some considerable interest. When you structure a deal, is it a question of you setting the valuation and they walk away because it is too high, assuming you want to keep the assets? Alternatively, is there an independent valuation that has to be agreed in order to enable Novartis to exercise an option at a reasonable price if they so wish?

Emma Walmsley: Thanks, Andrew, I shall ask Simon to comment on the deal structure and, David, we'll go back to you regarding the commercial environment on HIV, recognising that we are not going to make any comments on individual customers.

Simon Dingemans: Andrew, it is a bit more straightforward. If we file a product, so BCMA as an example, we have to show it to Novartis and they have the right to make us an offer which we have to take seriously. There is a timeline set out to allow each party to do that but, importantly, we do not have to accept it if we think we can generate better value by ourselves. I believe that we have given you some sense of the opportunity that we see there, so we are very comfortable that we are fully flexible in how we develop that programme and that we can go it alone if that is what we see as the best opportunity. It is a right of first look, it is no more than that.

David Redfern: Andrew, what I would say is that there has to be some correlation between what happens in the private insurance market in the US - Medicare - not least because a big proportion of the Medicare business, as you know, is administered through managed care. There has to be some cross-over there but how much it plays into all the politics and what Washington does is very hard to say.

I would come back to what I said earlier and that what matters most to HIV patients and their physicians in the US market is that they get access or retain access and treatment on what they perceive to be the best and most innovative and most modern medicines for HIV that has the best profile for efficacy and particularly tolerability and side effects. It's a very, very guideline-driven marketplace and the guidelines are regularly updated to reflect what in the opinion of the regulators and the guideline formulators are the best medicines. At the moment it's very clear that second generation integrases, and particularly dolutegravir, is right at the heart of all of that, so that really outweighs any kind of peripheral measures that is happening around generics or the NNRTIs or the older proteases and so forth and why I am confident we don't really see much impact from where we sit today.

Emma Walmsley: Yes, and the only other thing I'd add to that, Andrew, is obviously we have the opportunity to think quite strategically about the pricing of our new launches.

The next question, please.

Steve Scala (Cowen): Thank you, I have two questions. First, *Shingrix* certainly has been impressive but drawing on a related situation, Prevnar in adults taught us that the accessible population is limited, could be worked through in a year or so and success won't be replicated outside the US or do you think Prevnar in adults is simply not a good proxy and if you don't think that, why do you think it is not a good proxy? That's the first question.

Second, what does 'a bit more challenging' mean for *Nucala* sales going forward? Does that mean flat, if not down and what is the *Nucala* sales call against Fasenra and Dupixent other than long-lasting impact against exacerbations which was mentioned? Thank you.

Emma Walmsley: Thanks very much, Steve. Luke, it would be good if you could pick up both of those questions, please.

Luke Miels: Yes. Steve, Prevnar of course is an enormous product. I don't think the parallels are necessarily straight there and I think the key thing to remember right

now if we first look at the US, we have done no DTC, we really haven't made any efforts to build the marketplace ourselves. It has been largely through media articles in *The New York Times*, etc, word of mouth, so I think the potential to penetrate more broadly still remains. Remember Zostavax got to 22 million with an efficacy profile that you would say 'Okay, *Shingrix* is certainly in a much better place', and of course there are symptoms that come through if you subsequently get shingles and the odds of getting shingles of course, depending on the age group, are up to one in three, so most people know someone that has had shingles. These are the things which will enable us to build.

If you look ex-US, we have had a good trajectory in Canada. It's really about getting on the UMV (universal mass vaccination) listing. In Europe I think the build will be slower because there's no market there right now, but we are very focussed on discussions with groups like STIKO to build the clinical argument for use.

And I am actually very excited when you look at markets like China and Japan where you have large older populations and you have the potential to create quite an opportunity there, so long story short, these are all really nice but the thing that is restraining this is less demand and more supply for the next couple of years, as we've mentioned.

In terms of *Nucala*, it really is about anchoring people so I'll start with Fasenra and let's talk about Dupixent after that. If you go back 12 months ago, I think we were very much behind on several parameters in terms of perception of *Nucala* versus Fasenra. We were behind on interest in the mechanism of action, and I am talking about prescriber perception here, speed of onset, on efficacy when we looked at market research we were behind and dosing frequency.

What we have been able to do by very much focussing on efficacy and going through our studies systematically and looking at equivalent patient populations, is we have neutralised the mechanism of action, we've neutralised the speed of onset in the market research tracking and we are very much in a position now to compete with them. What we can't address right now of course is dosing frequency. We are four weeks versus their eight and that's why the importance of the autoinjector at home injection is very attractive and important for us as we look to the future.

If you look outside the US actually we have done a fantastic job and we have very much held Fasenra in place in Japan and Europe so I am very encouraged by that, we can compete, but the fact remains we are not getting enough of these patients in the US and I put that down to more execution rather than data.

If you look at Dupixent, again it's early days but I think again there is no change to our strategy here. We need to focus on efficacy and make our case. If you look at the

population that Dupixent had in their label of course it's a bit broader. I'm personally not too worried about the moderate population. We only have 25% population in the severe, so I think the usage in milder patients is likely to not be extensive.

If you look at OCS and their label and then you apply a screen of EOS then the overlap is quite extensive based on the data that's published, both ours and other people's data, so that ranges between 70% and 90% overlap.

If you then look at the data that they report, I think the key thing you have to adjust for is around 52% of people in the Dupixent population were controlled on ICS, background ICS, whereas with *Nucala*, our entire population was more severe and it was maxed out on background therapy. The question there with Dupixent, of course, is that if you gave these patients more steroids, what would happen?

If you then cut the data by EOS at 300, then it becomes much, much closer - Dupi's exacerbations are 66% to 67% versus our range of 61% to 64% in our approved doses. I see equivalence there, and the same with OCS reduction where they are very similar at around 50% when you correct for placebo.

The key thing that we have to focus on, of course, is that allergists are very familiar with the product and you have at-home dosing. These are the things which, again, we think will put some headwinds behind *Nucala*. This is very much a three-dog fight between us, Fasenra and Dupixent but, if I look in the medium-term, if we keep working on these things and we can neutralise the dosing frequency then, in the second half of 2019, I am more optimistic. However, we have to be realistic in the short-term: there will be volume growth but there will also be competitive pressure in terms of patients. That is why we have said what we are saying about *Nucala*. I am sorry about the long answer but it is quite a complex one, as you can imagine.

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

James Gordon (JP Morgan): Thank you for taking my questions. I have one question just following up on the comment on *Nucala* and the autoinjector. How important is the autoinjector, and what proportion of *Nucala* use do you think would come from autoinjector use at home? How does that interact with how US doctors might be reimbursed? Could there be incentives, one way or another, in terms of what is better for them?

My second question is on *Shingrix* around the implied 40% sequential decline in Q4. It sounds as though that is the figure – it is the amount you can manufacture. Can you talk

about how much of a deficit there was in Q3, as in how much more did you sell in Q3 than you could manufacture? What is the starting point, where your capacity is at the moment, from which you will have this dramatic expansion?

Lastly, just for clarification, there was a slide about *Benlysta* and the new Phase 3 combo study that you are starting with rituximab. Am I right in saying that the patent actually goes in 2025 and so you would have less than four years from when the Phase 3 reports to actually capitalise on any good results there? Or could this be a much longer-lasting product?

Emma Walmsley: Thanks. Luke, would you like to pick up on *Benlysta* and the autoinjector profile. I am not sure that we will give you quarterly phasing of our capacity on *Shingrix* but, Simon, if you would like to add anything on that, you can.

Luke Miels: Yes, James, there is some work we can do around IP. I can't remember the full point at which we would expect a theoretic exposure to biosimilars, but it is further out than that. The second thing I would say is that, right now, there are no biosimilars on the horizon for *Benlysta.* That is how I would answer that.

Simon Dingemans: *Shingrix* is very much boluses: as the team is producing that, and you combine that with the seasonal effects, if people are going in for their flu vacs then, in many cases, pharmacists will in effect up-sell them on *Shingrix* and you can see those patterns. That is the combination of why you see the ups and downs there.

Emma Walmsley: Thank you. Next question, please.

Luke Miels: Sorry – the autoinjector. We see this as very interesting and very compelling. In terms of the dimensions, in terms of physician motivation and so on, that is a harder one to call but, ultimately, patient preference and the judgment of the physician as to whether the patient is confident and has the capacity to inject at home will drive that. Of course, we will have some early indications from Dupixent and those patents there. I think it is a very important thing, opening up and unlocking – 75% of patients who should be treated with a biologic, an IL-5, when you look at EOS and the severity of asthma, are currently not being treated in the US. I think home injection is an important component of converting that.

Emma Walmsley: Just to reiterate, for these patients who are at the severe end of asthma, they are 10% to 15% of asthmatics but they are 60% of the cost to healthcare. The efficacy of exacerbation reduction is absolutely the primary point and obviously, if there is a convenience aspect to it as well, we don't want to have any competitive weakness.

We have time for one more question, just to finish up, please.

Jo Walton (Credit Suisse): Roughly one third of your Pharma business is still the established pharmaceuticals and the rate of decline has accelerated a little, to down 9% in the third quarter. I wonder if you could just explore the opportunities and growth there, going forward? I understand that Luke has really focused the promotion and so presumably there is even less promotion on these products and they are probably incredibly profitable. What sort of rate of decline do you think we should look for and is it still a feasible opportunity to get rid of some of these assets and use them – I don't know – asset swaps or whatever. I know that people says it is always very difficult to do that, but other drug companies have been much more active in their disposal of legacy products than you appear to have been.

A second question, if I could just ask a little more, you say that you have done your first meeting – a paid, speaker meeting – and I just wonder if you could tell us what you think the advantages of that are, and how extensive that programme will be as we move into 2019?

Emma Walmsley: Thanks, Jo. Perhaps Simon could speak about the established products outlook. I think we have guided to this anyway. You know that this is a key profit contributor but we are constantly looking at the portfolio Jo and being thoughtful about how to continue to evolve it. Are there any specifics that you want to add, Simon, on the outlook?

Simon Dingemans: As we said at the beginning of the year, we expected a slightly better performance in the first half and we are seeing some significant genericisation going through the portfolio in terms of *Coreg* in particular this year. Overall, that should even out to a mid to high delivery for 2018. Going forward, we are then largely through the major generics in the portfolio, so we should see a slightly slower rate of decline and, as you point out, it is a big profit contributor. While we are always looking for opportunities to drive value if they come up, as far as the overall funding we see quite a lot more opportunity that we can bring to the Group. If we can slow the decline down by focusing that portfolio more, I believe we can do more on top. Luke, I don't know if you want to add anything?

Luke Miels: You also have *Lamictal* so there are a few there which we shall rebase throughout the year. We are very focused on these products in a select group of countries where we can drive growth so for products like *Augmentin*, *Ventolin*, *Seretide*, where we can drive growth we certainly do that in a very disciplined fashion. As far as divesting them, there are no plans to do that at this point.

Regarding the speaker programme with *Nucala*, the initial feedback is very positive. Why did we make this change? When we looked at the dimension of trust and the feedback we were getting from physicians, they wanted to hear from someone with recent, current clinical experience who had used multiple agents and get their perspective on *Nucala*. Now that we have this in place, it is something we are very focused on. I don't want to give away numbers at this point but you can imagine that it is something we are very focused on and actively rolling out in the US and Japan through the rest of the year, and then we shall open it up to Europe and selected markets beyond that in 2019.

Emma Walmsley: Thanks, Luke, and I would like to reiterate that we underpin this with strengthened commitment to transparency and all due controls around disclosure of payments. It is an important move when you think about the strategic shift in our portfolio we expect towards more specialty medicines where the science is moving fast, and hearing from a practising clinician about a paradigm shift in treatment will be very important.

With that, thank you very much everybody for joining the call and I look forward to speaking to you soon.

[*Ends*]