

GlaxoSmithKline
Q1 2020 Results
Wednesday, 29 April 2020

Sarah Elton-Farr (Head of Investor Relations): Good morning and good afternoon. Thank you for joining us for our Q1 2020 results, which were issued earlier today. You should have received our press release and can review the presentation on GSK's website. For those not able to view the webcast slides that accompany today's call, they are located on the Investor section of the GSK website.

Cautionary statement regarding forward-looking statements

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

Agenda

Our speakers today are Chief Executive Officer, Emma Walmsley; Luke Miels, President, Global Pharmaceuticals, and Iain Mackay, Chief Financial Officer. We have a broader team available for Q&A. We request that you ask only a maximum of two questions so that everyone has a chance to participate.

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

Emma Walmsley (Chief Executive): Thanks, Sef, and welcome, everybody, to today's call. First and most importantly, I very much hope that all of you and the people around you are safe and well and we appreciate you joining us today.

Significant mobilisation in response to COVID-19

We are facing an extraordinary global health threat, with enormous direct and indirect consequences. Alongside updating you on our Q1 performance today, I want to start by sharing how we are responding to this.

Supporting the global response to COVID-19 is at the heart of GSK's purpose as a company and our businesses and portfolio are highly relevant and much needed. We have mobilised across the company to respond to the pandemic, and I am pleased to report that our company is performing well and has demonstrated resilience in the face of significant pressures and uncertainty. Our people have been outstanding, showing courage and deep commitment to ensure that our products continue to be made available to patients and the people that need

them. Today, we have over 20,000 essential workers going every day into our manufacturing and R&D sites.

We are working hard to make sure employees stay protected and supported, and are investing in high-frequency communications as well as providing teams with the technology, resources and adjusted policies to support them, whatever their role.

We have implemented business continuity plans across all our essential operations. In our supply chains we are closely monitoring all parts of our manufacturing network and our teams have shown tremendous agility to respond quickly to fluctuations in demand.

For clinical trials, we have implemented proactive measures to protect study participants, staff at clinical trial sites and our employees, while ensuring regulatory compliance and the scientific integrity of our studies are maintained. While recruitment to clinical trials has slowed due to the disruption of the pandemic, and diversion of resources to other clinical priorities, for the vast majority of our studies, we estimate that we have incurred a one- to three-month delay. Where necessary, and based on our own assessments, we have also proactively paused recruitment, including the pivotal programmes related to otilimab in rheumatoid arthritis, and *Nucala* in COPD.

In the meantime, we are continuing to support the enrolment of new patients into ongoing clinical studies, provided that investigators are confident they will be able to ensure the safety of the study participants and appropriately conduct the study per the protocol. The ultimate impact caused across our pipeline will depend on the duration and the severity of the pandemic.

From a regulatory standpoint, we have a number of products undergoing review and, at this point, we do not anticipate any significant delays to approvals as a result of the pandemic. However, the situation is dynamic and we will continue to watch it carefully and provide updates as and when appropriate.

As I have mentioned, GSK's businesses and portfolio are highly relevant to helping to tackle the COVID-19 virus, whether that be Respiratory products and Pharma, pandemic adjuvant technology in Vaccines, or needed everyday products in Consumer Health. We are determined to help by offering solutions, using our portfolio, science, technology and resources to support the global response.

GSK pursuing solutions based on four principles

We are using four principles to guide our pursuit of these solutions: working in partnerships; taking a global approach while, of course, providing strong focus and practical support to our base in the UK; maintaining a deep commitment to access, and investing in long-term pandemic preparedness.

Our No. 1 focus is the development of a vaccine and this is core to the exit plan the world needs. We are working with companies and institutions globally, including in North America, Europe and China, to help find the best and most effective vaccine. Our aim is to develop multiple adjuvanted COVID-19 vaccines. GSK has long been the leader in vaccine adjuvant technology and our expertise in this area is proven.

As many of you know, the use of an adjuvant can be of particular importance in a pandemic situation since it may reduce the amount of vaccine protein required per dose, allowing more vaccine doses to be produced and therefore contributing to protect more people sooner.

GSK Vaccines Collaborations

One of the most recent collaborations to be announced was with Sanofi. Together we bring proven technologies and considerable scale. We're planning to start trials in the next few months, and if successful and subject to regulatory considerations, aim to complete development and make the vaccine available by the second half of 2021.

Of course there is a lot of work to do and no guarantees given this is at an early stage of development, but we believe if we are successful we'll be able to make hundreds of millions of doses annually by the end of next year.

Data from our other collaborations will be available in the coming months. We remain, as we always have been, committed to global access, and across this portfolio, vaccine collaborations, we will reinvest short-term profits generated in coronavirus related research and long-term pandemic preparedness, either through GSK internal investments or with external partners.

Therapeutic approaches: new collaboration with Vir

Alongside vaccines, we're also exploring therapeutic options and earlier this month, we entered into a new collaboration with Vir Biotechnology. Together, we'll use Vir's proprietary monoclonal antibody platform technology to identify and accelerate new anti-viral antibodies that

could be used for therapeutic or preventative options for COVID-19 or future coronavirus outbreaks.

Our first priority is to accelerate two very promising antibody candidates that target COVID-19 directly into Phase 2 clinical trials within the next three to five months. The Vir platform is highly complementary with our R&D approach to focus on the science of immunology.

Additionally, and more broadly, we're screening GSK marketed and pipeline assets for anti-viral activity or potential use in prevention or treatment of symptoms related to COVID-19.

So all in all, you can see we're pursuing a broad set of initiatives as part of our response and commitment to being part of the solution.

Strong start to 2020

Let me now move to our Q1 performance. We have seen a very strong start to the year with our performance reflecting good underlying execution, the addition of the Pfizer Consumer Healthcare portfolio, and towards the end of the quarter, a significant step-up in demand, including patient and consumer stock-building for many of our products as a result of the pandemic.

Pro forma group sales growth of 10% in CER terms reflected an increase in sales in all three of our global businesses with particularly strong performance again in Vaccines, driven by *Shingrix* and Consumer, where we saw double-digit pro-forma increases in four of our five main categories.

Growth adjusted operating margin this quarter with 29.4% reflecting the strong sales growth across all three businesses, a more favourable mix in vaccines, and the continued benefit of restructuring.

On a total basis, earnings per share are up 89% to 31.5p and adjusted earnings per share increased 26% to 37.7p. Earnings growth benefited from a reduction in our affected tax rate in the quarter, reflecting a number of one-off items including the revaluation of tax assets.

Our free cash flow this quarter was £531 million benefitting from our strong operating performance across the business.

Q1 progress made on our 3 priorities

We've also continued to make progress on our long-term priorities of Innovation, Performance and Trust. Sustained focus on commercial execution delivered good growth of our

new products; *Nucala* and *Trelegy* in Respiratory and our two-drug regimens, *Dovato* and *Juluca* in HIV.

Meanwhile *Shingrix* also continued to perform strongly with some RAR benefits, as we further accelerate supply, although short-term demand is now being impacted by slowing vaccination rates in the US under containment measures.

We've also made progress on our pipeline with regulatory submissions accepted on three oncology assets. We're anticipating FDA approval of *Zejula* in the first-line maintenance setting for ovarian cancer shortly, and Luke will talk to the opportunity here in just a moment.

We've also had regulatory submissions accepted for two other oncology assets; belantamab mafodotin in relapsed/refractory multiple myeloma, and dostarlimab in the second-line treatment of recurrent or refractory endometrial cancer.

We've set the belantamab review to complete close to the PDUFA date in August, and as we said previously, the events associated with belantamab are a unique adverse event that we take very seriously and we are working with the agency to ensure its safe and effective use in the target population.

We were pleased to see our long-acting two-drug regimen in HIV, *Cabenuva*, receive approval in Canada, and we've been engaging with the FDA on the path forward for *Cabenuva* in the US and expect to make a re-submission around mid-year.

Also in HIV we have filed for European approval for fostemsavir for heavily pre-treated patients and we look forward to making these important options available to patients.

In performance we have continued to drive growth in sales and have seen an improvement in our profitability this quarter with continued good cost control. We have built up capabilities in Oncology ready to support our expected launches. In Consumer, integration of the joint venture with Pfizer is progressing very well. We are on track to deliver our cost synergy targets and 90% of leadership roles are now in place. We have also, as planned, completed the divestment of our Indian Nutrition business to Hindustan Unilever.

We are progressing a number of other Consumer-held brand divestments and alongside streamlining our portfolio, proceeds from these divestments will also help to fund cash costs of the integration.

In February, we announced our programme to prepare the Group for separation into two new companies. We have now started this important project to get us future ready with no change to our medium-term targets and timelines.

And finally, on trust as I have always already described, we have focussed our efforts on solutions for the pandemic and on supporting our people.

I will now hand you over to Luke who is going to give you more details on our commercial performance in Pharma and Vaccines this quarter.

Luke Miels (President Global Pharmaceuticals): Thanks, Emma, and I hope you are all well.

Business Update

Pharma commercial performance

The good news is that we have had a strong start in Pharma in 2020 with growth in our new products across the portfolio. We did see some impact from COVID-19 towards the end of the quarter in Europe, and in the last two weeks of March in the US and this was most notable in HIV which benefitted from customers stockpiling and as you would expect, *Ventolin*, which saw some stock building but also increased use.

Excluding COVID-19 impacts, the underlying trends are good and our new products continue to perform well.

To give you some examples, for *Trelegy* we continue to see good growth in the class and in our share in all key markets, and we expect to get US approval of asthma later this year.

In the case of *Nucala*, we remain the market leader in the EOE disease segment and I am pleased to say that we are benefitting from strong launches of our home admin, especially in Europe where we have seen a significant shift.

We also have good data in nasal polyps and plan to file in the second half of the year.

Benlysta which is in its tenth year on the market, continues to generate strong double digit growth and the sub-cut formulation is increasingly important here. We are pleased that the FDA designated our lupus nephritis indication as a breakthrough this quarter and filing is planned for later this year.

On *Zejula*, I will talk to the first line ovarian cancer indication in a minute, but we are picking up a greater share of new patient starts as we benefit from the operational and execution changes we have made.

We have also increased HCP engagement and are actively using the QUADRA data that was added to the label late last year.

As David can comment in Q&A, there has been a good uptake of the two-drug regimen in HIV benefitting from *Dovato*'s inclusion in both US and EU guidelines.

Like most companies, we did see some impact of COVID-19 towards the end of the quarter in Europe and the US. I think this was seen across the portfolio and shown clearly here on the slide in the prescription data for some of our inhaled respiratory assets.

We would expect some of that to unwind during Q2, but underlying demand for our products remains strong. Our people are focused and using this time as productively as possible. We move fast to adapt and to move calls and content on to digital very quickly. Right now our people are at home, but they are engaging with HCPs and we are active in areas like virtual speaker programmes.

I really want to stress this. From the start of the lockdown, we have also focussed not only on managing the initial phase but on plans to re-engage when restrictions are lifted. We expect that going forward we will see an increase of digital engagement but we are ready to engage with more traditional means as well, so I think agility and flexibility here are going to be key.

Zejula well positioned for 1LM OC opportunity

PRIMA data & NCCN guidelines

Moving on to *Zejula*, with the strong PRIMA data that you will know, *Zejula* is positioned, if approved, to be the only PARP approved as a monotherapy in first-line for women who do not have a BRCA mutation which equates to about 80% of women with ovarian cancer.

In March we were also pleased and proud to see *Zejula* included in the NCCN guidelines as a first-line treatment option, with a recommendation that covers 80% of patients in the first-line maintenance setting. Upon approval, *Zejula* will be the only treatment option recommended for BRCA wild type patients, who did not receive Avastin in treatment. Watch and wait is still an option here, but only for patients, if you look at the guidelines, with a complete response. Plus

Zejula is recommended for all BRCA mutant patients, which is at parity with Lynparza monotherapy.

We think this will put us in a competitive position once we receive approval, which as Emma said, we expect shortly. Preparation for launch, as you can imagine, is very active and under way, and we've fully integrated the TESARO teams and we have some really strong leadership in place. The sales team is fully recruited, and we are equipped to launch virtually under COVID-19 restrictions. In the short term I think it's fair to say we do expect that COVID-19 could have an impact on the diagnosis and treatment of ovarian cancer, but we remain confident in the long term in the profile of this remarkable product.

Shingrix: strong Q1 performance

I will finish on Vaccines. In Quarter 1 we were really pleased to see the acceleration of *Shingrix* supply continue, and that drove excellent growth. I want to stress, though, that the underlying demand for this product remains very strong. That said, towards the end of the quarter, as the prescription trends illustrate, we began to see the impact of stay-at-home measures prompted by the pandemic.

Although wholesalers and distributors kept ordering stock through April, we expect to see a significant impact in the coming months. That being said, once the stay-at-home restrictions are lifted and patients can visit their pharmacies in person and access routine physician visits once again, we expect demand to rebound, and we're planning for that. We are planning for measures to accelerate, including driving prioritisation of adult vaccinations and linking it to the upcoming Q3 flu season.

In terms of supply, we are also on track for 2020 in our capacity expansion plans, including bringing new facilities online, which remain unchanged. Our limited phased *Shingrix* launch in China this year remains set to commence as we move through this year, subject of course to appropriate market conditions. We filed *Shingrix* for expanded use in immunocompromised adults in Europe last year, and we are on track to file the FDA this year.

In conclusion, before I hand over to Iain, I'd just like to leave you with the following. Although we are seeing fluctuating demand for our products, the underlying dynamic remains strong. We are using this time as productively as possible, to accelerate our digital capabilities and make changes to be more competitive. Finally, almost from the beginning of restrictions we have been planning for a strong start when we are able to resume more normal activity.

With that, I will hand over to Iain.

Q1 2020 financial results

Iain Mackay (Chief Finance Officer): Thanks, Luke. I hope everybody is fit and well today. All the comments I make today will be on a constant currency basis, except where specified otherwise, and I will cover both total and adjusted results.

Headline results

On Slide 16 there's a summary of the group's results for Q1, which was a very strong quarter, with 19% reported turnover growth, reflecting the addition of the Consumer joint venture with Pfizer, turnover growth of 10% on a pro forma basis. As you've heard from Emma and Luke, we continued to see strong underlying performance of the business during Q1, even in these challenging circumstances.

Additionally this quarter, we saw our turnover growth impacted by the COVID-19 pandemic in various areas across our businesses. In Pharma we saw a turnover growth of 6%, approximately half to two-thirds of which was related to pull-forward and stocking patterns, primarily in Respiratory in Europe and International, and HIV in the US.

In Consumer, turnover grew 11% pro forma, 14% excluding the impact of brands that are under review or being divested, again around two-thirds of which is related to increased COVID-19 demand, particularly in the US.

Finally in Vaccines, where we've seen some adverse changes to prescription trends in the last two weeks, we did not see any material financial impact in the first quarter.

I'll go into more detail on each of these businesses and the drivers in a moment.

Total operating profit was up 42%, with total earnings per share up 89%, primarily reflecting the strong operating performance as well as an increase in the value of shares in Hindustani Unilever. On an adjusted basis, operating profit was up 24% reported and 14% pro forma, while adjusted earnings per share was up 26%, reflecting both the operating leverage as a result of higher sales and the one-off impact of a revaluation of deferred tax assets during the quarter.

With over £531 million of free cash flow in the quarter, also reflecting the strong sales growth, improved operating performance and timing of RAR payments.

In currency, the net impact on Sales was broadly flat, with a 1% headwind to adjusted earnings per share.

Results reconciliation

The next slide summarises the reconciliation of our total to adjusted results. The main adjusting items in the quarter were major restructuring, focused on improving the efficiency of the supply chain, with also some initial charges for the separation preparation programme we announced earlier this year.

Within transaction-related, the main contributor was a charge for the emergence of the contingent consideration liability relating to ViiV, primarily as a result of movements in exchange rates.

Finally, the disposals column includes a gain from the revaluation of the embedded derivative in respect of GSK's exposure to movements in Hindustan Unilever share price.

The comments from here onwards are adjusted results, unless I state otherwise.

Pharmaceuticals

Slide 18 summarises the Pharmaceuticals business, where revenues were up 6% in Q1. As well as our new launches, which continued to perform well with encouraging trends, we saw some impact from COVID-19 towards the end of the quarter. This was primarily due to stocking and longer prescriptions being written. We have seen an increase in demand for certain respiratory products.

Luke has just taken you through the performance of some of our products, so I will just point out a couple of important considerations. Starting with Respiratory, sales were up 38%, from *Trelegy*, *Nucala* and *Relvar/Breo*, across all regions. *Relvar/Breo* grew 32% globally, benefitting from a prior period RAR adjustment in the US while, outside the US, sales grew 33% in Europe and 16% in International.

Nucala continues to perform strongly, following the launch of the at-home application, with growth of 38% globally. In HIV, revenues were up 8%, with the dolutegravir franchise up 9% globally. In the US, dolutegravir grew 2%, reflecting the shift within our portfolio towards our two-drug regimens, where we continue to build momentum, as well as customer stock-building related to COVID-19 towards the end of the quarter.

Excluding the impact of customer-stocking, we estimate that sales were flat, year-on-year, in line with our previously stated expectations.

Within the established Pharmaceuticals portfolio, it declined 6% overall, driven by US *Advair* sales, which were down 40%, as expected, given the generic competition. This was

offset by continued strong performance from *Ventolin*, in which we saw some incremental demand as a result of COVID-19. Outside Respiratory, the established Pharma portfolio declined by 2%.

Overall in Pharma, trends remain encouraging and our new products continue to perform well. As I mentioned, we estimate that approximately half to two-thirds of the turnover growth of 6% in Q1 was related to pull-forward and stocking patterns. Over the balance of the year, we expect that there will be volatility in demand due to COVID-19 and also a degree of unwind, giving the stocking impacts we saw during Q1 in Respiratory and HIV.

Turning to Pharma operating margin, as anticipated in our guidance at the full year, we saw a decline in Q1, informed by decisions we had made to invest in R&D behind priority assets; promotional activity for new product launches, and building specialty capability. In addition in this quarter, we also saw price impacts, including notably the impact of generic *Advair*, as well as high provisions for legal settlements in the quarter.

Vaccines

On Slide 19, we give you an overview of Vaccines performance, with sales up 19%, driven mainly by *Shingrix*, as well as our meningitis vaccines. As I mentioned, we did not see any material impact on Vaccines in the quarter as a result of COVID-19. *Shingrix* continues to benefit from our actions to increase our supply capacity, with revenues in Q1 of £647 million, driven by a continued strong uptake in the US, as well as a benefit from a one-off RAR adjustment.

As Luke has covered, underlying demand for the vaccine continues to be very strong and we are on track with our supply delivery plans for the year. However, we have recently seen a decline in *Shingrix* prescriptions as containment measures have limited patients' ability to access the vaccine. We expect that in Q2 we will see a significant impact on *Shingrix*'s performance as a result. However, we see this as a relatively short-term issue and we are putting the right plans in place to support increased demand once containment measures are relaxed, notably in the US.

Other vaccines that may be impacted by the ongoing crisis are our meningitis portfolio, with a potential impact of the back-to-school season in the US, as well as lower out-of-pocket sales in other countries; and also hepatitis, which is likely to be impacted by the global reduction in travel. Note also that the divestment of the travel vaccines, *Rabipur* and *Encepur*, will have a slight drag on sales growth this year, in the region of 3%. The operating margin of 48%

primarily reflects operating leverage as a result of strong sales growth in the quarter, particularly from *Shingrix*, as well as an improved product mix and higher royalties.

Consumer Healthcare

Turning to Slide 20, revenues for our new Consumer Healthcare JV on a proforma basis were up 11%, with those significantly impacted by consumer and government responses to COVID-19. We now have a revised category reporting structure in place, to appropriately reflect and help you understand the key drivers of the combined business. Under this structure, proforma growth was 14%, excluding brands either divested or under review. The divestment of the nutrition business to Hindustan Unilever closed on 1 April and we are moving forward with other divestments which will continue through this year to refocus our portfolio and fund integration and restructuring activities within Consumer Healthcare.

So it was a strong quarter with good power brand growth and the benefits from the formation of the GSK-Pfizer JV becoming increasingly visible.

We have also seen a significant impact in Consumer from COVID-19 in the quarter. This varies across regions with a number of markets, including the US and the UK experiencing increased demand while others, including China and India were negatively impacted by retailer shutdowns.

We estimate around two thirds of the overall Consumer growth in the quarter was related to increased COVID-19 consumer demand. We believe the majority of this is pantry loading but there is some incremental consumer usage in the Vitamins, Minerals and Supplements category and in Pain and Cough and Cold.

We would expect much of the pantry loading to unwind through the year, particularly over the next few months.

Operating margin for the quarter was up 320 basis points mainly driven by higher sales. With integration on track, we are delivering the planned synergies and continue to maintain strong cost control while investing behind our brands.

Sales and Adjusted operating margins

Q1 2020

On Slide 21 we summarise the sales and adjusted operating margin for the Group. As I mentioned, the Group operating margin, up 90 basis points reflects primarily the operating leverage from strong sales growth in the quarter. However, this also reflects the high levels of

resilience and agility we have demonstrated within our supply chain and the overall effectiveness of business continuity planning across the Group.

We are also seeing the continued benefit of restructuring and tight control of operating cost across the business.

Adjusted operating profit to net income

Continued delivery of financial efficiency

Moving to the bottom half of the P&L I would highlight the following. Interest expense was £187 million in line with last year, despite higher debt levels reflecting the financing actions undertaking in 2019.

The quarter also included a fair value gain on interest rate swaps offsetting lower interest income on cash and adverse foreign exchange. The effective tax rate of 13.7% reflected the one-off non-cash impact of the devaluation of deferred tax assets as a result of the cancellation by the UK Government of a previously planned reduction in the corporation tax rate.

A non-controlling interest reflected Pfizer's share of profits of the new Consumer Healthcare JV.

Free cash flow of £0.5bn

Free cash flow of £531 million in Q1, higher than expected reflecting the strong operating performance we have seen across the business. The increased operating cash flow is accompanied by beneficial timing of RAR payments offset by adverse working capital, primarily driven by higher trade receivables. We also received the milestone income from Novartis relating to ofatumumab, and as well as the positive cash flow we delivered in Q1, we close the quarter with strong cash balances from an effective approach to working capital management and maintain access to extensive undrawn committed facilities.

2020 guidance

Turning now to our outlook and guidance for this year, when we first issued our guidance we specified that it excluded any impact of coronavirus which as we have discussed has already had an impact on our performance in Q1.

We have presented a good set of results today with continued strong underlying performance along with some additional demand across our businesses reflecting customer behaviour and stocking patterns as a result of COVID-19.

With the dynamic and uncertain situation, there are significant risks to business performance for the remainder of the year and particularly over the next few months. In the coming months as Government-imposed containment measures remain in place we do expect to see the impact of changes to stocking patterns and reduced demands for those products which are patient or consumer discretion, notably vaccines, including *Shingrix*. We are confident underlying demand dynamics are strong and are focussed on supporting patient access as restrictions are relaxed.

Based on our current assessment of the impact of COVID-19, we are maintaining our full year 2020 guidance at this time. We will of course, if needed, update guidance as more information becomes available to inform our expected financial performance for the full year.

There is no change in our capital allocation priorities, investing in R&D behind priority pipeline assets and returns to shareholders, and as noted in our Earnings Release, we have declared a 19p quarterly dividend in line with last year and the expectations we set out earlier this year.

As mentioned, we have strong liquidity and access to substantial undrawn committed facilities. We are focussing on business continuity, the safety and wellbeing of our people and delivering solutions.

And with that, I'll hand over to Emma.

Emma Walmsley: Thanks, Iain.

Staying focused on long term priorities

While navigating COVID-19 crisis

So in summary, the business has performed strongly in the first quarter. Although of course we have uncertainty especially over the next few months, we are confident we can navigate this crisis by prioritising our people, business continuity and leading the way on solutions.

At the same time we remain very focussed on delivering our long-term priorities of innovation, performance and trust, and our 2020 areas of focus.

We are progressing our pipeline, we continue to drive improvements in our operating performance, we are moving at pace with the Consumer JV integration, and finally we have started our programme to prepare the Group for separation into two new companies. One, a

biopharma company focussed on the science of immunology, the other dedicated to everyday consumer health.

These two companies' purposes, priorities and capabilities have never seemed more relevant. Ultimately we remain confident in the resilience and sustainability of GSK's business, our ability to deliver on our strategic goals and that we can be part of the solution for the COVID-19 pandemic.

We are now joined for Q&A by Hal, Brian, David and Roger and so with that, operator, this team is ready to take your questions.

Question and Answer Session

James Gordon (JP Morgan): Thanks for taking the questions. Two questions; both on Vaccines. The first one was about Vaccines' recent performance. If I heard correctly, Pharma and Consumer did get the COVID boost in Q1, I think 4% and 8%, but the Vaccines growth rate was clean, but then the Vaccines pressure probably really only started right at the very end of the quarter in the West. So can you talk about what you saw at the end of Q1 towards the exit rate for Vaccines division performance or can you talk about what you have seen for April. How much deceleration have you seen already? Is the US prescription trend for *Shingrix* much of a guide or is it a lot more benign than that?

The second question also on Vaccines was flu, so we speculated the governments might want to mandate or much more strongly encourage people to get flu vaccinations this year or for the next few years because they don't want to deal with flu and COVID at the same time in older people. If that happened, is GSK placed to capitalise on much of that? Can you really stay with your flu vaccines or is that much more challenging – because I think yours is egg-based and Sanofi's is cell-based, so is your flu vaccine sustainable or can you participate in that upsize?

Emma Walmsley: Thanks, James. I am going to pass this to Luke because it is related to Commercial and front-line demand, but headline is you are right. Great demand and a clean performance from Vaccines in Q1, but definitely, as both Iain and Luke mentioned, we're expecting a slowdown in Q2 just because of both healthcare capacity and consumers' enthusiasm for going outside, but we are expecting a revamp and it is not least linked to the flu demand in fact, although you should reasonably anticipate no significant incremental supply on flu from us, but, Luke, do you want to talk through the dynamics there?

Luke Miels: James, I will answer your second question first. Last year we sold 46 million doses in the US, which was pretty much everything we had allocated, and we have been able to do that consistently because our supply is so far, touch wood, very predictable, with purchases like that. That said, we rely on GMP chickens for the source of this, and that is a 12-month at least notice time, so there is limited up-side for us in the coming flu season, but linked to your other question, there is the benefit of having this flu volume there linking it to the *Shingrix* recovery.

Before I go through specifically individual vaccines and the dynamics there, if you take a medium to longer term picture, I think we'd all agree that the world is in a way seeing a very unpleasant experiment where you don't have vaccine coverage for quite an aggressive pathogen. When people reflect on this overall, physicians' confidence to suggest vaccination to patients should be increased than it was before COVID-19 emerged.

I will go to Europe first. Europe, we saw a big drop-off in vaccines. If you look at Spain and Italy, it dropped off, but we already seeing signs of the early shoots of a recovery led by paediatric vaccines, and that is very clear. Governments are signalling that they want these vaccines recouped very quickly, and the US is aligned with that.

If you look at retail pharmacy in the US and doctor visits, they follow the CDC guidance. When you look at in-arm administrations for *Shingrix*, it dropped by about 90%, but again, the key thing here is we haven't seen a reduction in people wanting to get a *Shingrix* shot. What we have seen is a reduction of people who don't want to get COVID and who have been told to stay at home, so our expectation is that when people can go back out there they are going to seek these doses out. What's interesting is we have two ordering points in April for the major wholesalers, and the first one in April covered about 80% of the April sales, and that was filled. This actually helps us re-stock and clear some backwaters.

If you look at the rest of the business, it was interesting. Paediatric vaccines are really being prioritised, you don't see a big drop in visits. So *Pediarix* ship-outs went down about 40%, but we do see a bigger impact in *Bexsero*, for example.

Normally, Q1 is our lowest month, but the volumes went down in terms of shipping to practices and wholesalers by about 80%, and *Boostrix* and *Menveo* are about 70%. So there is an impact there. It makes sense. Wellness visits are down by about two-thirds, but I think ultimately we are in a position to capture these back. I think some of these orders were also driven by physicians being careful financially, and I think that is the other important thing to

remember, which is once these restrictions are lifted, these physicians are going to seek to recover these patients. They have practices to run, staff to pay, so we think there is going to be surge in activity after the restrictions are lifted, and as I said, early signs in Spain and Italy would indicate that is true.

Emma Walmsley: Thank you very much, Luke. Next question, please.

Steve Scala (Cowen): Thank you. I have two questions. The first is just to be clear is the *Shingrix* 2020 guidance, which I think is about flat to slightly up with 2019, still intact?

The second is GSK has 96 recruiting trials on clinicaltrials.gov. That number is down by only 12 in the last five weeks. These facts don't seem to fit with your cautionary comments on trials overall, so can you clarify these two points?

Emma Walmsley: I'll come to Hal to comment on the overall trials, and you're right, Steve, that the vast majority of our trials are not significantly impacted to date, but Hal will comment in more detail.

Just to be clear, on the *Shingrix* guidance, what we guided was a maintained run-rate plus a bit, of the Q4 sales at the end of last year, which would still be, certainly not flat year-on-year. That guidance at the moment is unchanged, there is no update to that, we obviously had a strong Q1, we are really pleased with the progress we're making on supply. We do expect Q2 to be tougher because of the drop in rates under containment, but the underlying demand is very strong and our supply is on track, so we think we would be targeting a bounce-back as containment is relieved. So, no changes there in overall outlook at this stage. Obviously we will update you as we get more information.

Hal, would you like to comment on the to-date impact on trials, please?

Hal Barron: Thanks for the question. I think the simple answer is, that data is consistent with what we said, that we haven't really terminated, only a few programmes, so most programmes continue to enrol, albeit some of them less robustly than we had previously anticipated, so as Emma mentioned, one- to three-month delay for the vast majority, a few have been significantly impacted more than that, and a couple have been terminated, or put on pause, but I think that data is very consistent with the impact we are seeing, which is non-trivial, but because of the importance of the programmes that we have ongoing and the ability for us to

come up with somewhat novel ways of doing these trials, we are confident that the impact is modest.

Geoff Porges (SVB Leerink): Thank you very much. Congratulations, by the way, on doing all of this and also delivering good results. Just on first of all the COVID vaccine efforts: you must be taking a close look at these programmes – are you confident that you have a surrogate for protection yet, and could you just talk about the scale of safety that you think you will need for a general use vaccine?

Then Luke, could you just talk about the upcoming pharmaceutical launches you have – obviously *Zejula*, *belantamab* – are you intending to launch, first of all, and secondly, what kind of degree of your typical effectiveness are you expecting, given the way that you are going to have to introduce them more or less on a virtual basis? Thanks.

Emma Walmsley: We'll come to Luke on the commercial launches and readiness in a new environment first, and then I think maybe hear from Roger first on the overall vaccine candidates and how we see that. We already have multiple partnerships going on. Luke, do you want to shoot first?

Luke Miels: The short answer is PRIMA will go ahead virtually, I think we can do that quite effectively and have been very thoughtful about that, and we've actually started that process with the NCCN guidelines as well. With BCMA, ideally we will wait, because that's a novel agent, it's new, so we would hold back until the restrictions were lifted. I hope that answers your question, Jeff.

You also asked about effectiveness. There are lots of consultants running around right now with reports. I think the data that we've seen just through our own good sell outcomes – this measures whether the call related in a change in behaviour – it's about 20% to 30% on average as effective as a face-to-face call. That being said, there are some very, very interesting outliers, where you can see some physicians really, really go with this medium, and we're seeing calls in people who normally might have only seen someone for 10 or 15 minutes drawing their calls out to 35 minutes. That might be because they don't have much to do, because they're not seeing many patients, but interestingly, even in some of the more busy physicians like pulmonologists right now, we're seeing longer calls.

I think it's going to be very stratified by the individual physicians, what they prefer. The bulk of value, though, is still going to be derived from face-to-face rep calls and HCP events.

Roger Connor: Thanks for the question. I think from a vaccines point of view, Emma has mentioned collaborations we believe are going to be key to, we think, finding a vaccine solution. We have seven partnerships in place and I think it's a busy few months ahead as we start to see the data read out on those various candidates.

I'd say on your specific questions, I think it's too early to say if there is a surrogate, but obviously we will be in discussions with the regulator about that. In terms of the level of safety testing as well, that's another regulatory discussion we'll have as we look ahead, at what are quite aggressive, accelerated timelines for this vaccine development, compared to what would normally be considered.

What I would say is, with our adjuvant technology, this is a proven adjuvant that has been used before, in previous pandemics, and has very strong patient safety data, and history as well, which means we have a proven track record here of a platform that can be used for a number of partnerships to develop vaccines going forward.

Andrew Baum (Citi): Thank you. I was listening carefully to Hal. Emma, you described GSK taking very seriously – I can't remember what you said – ophthalmic – but you referenced the adverse events associated with belantamab. Perhaps you could share with us, now that FDA has advanced discussions with you, the type of monitoring restrictions you might expect in the label, and more focused on the early lines of therapy than the third line, given the commercial opportunity, and how restrictive they may be. That would be helpful.

Then, second, on your HIV franchise, I would imagine that switching patients will be increasingly problematic if they don't present in person, so perhaps you could talk about *Dovato*, in the current environment.

Emma Walmsley: Thanks, Andrew. You are absolutely right. The switch market will be a little tougher near-term.

Hal, why don't you give a little more commentary on BCMA and views on that, and then we will come back to David.

Hal Barron: Thank you, Andrew. I want to be careful because our discussions with the regulatory agencies are confidential and therefore I will not comment on the ongoing discussions. However, there are a couple of things which it is important to remember. The data in this heavily pre-treated, refractory, relapsed patient population from DREAMM-2 was very

robust and we see the benefit outweighing the adverse events experienced, particularly of the ocular events seen in the programme.

What we have noticed, and discussed with all of you on the call before, is that these ocular adverse events are unique. Although they were well-managed in the clinical programmes, it is important to us to make sure that myeloma experts and eyecare professionals in the real world are able to work together to ensure that the drug is used safely in patients. Of course, we are open to any approach that ensures that patient safety is well-handled.

In addition to managing it well, we also have – as alluded to earlier – the opportunity to do more dose exploration when belantamab is added on to standard of care therapies or other active medicines. It is possible that the dose needed would be lower and therefore managing these unique adverse events through dose reduction is possible. In addition, we are evaluating various schedules that might enable that.

Lastly, the one combination that I have mentioned, and this is part of an ongoing proof of concept study – and Andrew, I think you are aware of this study – and there is really interesting data with a gamma secretase inhibitor, in a small number of patients, and much support from preclinical data, looking at inhibiting gamma secretase to prevent the clipping of the BCMA off the plasma cell. In CAR-T therapy, this has resulted in a very high response rate and, again, a small number of patients, and we are cautiously optimistic that that combination may even be a third avenue by which we can lower the dose and, in addition, manage the ocular adverse events. Again, we are continuing to believe the benefit seen in the 2.5mg/kg, three week-dose in DREAMM-2 outweighs the adverse events, but we take that seriously and we are looking at ways to optimise the drug's use in the real world.

Emma Walmsley: Thanks, Hal. David, would you like to talk about the 2DR and switch dynamics, please?

David Redfern: Yes. Thanks, Andrew. The first point, of course, is that HIV is a lifetime disease and patients living with HIV need to take daily oral medication otherwise their viral load will rebound and they become sick and potentially, ultimately, resistant. That oral medication is pretty straightforward to renew prescriptions on an outpatient online basis. Overall, we expect the HIV business to be pretty robust and resilient through the COVID-19 period. As you have seen, there were pretty strong sales in the first quarter: of course, there was some stocking in that in the US and Europe and probably about a week of early resale of extra stock coming forward.

The underlying performance was still strong, particularly of 2DR at £186 million, and we are pleased with progress on *Dovato* and *Juluca*. *Dovato* is now recommended third in the guidelines in the US and Europe. You are absolutely right, Andrew, that there is definitely less switching: it was around about 60% in the US and I think it is probably around about 40% right now, as physicians just renew patients' prescriptions online and they are not coming in and being revisited. That will lock in the market share for the moment, and it will probably mean that we will sell a little more *Triumeq* and *Tivicay*, and *Dovato* will stay stable. Hopefully, once patients get revisited, that will start to revamp, but there is definitely an impact of the switching in the short-term on the 2DRs.

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

Jo Walton (Credit Suisse): Thank you. Could I return to Vaccines and, in particular, your COVID vaccine work. Are you largely related to helping other people with adjuvants and then doing manufacturing of the resulting vaccine? I was just wondering where you have this spare capacity. We know how difficult it is to add capacity for something like *Shingrix* and yet, between you and Sanofi, you seem to be able to promise hundreds of millions of doses. So, just some help on how that comes about and if you could give us some sense of if you are planning on this being an annual or every few year vaccine or whether you think it is likely to be effectively a one and done, even if it's a couple of shots within that.

And secondly if I can just push you on *Shingrix*, the level of the RAR that came in there versus the incremental supply. Clearly if we were just to take four times the first quarter, we would be way higher than consensus for the year. I am just wondering how big that RAR component was. Thank you.

Emma Walmsley: Yes, I think the RAR, Iain, correct me if I am wrong, was £50m for the quarter, is that right?

Iain Mackay: In the quarter it's £50m, yes.

Emma Walmsley: In the quarter was £50m and there's no change, as we said earlier, to our overall outlook for the year on *Shingrix*. We had a great Q1. Q2 is expected to look a bit different but again we are working on the rebound and supply is very much on track with what we have been aiming for.

I completely understand your question in terms of how come a vaccine that normally takes ten years is 18 months and you are in this kind of capacity provision. I will ask Roger to explain the very significant differences and by the way, it's one of the reasons why when the question we were trying to answer is how do you get to a vaccine that works at scale, the best probability of success as fast as possible with COVID, a very different scenario in a pandemic crisis than with a new technology of *Shingrix*.

But perhaps, Roger, you can give a little bit more colour on that in terms of the difference between that and the *Shingrix* capacity expansion.

Roger Connor: Exactly. Listen, thanks very much for the question. I think to be clear that the partnerships that we have in place are adjuvant partnerships, so we are obviously providing our adjuvant which for those who don't know is a separate vial of product that we deliver and is in preclinical and then moving into clinical testing.

I think it's important to know that that adjuvant technology already exists. It's a proven adjuvant that we have supplied before. It's our adjuvant system No. 3, so the supply chain actually already exists for it and is a discrete supply chain. It is quite different technically from *Shingrix*, a completely different technology, so the two aren't interchangeable and we keep some redundant capacity in it for this very reason, for pandemic preparedness on flu, so the supply chain is there now.

We still have expansion to do so to reach the levels that we believe that will be required for the partnerships that we have and for the populations involved, we believe that we will have to expand and that will take time but we're not starting from zero like some other vaccines will have to, so that's important. *Shingrix* is also a much more complex bulk process and also supply chain as well, so I think that's a difference.

On the seasonality question as well, I think it's too soon to tell, who knows, but the fact that we will be part of a number of different vaccines hopefully means that if that does become seasonal, we will be part of that solution as well.

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

Emmanuel Papadakis (Barclays): Thanks for taking the questions. Maybe just your perspectives on the data you reported earlier this month in terms of the nasal polyps opportunities. It seemed somewhat at face value inferior to the incumbent competitor in that

space, but perhaps you could just give us some early thoughts in terms of the commercial potential and the degree to which that is synergistic on your current business in severe asthma and the timing for that ramp, if any?

And then perhaps the second question just coming back to HIV, cabotegravir, you said you are going to refile in the early part of the summer. Is there any colour you can give us now in terms of the class of response, the timing it could be on the market and indeed, assuming we are back in a semi-normalised world, the speed of launch we might anticipate? Thank you.

Emma Walmsley: David, do you want to talk about CAB and then we'll come to Luke for the life cycle management, the commercial potential on *Nucala*?

David Redfern: Yes, thanks, Emmanuel. We have had discussions with the FDA on CAB and as we have said today, we expect to resubmit in the middle of the year. We do expect it to be at Type 2 so that can take up to six months for the FDA to review, so on that basis, if all goes well we would expect to hear the back end of this year or the early part of next year. And just remember, this is entirely related to CMC and particularly data on the specific quality control, it's not related to the clinical safety data.

Luke Miels: Emmanuel, a great question. I think the key thing to zone in here, if you compare our study, SYNAPSE versus SINUS-24 and 52 with dupilumab, the key area to look here is the number of previous surgeries. For mepolizumab, *Nucala*, 100% of these patients had had at least one previous surgery whereas with dupi in SINUS-24 it was around 69% and in SINUS-52 it was 58% and similar rates for the placebo in both those arms.

If you look at three or more previous surgeries, so a very, very resistant disease, complex disease, one in four mepo patients had three or more previous surgeries, where that was 23% and 15% respectively in SINUS-24 and 52. Our thinking is that there are numeric differences there really driven by a difference in patient populations with 34% of patients in dupi studies having no previous nasal polyps surgery and, therefore, had less persistent polyps, which may theoretically be more easy to treat.

In terms of the opportunity, I would say if you look about five years out, the opportunity is probably £80-100 million, so it is a nice add-on, it reinforces the products, but it is not transformational in itself.

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

Kerry Holford (Berenberg): Hi, a couple of questions from me, please. Firstly, on SG&A, many of your global peers reported SG&A figures that were lower than the previous run rate. That has not happened for you in this quarter, but is it something we should anticipate being more apparent into Q2? Have you seen a significant decrease in your marketing spend, travel budgets, and the like, or is that simply being reinvested into digital and telemarketing?

Secondly, thinking about utilisation, particularly in the US, how do you think about the risk to your business in the rising US unemployment, and could the effect of negative peer mix shift be a significant risk to you this year, if not next, and I wonder if you would comment on which of your products may be most at risk? Thank you.

Emma Walmsley: Thanks, Kerry. I am going to ask Luke to comment, although it is very much in the bucket of 'unknown', although clearly unemployment figures are significant, but in terms of direct impact, I am not sure we are going to give a lot of details of which products, but Luke will talk a bit about the shifting mix.

Just in terms of SG&A, I think half of that growth came from either one-off legals or Tesaro. Is that right, Iain?

Iain Mackay: Yes, that's right.

Emma Walmsley: Clearly, our goal is to invest behind our new launches and oncology preparedness, and make sure that non-customer facing costs just keep coming down, and obviously we're going to make savings in travel, like everybody is. As Q2 experiences what it does, we would expect that to see a lot of control, but exactly as said, we are very invested in making sure we have fast opening as markets do open up, and the investment in digital is ongoing. Obviously we are not making COVID-related redundancies but, Luke, do you want to talk a little about thoughts?

Luke Miels: Thanks, Emma, and thanks Kerry. You can imagine we are looking at this very, very closely. As Emma said, it is very hard to predict, but if I can just lay out our thinking, and I will just take you through the products after that.

As you know, if you get laid off in the US, you have the option of COBRA to bridge your commercial insurance. Some people are going to go into the Obamacare health exchanges, and people can enrol in those, and then unfortunately some people may fall into the Medicaid category or that may be expanded.

What is interesting is that Congress did provide subsidies for COBRA 2008, but they don't seem to be signalling that they are going to do this in 2020. Also let's not forget that employees that are furloughed lose their salary but, so far, not their health insurance, and there are good examples with Disney and other companies like that that are doing that. We are trying to calculate where everyone will land, and it's really hard at this stage. The baseline if you look right now we think is about a reduction of £9 million so far, so that is roughly where we think it is, but it depends. With bankruptcies, companies can still provide insurance under bankruptcies unless they choose to walk away from their plan, and then people aren't eligible for COBRA at that point, so Chapter 11 doesn't necessarily mean that you lose your benefits.

In terms of the products, the ones which had the higher commercial component – *Breo*, *Advair*, *Flovent*, and *Ventolin* – are the ones which obviously we will watch closely. *Nucala* is a bit lower. There may be some impact on biologics because they are bit more expensive, but again, these patients tend to have severe disease as well. *Trelegy* and *Anoro* are mostly Part D, so they are in a good spot, as is *Incruse*.

Vaccines we think are going to behave differently. Again, these are single events or double events. From a cash flow point of view it is not as challenging as a chronic medication. We think that if you look at paediatrics with the existing government private partnerships in place they won't be disrupted.

In terms of *Shingrix*, again, two times 150 is in reach for many people versus chronic medication. Again, we are confident on the mid to long-term there.

On *Zejula*, I think ultimately it is going to be driven by the level of people that are coming forward for treatment. We have seen that drop, but again I think in the mid to long-term we should be okay with the product. I hope that answers your question. Short answer is some of the respiratory products are more exposed, but they are ones which were under pressure anyway. The ones that we need to grow aggressively like *Trelegy* and the vaccines and *Nucala* are less exposed, and *Zejula* of course.

Emma Walmsley: We are at the hour, but maybe one more question.

Graham Parry (Bank of America): Thanks for taking my questions. Firstly, on *Shingrix*, I just wanted to square a couple of comments.

So you said the full year guide is unchanged, but Q1 was running quite a long way above the fourth quarter plus a bit rate, so is there a level of conservative in the full year guidance and Q1 capacity, indicative of what you think you can actually produce through the year? You also said you expect an impact in Q2 but also the fact that April orders are being filled, so again, is that just anticipating some drop-off down in April?

Then secondly, in your comments around COVID impact you specifically mentioned supply chain manufacturing as a COVID risk, and I would say that's an area that most other companies have been perhaps more robust in their statements on. Is this because of a particular difference in GSK supply chain vulnerability, or just a different communication style in terms of communicating risk to the market? Thank you.

Emma Walmsley: First of all, on *Shingrix*, there is no change to our outlook, because as we said, we are on track with our supply plans. We have had a strong quarter, but there is no question Q2 will be tougher when, as Luke said, the vaccination rates dropped by 80, 90% in the US market. The signals from wholesalers in the first two ordering dates of April are positive signals on the underlying demand, but that is going to flow through, but it's a signal of the confidence of a bounce-back. We do think the curve will be differently shaped, and we'll obviously update you as we go through the year and results come through.

In terms of supply chain, I certainly wouldn't want to be signalling any specific concern. You may be right in terms of different company styles in communications. We think we have a very robust supply chain, we're really pleased with the way our 70-plus factories have mobilised to fluctuating demand. We just want to make sure that we are responsibly signalling the potential risks with a lot of uncertainty in the world, and this may be related to third party suppliers or indeed government actions that one can imagine in the external environment, perhaps more fundamentally than internally. But no specific concerns that we are looking to flag.

Iain Mackay: I think our commentary is directly responsive to guidance from both the SEC and the FRC in terms of laying out the risks that *may* be forward-looking, but I'd echo completely Emma's comments with respect to the resilience and performance of our supply chain.

Emma Walmsley: With that, everybody, again, thank you very much for taking the time to join us. Please do stay well and we'll look forward to catching up with you soon.

[Ends]