Iain Mackay (CFO): Good morning and good afternoon, thank you for joining us for our second quarter 2021 results, which were issued earlier today. You should have received our press release, and can view the presentation on GSK’s website. For those who are not able to view the webcast, slides that accompany today’s call 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 a Cautionary Statement.

Agenda

Our speakers today are Emma Walmsley, Luke Miels, Deborah Waterhouse, Dr Hal Barron, Brian McNamara and myself, Iain Mackay. Joining us for the Q&A portion of the call will be Roger Connor and David Redfern. We request that you ask only a maximum of two questions, so that everyone has a chance to participate.

Our presentation will last for approximately 30 minutes, in order to maximise the opportunity for questions, and with that I will hand the call over to Emma.

Q2 2021: Strong financial performance and execution of strategic priorities

Emma Walmsley (CEO): Thank you, Iain, and a very warm welcome to you all.

We are pleased to report a strong financial performance and continued progress against our strategic priorities this quarter. Second quarter sales and adjusted EPS were up 15 and 71% respectively at CER. These excellent results were driven by a combination of strong double-digit growth in New and Specialty pharma products, a significant increase in Vaccines sales, reflecting both an improving picture of vaccination rates and a major sales contribution from our pandemic adjuvant, good growth in Consumer Healthcare brands, with double-digit growth in six of the nine power brands, and continued discipline in control of costs.
As expected, the quarter did benefit from a favourable comparison to the second quarter last year, which was heavily disrupted by the pandemic, and whilst further disruption cannot be ruled out, we are seeing positive momentum which we expect to continue through the second half of the year.

Assuming a second half backdrop of improving demand for adult vaccinations and normalising health and consumer trends in key markets, we believe we are likely to deliver adjusted EPS at the better end of our guidance. I just want to remind you that this guidance excludes any contribution from COVID-19 solutions, which we expect to add between 4 and 6% to our adjusted EPS in 2021.

Alongside our financial performance we continue to make good progress in R&D and our strategic delivery. Among our key assets, we completed the filing of long-acting cabotegravir for prevention of HIV and we announced positive headline results for all five Phase 3 studies of our promising Specialty medicine daprodustat. Very importantly, we also continued to strengthen the pipeline this quarter, securing three exciting new collaborations in HIV, immuno-oncology and immuno-neurology.

Lastly, this quarter also saw us lay out our new growth outlook for GSK and the proposed de-merger of Consumer Healthcare: delivering scale health impact, and maximising value for shareholders, are at the core of these plans, and we have received widespread support from shareholders for them, together with a clear message to focus on execution and successful delivery. We are all strongly committed to doing so.

**Progress made across all strategic priorities in Q2**

Progress for this quarter is reflected across all three of our strategic priorities: in Innovation we continue to build a high-value pipeline across prevention and treatment of disease through organic and inorganic delivery; in Performance improved commercial execution is driving strong growth in New and Specialty pharma products.

For *Shingrix* specifically we are clearly seeing the beginnings of a recovery in performance as COVID vaccination programmes amongst older populations near completion. The US new to brand prescriptions for *Shingrix* were up 73% in the quarter, and we saw good performance across the Consumer business, with the exception of sustained weakness in cold and flu and a few specific areas where consumer trends haven’t yet returned to normal.

On Trust, we continue to maintain leadership in ESG, as evidenced by new index ratings. We recently signed a principal partner for COP26 and continue to progress our environmental commitments to be net zero and nature positive by 2030.
Priority is to unlock potential and maximise value for shareholders

As you heard at our Investor Update, the scale of the changes we have made in the last four years is unprecedented; to improve performance, strengthen capabilities and prepare GSK for a new future. Our clear priority is to unlock the potential of two world-class businesses and in so doing, maximise value for shareholders.

With the platform we now have for GSK, we expect to deliver highly competitive sales and operating profit growth in the next five years, a step-change in expected performance and we aim to achieve sales of more than £33 billion by 2031 all underpinned by an R&D focus on the power of the immune system, a portfolio shift to Vaccines and Specialty medicines to prevent and treat disease and impacting the lives of 2.5 billion over the next ten years.

Through the proposed demerger we will create a new category-leading Consumer healthcare business serving over 100 markets with annual sales in 2020 of £10 billion, driven by brands and innovation to deliver better everyday health. This business has strong prospects for sustainable sales and profit growth, high cash generation and to deliver attractive returns for shareholders.

Let me now hand over to the team to talk you through this quarter’s performance in more detail. Luke, first over to you.

Growth Drivers

Luke Miels: Thanks, Emma. We continued to make progress on commercial execution and competitiveness in the quarter against a complicated external environment due to COVID. The strong in-market performance I highlighted in the recent quarters for products such as Trelegy, Nucala and Benlysta has continued driving growth of New and Specialty pharma products of 25% in the second quarter and 14% in the half year.

We also saw a good recovery in the quarter in Meningitis and Established Vaccines, so today I want to focus my remarks on the performance and growth prospects for Shingrix and our Oncology products.

Shingrix: strong underlying demand supports confidence in recovery

For Shingrix, our confidence in recovery has been tied to the prioritisation and successful rollout of COVID-19 mass vaccinations, particularly in the US. Underlying trends illustrate that Shingrix volumes are expanding as we move into the second half of the year. Overall, despite a slower rate of recovery in ex-US markets, we anticipate a strong half two
global performance from *Shingrix* with the potential for slight growth in sales on a full-year basis.

In the US with nearly 80% of adults aged 55 plus now fully vaccinated for COVID, we have now seen a related increase in weekly NBRx volumes which have grown 73% since the start of quarter two.

In the coming months, it’s going to be important for the recovery of *Shingrix* in the US as our updated research shows that around half of those eligible to receive *Shingrix* have indicated that they expect to get it within one to three months following the completion of their pandemic vaccine series.

We have been implementing activities to drive this recovery with a comprehensive multi-channel DTC campaign and by focussing on our relationships with US retailers, particularly as we focus on the ‘flu vaccination season where adult vaccinations become increasingly top of mind for consumers.

We are starting to see similar trends in Germany where volumes are improving as more adults complete their COVID-19 vaccination series and in China we continue to make steady progress in the private pay market with *Shingrix* now in 50 cities.

Overall though, we are seeing a slower rate of *Shingrix* recovery ex-US due to the different rates of deployment of COVID vaccinations.

Looking ahead, we continue to roll out in new markets, including the UK, and we are now benefiting from an unconstrained supply position.

Now this is going to support the expected significant step up in *Shingrix* sales in 2022, assuming continuation of the improved operating environment, as well as our ambition to double revenues in the next five years protecting more than 100 million adults.

**Recent oncology launches contributing to growth**

If I now move to Oncology, *Zejula* had a strong performance, despite the impact of COVID on the ovarian cancer market. Sales were up 38% versus Q2 2020 and we are pleased that in the US we are significantly leading in new patient starts with 59% of patients going to a PARPi receiving *Zejula*.

We are also seeing progress in US patient awareness, which has significantly increased from 29% at April 2020, to almost 50% in June 2021, and a decrease, pleasingly, in the watch-and-wait usage, now at 57%, although there is room for improvement.

Unfortunately, with the backdrop of COVID, there is still a 20% decrease in ovarian cancer diagnoses, and we know that with delayed diagnosis there are less patients getting
debunking surgeries, and, therefore, less patients going onto maintenance about six months later. So, we expect that is impact will continue until the market returns to pre-pandemic levels.

For Blenrep we have seen encouraging progress, despite competitive entrants, and we are especially pleased to see demand increasing with community Oncologists in the US and also Germany.

We have a very robust clinical programme designed to continue to improve the profile of Blenrep through various combinations, optimised dosing and scheduling.

On this side we have outlined the patient opportunity and the associated clinical trials that align to earlier lines of treatment.

The outcomes of these trials will evolve our strategy, including potential use of novel combinations and the substantial opportunity we can see in second line, where we have dose-optimised pivotal trials, and with that, I will pass over to Deborah for an update on the HIV portfolio.

**HIV: Delivering sustainable growth**

**Deborah Waterhouse:** Thank you, Luke.

Second quarter HIV sales rebounded strongly, growing by 14% and more than reversing the 11% decline that we reported in Q1 due to COVID impacts and the strong 2020 comparator.

Growth in the first half of the year was 1%.

Strong commercial execution continues to drive the performance of Dovato, particularly in the switch market in the US and Europe.

*Dovato and Juluca* are on track to deliver £1 billion in sales this year. Our recently launched innovative medicines, including *Rukobia*, now account for more than 25% of our total sales.

A highlight this quarter was the market share of dolutegravir-based regimens in Europe, which for the first time exceeded 30%, driven by *Dovato*.

Share continues to hold firm in the US.

Turning to our portfolio of long-acting injectables, in January we received FDA approval for *Cabenuva*, the world’s first long-acting injectable treatment for HIV. It is also approved in Europe under the brand name of *Vocabria/Rekambys* and dosing every two
months. We anticipate approval of two-monthly dosing in the US by year-end and launch in early 2022.

Early signals are positive, with strong brand recognition from people living with HIV and high levels of physician attendance at our virtual launch meetings, which we believe will translate into increasing intent to prescribe. As with any new class of medicines, Cabenuva will take time to build, and, furthermore, the COVID backdrop is significantly constraining switch activity, particularly where a patient needs to visit a physician’s office.

We are confident about its potential to transform the HIV treatment paradigm, and with an anticipated five-year head start over competitors, we expect Cabenuva to capture a leading share of a long-acting treatment market that could reach £4-5 billion by 2030.

This quarter we also made significant progress with cabotegravir long-acting for prevention. We have completed the rolling submission with the FDA and anticipate launch in early 2022.

If approved, we believe cabotegravir long-acting will present a new and compelling option in the PrEP market, dosed every two months with efficacy believed superior to the current standard of care.

As for the treatment market, we believe the long-acting PrEP market could ultimately reach £4-5 billion in value, and cabotegravir long-acting is poised to play a leading role.

Last week at the International AIDS Society conference we presented week-48 data from the Phase 3 SALSA study, which demonstrated that Dovato is a compelling option, irrespective of the type of three-drug regimen a patient may be switched from.

We also presented the STAT study, which shows that Dovato is acceptable for same-day Test and Treat.

For Cabenuva we presented the CUSTOMIZE data, which not only shows that Cabenuva is applicable in a range of healthcare settings, but that 97% of people enrolled in the study preferred the long-acting injectable over daily oral therapy, and in PrEP we presented more data from the pivotal HPTN-084 women’s study, demonstrating that cabotegravir long-acting is the first and only long-acting injectable for PrEP to demonstrate superior efficacy and comparable safety to daily orals in preventing HIV acquisition in a diverse population.

Taken together, I am delighted with the progress we are making in HIV in both returning the franchise to growth, and building our portfolio of innovative and pioneering long-acting medicines.
I would like to turn the call next to Hall.

**Daprodustat: potential to be best in class for anaemia of chronic kidney disease**

**Hal Barron:** Thanks, Deborah. I’m going to provide a short update on some recent newsflows since the June event, and highlight some of the upcoming pipeline milestones over the next 18 months.

**Significant upcoming R&D data points in next 18 month**

Starting with daprodustat. We recently announced positive headline results from each of the five trials in the ASCEND clinical programme. As a reminder, the ASCEND programme recruited over 8000 patients from both the dialysis and non-dialysis populations, and was designed to demonstrate the safety and efficacy of daprodustat as a novel oral treatment for patients with anaemia due to chronic kidney disease.

We are very pleased with the results from ASCEND-ND and ASCEND-D studies which met the co-primary endpoints on both safety and efficacy. Daprodustat demonstrated an improvement in haemoglobin levels in untreated patients, and maintained haemoglobin levels in patients previously treated with an erythropoietin-stimulating agent, a standard treatment option in patients with anaemia of chronic kidney disease.

Importantly, the two cardiovascular outcome studies, ASCEND-ND in non-dialysis and ASCEND-D for dialysis patients, both demonstrated that daprodustat was non-inferior when compared with erythropoietin-stimulating agents in the risk of Major Adverse Cardiac Events, or MACE.

Additional analyses are ongoing and we aim to present these data at a medical conference later this year.

**Three significant business development transactions in Q2**

Moving to business development, as I highlighted in June, our strategy has been to leverage business development to augment our organic pipeline, and we made some recent progress on this with three deals which I’ll cover briefly now.

The first is our global collaboration with Alector for two clinical stage, first-in-class, monoclonal antibodies targeting sortilin for neuro-degenerative diseases. This collaboration brings together Alector’s leading immuno-neurology expertise with our focus on the science of the immune system and human genetics, and proven late stage drug development capabilities.
The lead asset AL001 is currently recruiting a Phase 3 trial for people with a progranulin gene mutation who have frontal temporal dementia, or are at risk of developing FTD. Those antibodies, AL001 and AL101 are designed to elevate progranulin levels by blocking the sortilin receptor. Progranulin is a key regulator of immune activity within the brain, through modulating lysosomal function. There are compelling genetic links to multiple neuro-degenerative disorders, including FTD, Parkinson’s and Alzheimer’s disease, and these assets could offer a new approach to the treatment of patients with these considerable unmet needs.

Second is our collaboration with iTeos for an anti-TIGIT monoclonal antibody in Phase 1 development, which I highlighted at our Investor event in June. This deal complements our focus on the CD226 axis where we now have an anti-TIGIT and anti-CD96 and an anti-PVRIG, all of which can be combined with our PD1 inhibitor, Jemperli.

Pre-clinical data, human genetics and recent randomised clinical trials all highlight the modulating CD226 axis which we believe could deliver transformational medicines for patients and usher in the next generation of IO medicines.

Finally, the recent Halozyome deal announced by Deborah and the ViiV team, which offers the opportunity for ultra long-acting regimens containing cabotegravir and other ViiV pipeline assets.

I also want to remind everyone that these three deals are not factored into the 2031 sales ambition we issued in June, and would represent upside if successful.

**Significant upcoming R&D data points in next 18 months**

Lastly, this slide summarises key data we expect to report over the next 18 months. As you can see, we anticipate a large number of pivotal data readouts in 2022, as well as some important datapoints in the second half of 2021. Among our specialty products, I have already spoken about the five positive Phase 3 studies with daprodustat which we recently reported. We also have a number of data readouts on Blenrep over the next 12-18 months including pivotal readouts looking to demonstrate a progression-free survival benefit compared to standard of care for patients with multiple myeloma.

Later this year, we should have data from the proof of concept DREAMM-5 sub-study of low dose Blenrep, in combination with the gamma secretase inhibitor for the treatment of patients with multiple myeloma.

We are investigating a number of strategies to optimise the dosing schedule for Blenrep, and we hope that this sub-study will maintain the efficacy of Blenrep, but at a lower
dose which could reduce or delay the incidence of ocular events and supports the potential use of Blenrep in earlier lines of treatment.

As I previously mentioned, not only is this study important for advancing Blenrep’s potential, but it can also serve as a potential additional proof point for our functional genomics strategy.

Other pivotal readouts on key assets in 2022 include otilimab in patients with rheumatoid arthritis, plus data from several important vaccine candidates including RSV for older adults, RSV maternal vaccine and data from our MenABCWY pivotal studies.

Finally, we should receive a number of readouts from our COVID vaccines and therapeutics over the remainder of 2021, including pivotal data from our vaccines collaborations with Medicago and Sanofi, and a Phase 2 data from the OSCAR trial of otilimab, and the COMET-PEAK study with sotrovimab.

With that, let me hand it over to Brian.

**Consumer Healthcare**

**Brian McNamara**: Thanks, Hal. Now turning to Consumer Healthcare in Q2. Continuing sales, excluding brands divested and under review, were strong, up 7% in constant exchange rates, which included a 2% drag from retailer stocking last year, ahead of the systems cutover in North America which reversed in the following quarter.

Our Q2 results were supported by an easier comparator, given destocking in the same quarter last year, following the pantry loading in Q1. The two-year CAGR removes the distortion from the pandemic and was up 3% in Q2, which would have been up 4%, excluding the impact of the unusually weak cold and flu season.

Let me talk specifically about our category performance in the second quarter. In Oral Health sales increased 12%, with the two-year CAGR up 5%, demonstrating good execution and successful innovations, with Sensodyne and Gum Health more than offsetting lower growth in Denture care.

Pain relief saw Q2 sales up 13%, and delivered a good two-year CAGR, up 5%. In Vitamins, minerals and supplements, sales declined 6% as we cycled the demand spike in the prior year, although the two-year CAGR was up 6% including particularly good growth in Centrum, Emergen-C and Caltrate.

Digestive health and other sales were up 3% in the quarter, with a flat two-year CAGR. Performance in this category was mixed, with strong performance of Smokers’ health
products and Digestive health brands, but continued weakness in brands more dependent on impulse purchase, such as ChapStick.

Respiratory sales increased 6% in the quarter, and the two-year CAGR was down 3%. This reflected very different results in the two sub-categories, with strong Allergy performance and continued weakness in cold and flu. Don’t forget that given seasonality, Q2 is a smaller quarter for the cold and flu business.

Our focus on innovation continued, and we saw further positive momentum with Sensodyne Sensitivity and Gum as well as good performance from newer innovations such as Centrum Essentials in Brazil and Pronamel Intensive Enamel Repair Whitening in the US.

In e-commerce we grew approximately 30%, and this was 7% of sales. Our ongoing investment in digital capabilities positions us well for growth, and with continued strong results in the last month, particularly in the US, we remain confident in our ability to outperform in this key channel.

Turning to our power brands, six of the nine brands gained or held share, with six brands reporting double-digit growth in Q2, and collectively power brands were up double-digits. Additionally, we saw double-digit growth in our continuing business in emerging markets, with particularly strong performance in India and China. Our full-year sales outlook remains unchanged.

**Consumer Healthcare**

**On track to create leading global consumer healthcare company**

Our separation and integration plans all remain firmly on track: commercial integration is now fully complete, our manufacturing site cutover is well under way, and separation activity is progressing well, and to plan. Importantly, all of our guidance for 2022, shared in 2018, including margin and synergies, remain unchanged.

Finally, I’d like to take a minute to remind you of who we are, and what we have created through the two largest Consumer Healthcare transactions in the last six years. At separation we will be the first listed 100% focused Consumer Healthcare company, as well as the global leader in Consumer Healthcare, operating in a sector with compelling fundamentals and leadership positions in categories now more relevant than ever. We have a fantastic portfolio of brands and strong capabilities to drive sustainable market outperformance, and I’m excited to share more information with you on this incredible business as we move closer to separation.

With that, I will hand over to Iain.
Iain Mackay: Thanks, Brian.

**Q2 2021 results**

**Headline results**

As I cover the financials, references to growth are constant exchange rates unless stated otherwise.

On Slide 18 is a summary of the Group’s results for Q2 and the half-year. In Q2 turnover was £1.8 billion, up 15%, and adjusted operating profit was £2.2 billion, up 43%. Total earnings per share was 27.9p, down 28%, while adjusted earnings per share was 28.1p, up 71%.

In the year to date, turnover was £15.5 billion, down 1%, and adjusted operating profit was £4 billion, up 3%. Total earnings per share was 49.4p, down 27%, and adjusted earnings per share was 51p, up 2%.

We generated free cash flow of £313 million in the year to date, in line with our expectations.

On currency, there was a headwind of 9% on sales and 25% on adjusted EPS, in particular due to the strengthening of sterling against the US dollar relative to the second quarter of 2020.

**Results reconciliation Q2 2021**

Slide 19 summarises the reconciliation from total to adjusted results. The adjusting items of note for the quarter were in Disposals, significant legal and other, which reflected a £325 million tax credit due to a significant positive revaluation of deferred tax assets in the UK, resulting from the Q2 enactment of the 2021 UK Finance Bill.

My comments from here onwards are on adjusted results, unless stated otherwise.

**Group sales and adjusted operating margins Q2 2021**

The key drivers of revenue and profits for the Group in the second quarter compared to the prior year are set out on Slide 20. Revenues grew 15% overall. Including revenues from our COVID solutions, sales were up 11%. The pandemic adjuvant sales of £258 million represent delivery of around two thirds of contracted volumes with the US and Canadian governments. The positive operating average from higher sales in the quarter was bolstered by continued focus on cost control, and the benefits of restructuring across the Group. This was partly offset by increased investment in R&D up 6%, as expected, and additional investment behind product launches with SG&A up 5%. 
The resulting Q2 margin was 26.7%, and the year-to-date margin was 26%. We expect R&D growth to be around 10% in the full year, with a first half increase of 5% reflecting phasing, particularly in 2020.

**Adjusting operating profit to net income**

Moving to the bottom half of the P&L, I would highlight that interest expense was £185 million, compared to £227 million last year. The decrease is primarily as a result of reduced interest expense from lower debt levels and favourable movements in foreign exchange. On share of associates, in May we sold our stake in Innoviva which was the main contributor to this income line. The effective tax rate of 18.4% was in line with expectations and reflects the timing of settlements with various tax authorities. And finally, lower non-controlling interests reflected a reduced allocation of Consumer Healthcare JV and ViiV Healthcare profits.

Next I will cover free cash flow for the quarter before going into more detail on performance drivers in each business.

**Free cashflow of £0.3bn**

In the first half of the year we generated £313 million of free cash flow and improving cash flow performance continues to be a constant focus for the team. The significant step down in the year-to-date was as expected and in line with our full year outlook.

In the first half, increased adjusted operating profit and lower dividends to non-controlling interests were more than offset by adverse timing of returns and rebates and taxes compared to the first half of 2020, an increase in working capital, adverse exchange impacts and increased purchases of intangible assets as well as reduced proceeds from disposals of intangible assets with the consumer brands disposal programme now complete.

Turning to performance of the Pharma business on the next slide.

**Pharmaceuticals**

**Q2 2021**

Overall, revenues grew 12% driven by strong growth in New and Specialty medicines, a prior year comparator that was impacted by destocking and favourable US return and rebate adjustments in the quarter.

The impact of prior year destocking and the prior period RAR adjustments, including the impact of lower than expected Medicaid usage on a number of products accounted for approximately three and four percentage points of growth respectively.
In the year to date, revenues grew 2% and our full-year outlook remains unchanged. The Established Pharma portfolio was flat. Within this, Established Respiratory grew 6% but the rest of the Established Pharma portfolio was down 7%. We still expect Established Pharma sales to decline high single digits in the full year.

The Pharma operating margin was 29.3% in Q2 and 29.1% for the first half. The increase in Q2 primarily reflected the positive operating leverage from the increased sales as well as continued tight cost control and restructuring benefits. R&D expense grew 3% in the quarter and year-to-date R&D spend also grew 3% which reflected phasing of spend, particularly in 2020 and we expect a higher growth rate in the third quarter.

**Vaccines**

**Q2 2021**

Slide 24 gives you an overview of Vaccines performance with overall sales growth of 49%. Excluding pandemic adjuvant revenue, sales growth was 24%. In year to date, total Vaccines revenues were flat and down 9% excluding the pandemic adjuvant sales.

In the quarter we saw improving paediatric and adolescent vaccination rates and adult vaccination rates, although improving, continue to be affected by COVID-19 vaccination deployment.

This resulted in *Shingrix* sales growing 1% while Meningitis sales grew 46% and Established Vaccines 28%.

The operating margin was 32.7%. The increase in operating profit and margin primarily reflected the positive operating leverage from sales growth including the pandemic adjuvant sales mix.

R&D spend increased 34% as we continued investment behind our RSV and Meningitis development programmes. Increased SG&A reflected investment to support business growth.

The year to date operating margin in Vaccines was 29.3%.

Recent trends in the US indicating strong recovery of paediatric, adolescent and older adult vaccines are very encouraging. There remains, however, uncertainty as to impact of COVID-19, the speed of deployment of mass immunisation programmes and easing of pandemic conditions. This is notable in other key markets across the Group such as Germany and China.

With these dynamics in mind and excluding pandemic adjuvant sales, we expect Vaccines revenues in the full year to be broadly flat.
Consumer Healthcare

Q2 2021

Turning to Slide 25, Q2 revenues in Consumer Healthcare increased 7% excluding brands either divested or under review. Including those brands, turnover grew 3% and Brian outlined the main drivers of this earlier.

In the year-to-date, revenues excluding brands either divested or under review decreased 2%. This reflected the continued negative effects of COVID-19 on consumer behaviour which has significantly impacted the cold and ‘flu category and to a lesser extent, Denture care.

The operating margin for Q2 was 21.7%, up 50 basis points at CER versus last year and this included 110 basis points of negative impact from divestments. The year to date operating margin was 22.4%.

The strengthening of sterling against the US dollar in 2021 year to date given the scale of the US Consumer business has had a significant impact on operating margins. We remain on track to deliver our mid-to-high twenties operating margins in 2022 at 2017 exchange rates.

For Consumer in the full year excluding brands divested or under review, we continue to expect low to mid single digit percent revenue growth.

2021 outlook

Confident in delivering FY guidance

I’ll close with considerations for our 2021 outlook. We are maintaining our full year guidance for adjusted EPS to decline mid to high single digits. This excludes any contribution from COVID-19 solutions. Our strong Q2 performance gives us confidence that if we continue to see improvement in demand for adult vaccinations through the balance of the year, as well as healthcare systems and consumer trends approaching normality in the second half in our key markets, we are likely to deliver adjusted earnings per share towards the better end of our guidance range.

However, as the pandemic landscape evolves we continue to see global differentiation in the pace of deployment of COVID-19 vaccination programmes and the speed of economic recovery. As a result, there remains potential for further pandemic disruption, and we believe it is premature to change guidance.

For Q3 specifically, there are some one-off items in the comparator reviews which will adversely impact the next quarter. These include a Blenrep recognition of pre-launch
inventory in Pharma R&D of slightly more than £50 million, and a one-time benefit from the restructuring of post-retirement benefits of a similar magnitude, which was primarily in SG&A.

With these one-off items in mind, we expect earnings growth in the second half to be weighted towards Q4.

Turning specifically to contribution from COVID-19 solutions, the positive impact on first half adjusted earnings per share was approximately seven percentage points, and, as mentioned earlier, we fulfilled around two-thirds of contracted volumes for our pandemic adjuvant, and expect that the full-year contribution will be approximately four to six percentage points for adjusted EPS growth.

The outcome within that range is dependent on pandemic adjuvant contracting for 2022, and the resulting potential charges within costs of goods sold as we continue to manufacture for this potential.

As part of keeping you informed of our progress in executing against our strategy, in the coming months we will host business and pipeline information sessions, covering among other topics, growth drivers in HIV, an updated outlook for daproductat, and early next year we will provide insights from our General Medicines Product area. We hope you will be able to join us for these events.

With that, operator, we are ready for Q&A.

Question & Answer Session

Andrew Baum (Citi): Many thanks. One question is for Deborah and the second is for Hal.

For Deborah, the translocation inhibitor that you are about to take into the clinic for HIV, you highlighted it as one of the long-term growth strategies. How confident are you in the freedom to operate on the intellectual property, given, I believe, it's a pro-drug of Merck's Islatravir, which has a very expensive patent estate, and last time I looked I couldn't see much in terms of on-going activity between you and the US PTO on securing a patent for your compound? That's the first question.

The second on Alector. Hal, I understand the interest in progranulin from an FTD point of view, but that's a relatively modest indication, so my question is how have you been
thinking about selecting patients in the larger indications – Alzheimer’s, Parkinson’s, given that some of the surrogate markers we have seen have a questionable significance in those indications?

Many thanks.

Emma Walmsley: Thanks, Andrew, and I think you directed your questions very directly, so Deborah, why don’t you kick off, and then Hal.

Deborah Waterhouse: Sure, so, Andrew, as we talked about the business investor update we have a strong pipeline which at its core has integrase inhibitors which we believe will form the heart of any two-drug regimen, either oral or long-acting moving forward.

We have a number of products in the pipeline of which we have an NRTTI, but obviously we have others as well - capsid being our maturation inhibitor, etc., and our plan is to progress all of those medicines to the point at which we will make choices around which of them is the strongest moving forward, so that is what I want to say on where we are today with that pipeline. I think we talked about it in more detail at the BIU, but I guess first our objective is to have maximum shots on goal and also with the help of our Halozyme partnership to be able to deliver for people living with HIV longer and longer-acting medicines.

Hal Barron: Thank you, Andrew, for the question. It’s a good question. The genetics really give us extreme confidence, I think, in the FTD progranulin gene-deficient patients, and we know a number of diseases, both from the biology of non-progranulin FTD, as well as potentially ALS PD, we know is a life sum of disease from lots of genetic data and other sources, and even for Alzheimer’s there has been some genetics suggesting that progranulin may be playing a role, so that is why we are excited. Of course neurodegeneration is a massive unmet medical need where the number of patients with these terrible diseases is growing and the treatment options are limited, so we are very excited about this.

You point out that in drug development for ALS, to some extent more so for PD, and a lot very clear in AD, that the Phase 2 surrogates haven’t been as compelling as we would like them to be. I think there is a lot of opportunity using genetics to identify subgroups. We are exploring a lot of different markers of life sum of function, of immune activation. Imaging data can also help and other biomarkers like NFT and other neuro-markers of degeneration are being explored, and we are hoping to field advances over the next few years to enable some of those to be used for go, no-go criteria, but to be really be specific, I think it is the massive unmet medical need, the genetics, and our confidence that with stratification
variables and these biomarkers that are emerging that we will be able to make informed decisions when we progress these things for Phase 2.

Emma Walmsley: Thanks, Hal.

Simon Mather (Exane): Thanks for taking the questions, I have two as well, the first one on the pipeline, and then secondly on the opportunities of COVID-19. Just on the pipeline, on daprodustat, obviously a less than straightforward advisory committee meeting for Astra and Roxadustat, do you believe you have the right dosing to reduce the risk of hemoglobin excursion and whether or not you’ve seen any any imbalance in the thromboembolism in your trials, and do the issues that AstraZeneca faced in the AdComm in any way change your commercial plans, given the lack of a renal franchise?

Then secondly on COVID-19 solutions, initially I was under the impression it was not for profit, but clearly a strong contribution for the quarter, could you maybe help us understand the large opportunity you could have, because obviously I think at the last count Sanofi had signed up two billion doses for 2021 and 2022, so any help here with respect to the doses that 260m relates to could potentially help us forecast the strong growth potential in 2022 and beyond. Thank you.

Emma Walmsley: Thanks. I think there are a lot of questions across the industry about the outlook for the COVID market in ’22 and beyond, but we’ll come to Roger in a moment to comment on where we’re at and how we see things evolving, but you’re obviously right that we also depend on our partners’ supply, even more than our own.

Let’s first come to Hal on dapro dosing, and I think it would be good, Luke as well, if you’d like to make some comments considering our proven commercial momentum more generally, how you see plans forward, and approach commercially too. Hal first then Luke, then Roger.

Hal Barron: Thanks for the question. I’m not going to comment too much on the Roxa AdComm, but let me just say that we’re very proud of the programme we ran, it’s a very robust programme, had over 8000 subjects treated for up to almost four years, three-and-three-quarter years, in a variety of patients – dialysis, non-dialysis, intermittent dialysis patient trials as well where we looked at quality of life, etc. The study is really very robust, also because these were single trials where they were powered, in ASCEND-D and ASCEND-ND, for non-inferiority and MACE, and we’ve looked at the primary endpoints both on safety and efficacy, but we haven’t done all the sub-group analysis you mentioned, but
we will be doing that later and hopefully presenting that at a major medical meeting ideally later this year.

What I can say is that the haemoglobin targets that we were pursuing as well as the interactions with regulators give us as a fair amount of confidence that we have designed what we think is a very large, simple but robust programme and gives us a clear understanding of both the safety and efficacy of the drug.

Luke Miels: I think from a commercial perspective, I hope the results that you’re seeing today give you confidence in the evidence that we can commercialise a diverse set of specialty care products, in what I think are competitive segments. I think from a forecasting point of view it still remains quite dynamic, and it’s certainly radically different from what it was 12 months ago, in terms of our assumptions, but yes, we’re quite excited about this.

In terms of COVID assets and commercialisation, Sanofi has the vaccines component, we’ve got sotrovimab, we’ve just signed a deal with the European committee for up to 220,000 doses. Just for clarity, that’s 16 countries within the EC are part of that framework, and they have until between now and July 2022 to purchase that.

Just before this call we had another contract come through from another government, and there was another attractive order that came through on Friday, so we’re starting to make progress there, with sotrovimab.

Emma Walmsley: Roger, would you like to talk about the vaccines?

Roger Connor: Certainly, thanks for the question. I think on the adjuvant partnerships, what we’ve seen booked this quarter are contracted volumes that we have in place between the US and Canada, but they represent about two-thirds of that overall expected demand for this year. I think it shows the strength of the adjuvant platform actually, first of all. We contracted separately on this, and governments understand that the adjuvant isn’t just for COVID-19, the adjuvant can be held and then used for future pandemics as well, whether that be a flu or further COVID type, there’s optionality in this platform from a pandemic preparedness perspective.

There are two variables, I would say, that will determine sales going post-2021: Emma mentioned we have to be able to match this up with antigen supply going forward, so whatever those volumes are will be a key variable. Then secondly, we’re talking to governments now around pandemic preparedness and potential use of the adjuvant as well, so those discussions could play out. Some uncertainty there, so it’s difficult to say, but there is certainly a lot of activity going on, and I think governments are realising the positive nature
of a stock build-up of AS03 in particular, which some governments had in place before this pandemic as well, and we will continue to update you as those discussions with governments conclude.

Emma Walmsley: I think more medium term as well, it is worth remembering the rather alarming statistics that only 13% of the world is currently doubly vaccinated, there is, as you will know, an ongoing debate around what the medium term profile is for a booster market or not and as you know, beyond our current adjuvant partnerships we are very involved in the mRNA platform, too, and so we will continue to keep you undated on all of that, but let me reiterate, none of this is in either this year’s guidance nor indeed in the outlooks that we shared with you in June.

The next question, please.

Laura Sutcliffe (UBS): Hello, thank you. Firstly a more specific question on the size of the opportunity for dapro. I think you mentioned an unrisk-adjusted peak sales range of half a billion pounds to a billion pounds back in June. Is that book-ended by use in dialysis and non-dialysis or are there some scenarios at this point where the peak sales could be greater than that billion pounds?

And then secondly could you maybe just give us your thoughts on combination opportunities for your older adult RSV vaccine? Thanks.

Emma Walmsley: Let’s come to Hal, please, and I think, Laura, Iain said during his remarks that we would bring you an updated review once we have more published data but also on the outlook for dapro and just to refer you to what Luke just said, the assumptions on the environment obviously shift according to competitors’ situations and still to date unclear outcomes there as well as our own data which is across dialysis and non-dialysis. So, you will get an update on that more later in the year, but Hal, I don’t know if you want to add any further comments on either dapro but more specifically on combo possibilities for our exciting RSV pipeline?

Hal Barron: Maybe I’m not totally understanding the question but does is it combination meaning adjuvant plus the pre-fusion, is that what you meant by combinations, or do you mean multiple vaccines combined? I didn’t quite understand the question.

Maybe she’s gone. I’ll talk through with the combination meaning why we have decided to use an adjuvant plus the pre-fusion protein if that’s what you think the question was.

Emma Walmsley: Go ahead.
Hal Barron: I think, Laura, when we did the Phase 2 study we looked at the pre-fusion protein alone and with various adjuvants and various doses and the summary of the data, there is a lot of complicated data, but the bottom line is that when you look at the cell-mediated immunity, the pre-F specific CD4 positive cells, you can see that in the elderly when you give the adjuvant, the AS01, you can see a very nice bump in the CD4 positive immune cells which actually elevate to the level that is pretty close to the what you see in young adults.

We think that not only is that a robust T-cell response which we saw actually both with the unadjuvated and adjuvant components, this T-cell immune response we think is very important possibly for efficacy as well as duration and so that's why we decided to combine it with AS01, the same adjuvant that's used with Shingrix which as you can see in the elderly is particularly effective and has long duration. That was why we went ahead as opposed to others with an adjuvanted approach with the pre-fusion protein.

Emma Walmsley: Thanks, Hal. The next question, please.

Jo Walton (Credit Suisse): Thank you. I wonder if I could ask Luke a little bit more about his expectations for Shingrix in the second half of this year. There is clearly very little progress in the ex-US sales overall in the first half of the year, so can you tell us a little bit more about your confidence in the second half, which additional countries you can go into, how the pricing is forming in those new countries now that you are unconstrained in supply and can you just give us some idea of your assumptions on use of, say, a third dosage versus the ability to put your Shingrix vaccine in the other arm which someone goes to get a ‘flu vaccine around September time?

And my second question would be again probably to Luke on the marketing side. You were down 15% on your marketing spend in the first quarter, up 5% in the second quarter. Given what we have learned about the ability to do more digital, etc going forward, can you give us some help as to what you think a reasonable rate of CER marketing growth should be over the next year or so? Thank you.

Luke Miels: On the second one, it's interesting, people were out of the field not spending, not travelling but if we look at face-to-face activity now in Europe and the US with the exception of oncology which is a bit lower, we are 80-85% versus pre-COVID levels. If you add in non-face-to-face digital, the total activity is actually higher than that so in terms of expenditure we will continue to allocate it to where we can drive top line and where we see a good return, so the trends that you are seeing historically are probably a better indicator than quarter one and quarter two.
In terms of Shingrix, it’s really, really interesting. We track these, as you can imagine very, very closely, and it’s a consistent pattern where you see countries vigorously pursue adult vaccination entirely disruptive to Shingrix vaccination, but the good thing is those patterns are consistent, so Germany we are now seeing more than 80% of 60-plus year-olds, which is the population where it is reimbursed are now covered with COVID, and we saw the beginnings of a rebound in June in Germany of Shingrix.

In China the emphasis is still on government vaccination centres deploying COVID vaccines, so we continue to see that disruption.

In terms of other markets, we are also seeing that disruption, so Hong Kong, Australia, for example, where we have just launched. They are obviously at the same point, but we have other launches in Spain, and Italy, and the UK, in broader populations, but also sub-populations.

In terms of pricing, we have seen that level hold up. Now, sometimes when we go into these markets we go in with immuno-compromised population first because we can get the most attractive price at that point, and right now we can use all the volume in those settings, so I think for the second half we remain confident that we will see a collective response in Shingrix.

In terms of boosters, we don’t assume the booster this year, and it is interesting, when you look at the market research in terms of people’s intention for vaccines, we have covered the 50% on the slide, but also if you ask them relative to other vaccines, it is significantly higher than pneumonia and pertussis, and other options for adults, and second only to flu in terms of future intention to get a vaccine.

I think there may be some vaccine fatigue on the part of adults, but, again, everything that we are seeing indicates that the second half will be as expected.

Emma Walmsley: Lastly, Jo, as well on COVID, you know that the guidance is that it is possible, but as Luke said, the experience will be that there is a bit of human instincts of fatigue that people would rather leave it for a few months, that we have the stats on that and we are running co-add studies as well, so that should equip us well.

Fundamentally, this is a disease that one in three people get. We know the underlying demand is good and, as Luke said, we are being able to maintain economics and confidentially outlook that we laid out for the five years, including with lifecycle innovation, which you also saw from recent announcements in terms of expansion of cohort.

James Gordon (JP Morgan): Thanks for taking the two questions.
The first question was on the older-adult RSV vaccine that is in competition, so potentially the biggest product in the pipeline, but I saw Pfizer just announced in their Phase 2 Challenge study there is 100% efficacy in adults, and they also said they are going to kick off their Phase 3 in September this year and they could report as early as Q1 next year, so my question is what does mean for GSK’s older-adult programme? Does the Pfizer data suggest their product could be at least as effective as yours or do we need to be careful in trying to compare quite different endpoints?

Could you do the same thing? Could you accelerate your Phase 3 and have data in the same sort of timelines, or are there reasons yours might take a bit longer?

The second question, which is a clarification on daprodustat. As already mentioned, Roxa has had a tough AdComm. Although they had a non-inferiority headline on MACE safety, the point estimate looked worse in the ESAs and that didn’t go very well at the AdComm, but it sounds like you are very, very confident in your product, so can you just confirm that’s because yours looks differentiated from Roxa, and then your point estimate on safety does actually look better?

Emmma Walmsley: Hal, why don’t you take both of those, and, Roger, if you want to add anything on these broader RSV’s perspectives, we can come back to you. Hal –

Hal Barron: Thanks, James. Look, I am not going to make too many comments on the announcement of Pfizer, but let me just highlight a few things about what we know about our project and why we are so excited about it.

First of all, just to anchor everyone. Of course, RSV in older adults is an enormous unmet medical need with just in the United States, alone, over 180,000 people hospitalised, and as many as 14,000 of those unfortunately die.

Our Phase 2, as I was alluding to this earlier, really does show pretty robust B-cell response with neutralising titers that are very comfortably in the range where we expect significant efficacy.

I am personally very pleased that this data, that the prefusion antigen is the right one, as evidenced by our data, as well as now with Pfizer’s, so that is exciting.

It is also important to remember that our programme has this AS01 adjuvant, which I explained earlier provides this T-cell immune response, which we think will actually increase efficacy like we saw with RSV, but also maybe potentially duration, etc., so it is a differentiated vaccine combination, if you look at the pre-f antigen as well as the very effective proprietary AS01 adjuvant.
I think it is also important, if I understood it correctly that while we are very confident that the immune response will be mounted effectively in the 18-to-50 year olds, this is again the older adults is an older population where, again, we need to be ensuring we have the most robust immune response to protect them as their immune systems are different and, as I said earlier, the T-cell immune response wasn’t normal in a non-adjuvanted RSV vaccine, and that’s why we chose to use the adjuvant because the T-cell response became much closer, actually almost identical to human adults.

In terms of the timelines and speed, it’s important to remember that, as we said, we are choosing this older adult population where we think the greatest unmet medical need is, and the timing of these studies is difficult to predict because, first of all, it has a lot to do with the size of your trial. Our study is very robust, we are enrolling 25,000 patients to ensure that we understand the safety and efficacy profile and potentially do sub-group analyses. Of course, the number of events determines how long the trial lasts, and the enrolment rate has a strong impact on that, as well as the treatment effect of the drug. I can tell you that we are very confident that this is one of the most important projects in our pipeline, and we are doing everything we can to expedite it as fast as we can, and we’re optimistic that we will complete this in a very timely manner.

As far as daprodustat, I’m again not going to comment on the Roxa AdComm, although what you stated I think was pretty clear from the discussion. We haven’t presented have any data from the ASCEND trials, so it would be inappropriate for me today to comment directly on the point estimate and confidence intervals.

I will say, however, that as you said, the recent Advisory Committee meetings have disclosed, I think pretty clearly, that the FDA wanted to see a non-inferiority margin of 1.25, I think that was pretty clear from the meeting, and stated many times. We have previously said that our design of the clinical studies were done with input from regulators and agreement from regulators, so I don’t want to say more than that, but I’m very excited about the fact that we have five Phase 3 studies that were positive, and that this robust programme is going to be a very robust package for regulators to review.

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

Kerry Holford (Berenberg):  Thank you. Two questions, please: firstly on the COVID antibody, I wonder if you are willing to give us an idea of the effective price per dose that you have secured for the dose order that you’ve secured to date, and over what timeframe you expect those orders to be delivered through the books. Then on the flu vaccine, following the recent news you’ve begun to ship over 50 million doses in the US. Is
it fair to conclude that the sales of flu vaccine this year should likely exceed the 2020 figure, which I think was around £730 million? Is that fair? Thank you.

Emma Walmsley: Thanks. I’m going to ask – only because I think he should have a question – Iain to talk about the flu outlook, and we’ll come back to Luke on the timing. I would say the short answer to - are we going to give you the precise pricing of our contracts would be no, but let’s go to Iain first, and then come over to Luke.

Iain Mackay: Don’t feel compelled to give me a question!

On a volume basis we would expect numbers to be broadly similar to last year. However, you will recall from our commentary on the 4th quarter last year results, which we did in early February, that we had a very significant RAR adjustment in flu last year, so netting out that RAR adjustment which we clearly won’t see the benefit of again, I think volumes would be expected broadly similar, but in sterling terms will be slightly less.

Emma Walmsley: Yes, and I would say that in the outlook of the 4-6% beyond guidance EPS, that includes the recent contract –

Iain Mackay: It does, indeed, yes.

Emma Walmsley: It does, so that’s worth noting. Luke, you mentioned it before, is there anything else you want to add on the delivery?

Luke Miels: What we now need to do, we have this overarching contract, we need to approach these 16 countries, which include all of the major European countries, and sign up volumes. We also have got a number of other countries outside Europe that we have contracts for, so I’m hoping that in Q3 we can give you a lot more granularity, because we’ll have those in hand.

In terms of pricing, the only price that was given publicly was 2100 WAC in the US, where we’re selling a small number commercially. For Europe, you should just assume it’s in the range of industry pricing.

Emma Walmsley: Next question please

Geoffrey Porges (SVB Leerink): Thank you very much, a couple of questions for Hal. First, just on the IO portfolio you’ve highlighted the CD226 portfolio many times, I’m just wondering if you could give us a sense of when we could see the first clinical proof of concept for the different combinations for that whole strategy. Then secondly, on daprodustat, do you believe that we should expect class labelling for daprodustat for infection risk, thrombosis risk, and seizure risk, given the imbalances seen in your
competitor’s trials? As you know, the FDA is being extraordinarily cautious about labelling in the CKD population for the ESAs, so would that be prudent on our part? Thanks.

Hal Barron: Thanks, Geoff. The IO portfolio is actually quite robust now and the CD226 axis I think is well covered with both now the anti-TIGIT from iTeos, we have the CD96 inhibitor, which is quite advanced in our collaboration with 23andMe, and the furthest behind but also exciting is the anti-PVRIG, which should get into the clinic next year with the deal with Surface Oncology recently.

All of those of course can be combined with each other as well as with dostarlimab, so the four-drug combos are quite complicated and there will be a lot of dose-ranging that is needed, indication-ranging if you will. We will be getting data from combinations with CD96 and dostarlimab first, so that will be the first readout. That should occur in 2022. We should be able to get some PVRIG data probably in 2022 as well. The TIGIT combinations with dostarlimab will be seen in 2022, hopefully some data.

Of course it all depends on how robust the data is and whether we see activity at various doses. The triplet will take a little longer just because we have to get through all the dose-ranging and safety, but that should come following the observation of proof-of-concepts with dose combinations, so an exciting opportunity we think to take the field beyond the PD1 era and enter into a CD226 era, possibly a doublet or maybe even a triplet. If the cards fall appropriately we can make a triplet that would be profoundly beneficial for patients if that was the case. We are excited about that opportunity.

In terms of dapro, I really don’t want to comment on discussions that we haven’t yet even started with regulators. The data that I mentioned that we are very excited by was the primary endpoint. We haven’t done any of the subgroup analyses and other sensitivity analyses that are going to be of course needed. We will be doing those very soon, we should have that data and hopefully be able to present that later this year.

Of course then that’s followed by discussions with regulators, digestion of the class as you say, and I think it would be premature to have any speculation on what anyone else’s labels might show for sure. Ours will of course follow the data. Thanks for the question, Geoff.

Emma Walmsley: Next question please

Keyur Parekh (Goldman Sachs): Good afternoon. Two questions, please, one on commercial opportunity for Blenrep. Luke, I noted that Bristol reported first quarter revenues for their BCMA CAR-T of $24 million that’s roughly similar to the £21 million you
reported for Blenrep. Just give us a sense of where Bristol is taking share and how confident you are for growth of Blenrep even without the additional studies reading out.

And then separately for Brian. Brian, congratulations on the CEO designate, not surprising there at all, but your slide talks about e-commerce being 7% of sales for the Consumer Healthcare business, up 30% for the quarter. I am just wondering if you can give us a sense for how that 7% stacks relative to your peer group, what was the corresponding number last year, so just give us a sense for how big you think e-commerce might be for the Glaxo Consumer Healthcare business going forward. Thank you.


Luke Miels: Sure. Keyur, I will just lay this out; right now we have about a quarter of patients in the US who are fifth-line in terms of patients on drug, but the rest are sixth, seventh-line but one in three new patients coming on to fifth-line, so we are starting to move up there.

There has been a bit of pressure in that fourth-line setting. It is a relatively small number of patients, there is a lot of competition for them with studies such as teclistamab and the biospecifics.

In terms of the CAR-T let’s see, there are some ordering patterns probably there. Again it’s concentrated in academic centres. Where we are now seeing our growth is in the community which is a natural progression. In the end, though, we need to address the dosing and as Hal has outlined, there is a lot of activities to do that to penetrate the earlier lines of treatment where the vast majority of the opportunity for this product exists.

We are less concerned around Pepaxto. Again, I think that is being used in the EMD population and some of the tox around haem is impacting treatment length so we have more work to do to capture those fourth-line patients in the community and we are working very hard to do it.

Brian McNamara: Good question and thanks for the congratulations also. As you said, our e-commerce percent of sales is 7% up 30%. Last year we were at 6% of sales, so we continue to see progression. As far as how that compares to competitors, it really is quite dependent on portfolio. If you look across our portfolio say in oral care, we are over-developed where we have higher share than any of our brands online versus offline. In OTC, we are pretty much in line but skewed towards again being over-developed, so slightly better than I would say the competitive set.

On VMS, it’s an area where we are catching up, so we were under-developed on VMS and there are many more digital native brands in that space but we are growing in that
area very aggressively and we are seeing really good progression in that area, so I continue to believe this is an area that is going to continue to grow really healthy. We have seen a massive shift in these categories to online shopping as part of the behaviour that came with the pandemic, and we see that consumer behaviour continuing, and I feel really great about where we are at in our capabilities in this area to continue to win in this space.

Emma Walmsley: Thanks, Brian, and I would also like to add my very public congratulations and pride in your appointment.

Brian McNamara: Thank you, Emma.

Iain Mackay: I am just glad you got a question at long last, Brian.

Emma Walmsley: Yes. The other thing I would just overlay, it is not only the brand power on digital, it is also the geographic mix, where because of our strong presence in Consumer in both the US and China, which are very e-commerce friendly regions that also helps drive both our capability and our competitiveness on that. Next question, please.

Emmanuel Papadakis (Deutsche Bank): Hi, thank you taking the question. I will make it two for Brian, actually.

A question on margins, please. You reiterated mid-to-high 20s for next year, I think, but obviously that’s, as part of the current business, not as a stand-alone. I know there has been some discussion of what additional standalone costs you would incur, so any insight you can offer us at this stage in terms of the step-down on margins we are likely to see as a standalone business, and, if not now when are we likely to get that number?

Then, maybe a question on the R&D side, you reported a miss in MOONSTONE. Perhaps you can give us some comments on the data even if it missed, on the target you were after for ORR and what does that imply, if anything, for clinical development programme for Zejula? I don’t actually think we are due any pivotal or proof of concept data points for the rest of this year or even next. Are we just waiting for that ZEAL lung maintenance study in 2024, or are there other things that we should be thinking about or looking at that you are considering? Thank you.

Emma Walmsley: Thanks very much, Emmanuel. We will hand them over to Hal, but first of all, Brian, do you want to comment on when it will be shared?

Brian McNamara: Yes, as Emma mentioned, we will doing a Capital Markets Day in the first half of next year. We haven’t identified that date yet, but at that time
is when we would share much more detail around the business in a lot of areas around our 
cash flow and our margin progression, and included in that would be any of the one-off 
costs, so you would expect to hear about that next year before separation.

Emma Walmsley: Thank you. Hal, MOONSTONE, any implication there?

Hal Barron: Yes, Emma, part of Emmanuel’s question dropped out. Could 
you just repeat it briefly?

Emmanuel Papadakis: I can briefly if you can hear me.

Hal Barron: Thanks, Emmanuel.

Emmanuel Papadakis: You are welcome. It was just a question on a miss 
in MOONSTONE, what that implies to the clinical development and next data points we 
should be looking for, thinking about?

Hal Barron: Thank you. That’s what I thought you said, I just wanted to 
confirm.

You are correct, MOONSTONE has been stopped. I think it is important to point out 
MOONSTONE was a single-arm open-label Phase 2 study where we were looking at 
response rate. It was in the most difficult patients with ovarian cancer to treat, the so-called 
platinum-resistant ovarian cancer patient populations, who actually do not very well even 
with chemo and bevacizumab. These are second-line, those who failed on bevacizumab, so 
a very resistant population, but was based on some very small numbers of patients that 
suggested maybe the combination of a PD1 plus PARP would be beneficial, so we had a 
very high bar and the study when we looked at the response rates didn’t suggest that it was 
going to achieve the bar that we had.

Now, the study that we have always been more optimistic about, because, again, 
MOONSTONE was in the treatment setting, where, frankly, the data for PARPs in the 
treatment setting has been very unclear on efficacy, and the maintenance setting is where 
you really see the benefit, and the study that we thought would most definitively identify an 
opportunity for the combination for a PARP plus PD1 was the FIRST trial, which is where 
patients who received a chemo with dostarlimab and niraparib versus standard of care 
platinum-based regimen, and that is enrolling well and we should see data for that before the 
next opportunity to have a direct readthrough for this potential synergistic impact.

We are also, as you mentioned, committed to other combinations of niraparib and 
dostarlimab. We have the Phase 3 RUBY Part 2 section where we are comparing 
dostarlimab in combination with niraparib for patients with endometrial cancer, and, of 
course we have the ZEST and ZEAL, both of which could be transformational for patients –
ZEAL being in the frontline lung cancer setting and ZEST being a novel study design for women with breast cancer who are surgically treated for the intent of cure, but who have evidence through tumour measurements in the blood, the cell-free DNA from the tumour being evident as a biomarker that we will be using to start treating people to potentially prevent the disease from recurring, so two innovative and I think exciting trials, in addition to FIRST will add hopefully a lot to patient benefit and to the lifecycle of niraparib.

Emma Walmsley: Thanks, Hal.

Iain Mackay: We have time for one more question and then we will have to wrap it up, if there is one more question.

Graham Parry (Bank of America): Hi, guys, thanks for taking the question. Firstly on Shingrix, I just wonder if you could help us square the circle of the different commentaries: the guidance is a little cautious, but you’re still talking confidence in strong recovery in 2H, so are you still expecting a very strong 2022? I think the consensus is looking for 25% year on year growth, so does that sit within the range of your outcomes internally?

Secondly, just following up on the question on Pfizer’s RSV vaccine timing, that suggests perhaps they might be expecting more RSV events coming this season, if they think they can get a data readout in Q1, so is it also the case that perhaps the RSV incidence is picking up, relative to what you assumed when you originally planned your studies, meaning your data could also come earlier? Thank you.

Emma Walmsley: Hal, we’ll come back again to the RSV study, and just on Shingrix, yes, we do see a significant step-up in 2022, we’re not going to start commenting on versus specific annual guidance on that one Graham, but Hal, would you like to comment on the RSV studies?

Hal Barron: Yes, just to reiterate, there are a lot of assumptions that go into determining how long a trial will take. Of course, as I mentioned before, it has a lot to do with sample size, so our enrolment of 25,000 people is going very well. It does have a lot to do with the number of events, which is actually related to some extent to the treatment effect, and there is some reason to believe that the events might be higher than anticipated, based on the fact that in 2020 there was very limited RSV and sometimes without the prior season immunity, there are more clinically significant cases. But again, we are all estimating these things, and it would probably be more like a class effect, if you will, that if there are more
events we’ll be seeing that in and any trials in RSV will not be unique to us or Pfizer or anybody else, so we just have to wait and see. Of course, anything is possible, but the idea that maybe there’s more RSV because of the 2020 low levels, there is some data to suggest that might be the case, but we just have to wait and see.

Emma Walmsley: Thank you very much. With that, everybody, we’ll finish today’s call and look forward to catching up with you in the coming days. For those that we don’t get a chance to speak to, I hope whether it’s near or far you get some kind of break, and look forward to catching up again soon. Thank you, goodbye.

[Ends]