

**GLAXOSMITHKLINE  
SECOND QUARTER 2020 RESULTS  
PRESENTATION TO ANALYSTS**

**Wednesday, 29 July 2020 @ 14.00 hrs**

**Sarah Elton-Farr (Head of Investor Relations):** Good morning and good afternoon. Thank you for joining us for our Q2 2020 results which were issued earlier today. You will have received our press release and you can view the presentation on GSK's website. For those not able to view the webcast, the slides that accompany today's call are located on the Investor section of our website.

**Cautionary statement regarding forward-looking statements**

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

**Agenda**

Our speakers today are Chief Executive Officer, Emma Walmsley, Iain Mackay, Chief Financial Officer, and Dr Hal Barron, Chief Scientific 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 and, with that, I will hand the call over to Emma.

**Emma Walmsley (Chief Executive Officer):** Thank you, SEF, and welcome everybody to today's call. I hope that you and those around you continue to be well.

**Q2 progress**

At this half-year mark amid what have been extraordinary circumstances, I am pleased to report that we have mobilised across GSK to respond to the pandemic and have simultaneously advanced our long-term strategic goals at pace. Adjusting rapidly to the new ways of working, we have secured supplies, strengthened the pipeline, progressed multiple solutions for the pandemic and our integration and separation programmes are all firmly on track.

While we have seen some COVID disruption impact our performance this quarter, we are pleased with half-year delivery and our confidence in our business and its prospects remains high.

Hal will give you an update on our innovation progress shortly but particular highlights from the last few months include: in Oncology, the US approval for *Zejula* as a first-line

monotherapy maintenance treatment for women with ovarian cancer. We are also pleased to see positive opinions from the FDA's ODAC and CHMP on belantamab mafodotin, a medicine we believe will be very important for multiple myeloma patients.

In Infectious Diseases, we made great progress in HIV with the presentation of truly ground-breaking data for long-acting cabotegravir in the PrEP setting, and in Vaccines we are poised to move into pivotal studies for very significant opportunities in RSV and meningitis, and we have just announced our collaboration with CureVac targeting up to five infectious disease pathogens.

Despite short-term pressures, our performance fundamentals continue to strengthen with good momentum and strengthening commercial execution on our key growth drivers. We are winning share in Respiratory, in Oncology with *Zejula*, with two-drug regimens in HIV and in Power Brands in Consumer, including a notable acceleration in VMS demand.

We have seen strong acceleration of our digital capabilities as we continue to increase our share of voice with HCPs, both virtually and face-to-face where possible, as well as winning share in an accelerating e-commerce channel in Consumer.

Our Consumer integration and company separation programmes both continue to progress well and undistracted, with over 90% of Pfizer revenues now successfully remotely switched over to GSK systems. Iain will update you on this and broader cost discipline later.

We continue to progress our Consumer divestments, including Horlicks, to set up the world's leading pure play consumer healthcare company with the most competitive portfolio possible.

On Trust, alongside others, we helped launch a \$1 billion AMR action fund to fight another major risk to global health. We were delighted to receive US approval for a new paediatric formulation of dolutegravir and, finally, I was very pleased to see all-time record levels of employee engagement in the quarter, driven by pride in GSK's purpose, our people's sense of being valued and the positive cultural changes we are making.

### **Comprehensive approach to respond to COVID-19**

We have taken a comprehensive approach to respond to COVID-19, using our science and technology to develop adjuvanted vaccines and therapeutic solutions, while, at the same time, accelerating momentum on existing R&D projects and investing in our future capabilities and competitive advantage.

We at GSK firmly believe multiple vaccines will be needed to fight COVID, which is why we have deliberately taken a unique collaborative approach with the proven technology to develop adjuvanted vaccines.

GSK's adjuvant is proven in a pandemic situation and, alongside improved efficacy, it can help reduce the amount of antigen needed and get to scale faster.

We can deliver more than a billion doses of adjuvant in 2021. We announced an agreement to supply the UK this morning and we are in late-stage discussions with multiple other governments, taking a global and access-led approach.

We are also making good progress to start clinical development of promising therapeutic antibody options, which could be in market next year.

We have moved to accelerate our access to new technology platforms through strategic collaborations that will advance our R&D in multiple disease areas and could be relevant in future pandemics. And we have continued to accelerate momentum with existing projects, which remains important while so much attention is focused on COVID.

## **Q2 performance**

Of course, COVID has disrupted our performance this quarter. Proforma Group sales declined 10% in CER terms with the greatest impact of the pandemic seen in our Vaccines business as access to vaccinations was limited. We also saw some of the patient and consumer stock-build in Q1 reverse, as expected.

Group adjusted operating margin for the quarter was 22.9%, reflecting particularly the performance in Vaccines, together with increased investment in our pipeline and new products, partly offset by ongoing tight cost control.

On the total basis, earnings per share were up over 100%, at 45.5 pence, and adjusted earnings per share decreased 38% to 19.2 pence.

For the first half overall, sales were up 8% reported and flat on a proforma basis, with continued progress on our performance in Pharma and Consumer, and despite the significant but short-term impact we saw from the pandemic in Vaccines. Adjusted operating profits were down 7% proforma, as we continued to invest behind advancing our pipeline and new project launches. The momentum here is encouraging in our key growth drivers.

## **Strong underlying demand and outlook for key growth drivers**

In **Vaccines**, despite lockdown impacts on vaccination rates, we believe the underlying demand for our key vaccines, including shingles and meningitis, remains very strong. Guidance from government agencies, including the CDC, is emphasising the importance of routine immunisations and catch-up for all age groups, including adults. We are seeing encouraging signs of recovery in selected geographies in Q3 and we are investing to support

it, though there remains some way to go to get back to pre-COVID levels for adult vaccinations such as *Shingrix*.

We expect to see vaccination rates recover in the second half of the year. We are confident it will come although, clearly, there remains a degree of risk for the exact timing. We continue to work on expanding capacity for *Shingrix* to support recovery and demand and to enable further launches around the world for this important and much-needed vaccine.

Sales in our Respiratory portfolio are performing strongly. With *Trelegy*, we continue to lead the market as a single inhaler triple therapy and also grow the market, with sales up 58% in Q2. We are looking forward to the FDA's decision, too, on the asthma indication for *Trelegy* later this year.

For *Nucala*, we continue to see strong growth, aided by strong uptake of at-home administration. We are retaining leadership in all key markets and expanding our label in other eosinophilic indications, which will further cement our leadership.

In **Oncology**, we have built a strong commercial platform from which to grow *Zejula* and also launch belantamab on approval. For *Zejula* in the US, the latest Flatiron data, which was for May, already indicated a 50% increase in *Zejula* share in first-line maintenance to 21%. Although, with the pandemic, we have seen delays in the initiation of chemotherapy and debulking surgery in recent months, which does add a near-term headwind, we remain confident in the long-term outlook for *Zejula* and there is a lot of opportunity with new guidelines and currently low levels of PARP penetration in first-line maintenance. We continue to believe that *Zejula* is an important medicine with potentially unique properties.

In **HIV**, as expected, we have seen the unwind of Q1's pull forward. Whilst the pandemic has reduced switching and new diagnosis, we nonetheless continue to see increases in *Dovato* and *Juluca* NBRx share, to 9% this week in the US, and we are optimistic that two-drug regimen growth will accelerate when the situation normalises. We also expect *Dovato* to benefit from a broader US label later this quarter, with the anticipated inclusion of data from the TANGO study.

We continue to make great progress on innovation in HIV and Hal will give more detail on this in a moment.

I will now hand over to Iain, who will take you through our financial performance and outlook.

## Q2 2020 Financial Results

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

### Q2 2020 financial results

On slide 10, there is a summary of the Group's results for Q2 and the half year. In the first half, turnover was up 8% on a reported basis and flat on a proforma basis, excluding the impact of disposals, where these were up 1%.

Adjusted operating profit was up 2% reported and down 7% proforma. Adjusted earnings per share was 56.9 pence, down 6%.

For Q2, turnover declined 3% on a reported basis and 10% on a proforma basis. Excluding the impact of disposals, revenues were down 8%. As you've heard from Emma, we continue to see strong underlying performance of the business. However, during Q2 we saw turnover adversely impacted by the COVID-19 pandemic with the most significant impact within Vaccines. I will go into the business drivers in a moment.

Total operating profit was up 90% with total EPS up over 100%, primarily reflecting the net profit on the disposal of *Horlicks* and of other Consumer Healthcare brands.

On an adjusted basis, operating profit was down 21% reported and 27% proforma while adjusted EPS was down 38%. Earnings were impacted by lower turnover, continued investment in R&D, support of new product launches, an increased effective tax rate and a higher non-controlling interest allocation of Consumer Healthcare profits. These were partially offset by continued tight control of operating costs across the business.

We delivered £2.5 billion of free cash flow in the first half, reflecting favourable working capital, timing of RAR payments and proceeds from divestments of intangible assets.

And on currency in the quarter there was a 1% tailwind on both sales and adjusted earnings per share.

## Results reconciliation

Slide 11 summarises the reconciliation of our total to adjusted results. The main adjusting items in the quarter were major restructuring which reflects continued progress on the Consumer Healthcare integration and Separation Preparation programmes; transaction related, within which the main contributor was a charge relating to the remeasurement of the contingent consideration relating to ViiV Healthcare; and finally the disposals column includes the disposal in the quarter of the *Horlicks* and other Consumer Healthcare brands.

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

## Pharmaceuticals

Slide 12 summarises the Pharmaceuticals business where revenues were down 5% in Q2, primarily resulting from the decline in Established Pharma.

As expected, the COVID-19 related customer stock-building in Q1, predominantly in Europe and the US, broadly reversed in Q2 with only a minor dolutegravir impact in Europe and the US remaining. We estimate that the impact of the stocking reversal on growth in Q2 was approximately 4%.

The quarter also saw lower levels of new patient prescriptions in the US and Europe, reduced market demand for allergy and antibiotic products in International and some pressure on net prices in the US informed by a shift in channel mix.

For the first six months, Pharma revenues were flat CER and adjusted operating margin was 25.4% CER.

Emma has just taken you through the performance of some of our key products so I will just point out a couple of important considerations with respect to the second quarter.

Starting with **Respiratory**, sales were up 16% with strong growth from *Trelegy* and *Nucala*. In **Oncology**, *Zejula* sales were at £77m in the quarter, up 32%. In **HIV** revenues were down 3% with the dolutegravir franchise down 2% globally. Sales were impacted in the quarter by customer destocking following the increased demand in Q1 due to COVID-19. We continue to see good uptake of the two-drug regimens, however, giving us confidence in the longer term growth outlook.

Excluding the impact of customer stocking, we estimate that HIV sales would have increased slightly in the quarter and we expect sales to be broadly flat for the full year.

Our **Established Pharmaceuticals** portfolio declined 17% overall, impacted by *Ventolin* which was down 39% as a result of generic substitution in the albuterol market as well as pandemic-related destocking in Europe.

*Seretide/Advair* sales were up 2% with the US up 34%, reflecting higher demand in the ICS/LABA class, offset by declines in Europe as a result of generic competition and pandemic-related destocking.

Outside Respiratory, the Established Pharma portfolio declined by 20%, primarily reflecting lower demand for our Dermatology products and Antibiotics during the pandemic.

Overall in Pharma, trends remain encouraging and our new products continue to perform well. We continue to expect Pharma sales to decline slightly in 2020, excluding divestments.

Turning to the Pharma operating margin, as anticipated we saw a decline in Q2 primarily reflecting sales performance while we continue to invest in R&D behind priority assets and promotional activity for new launches.

We have maintained a sharp focus on cost management across the business, with focus on increased efficiency in non-customer facing activities. More on this subject later.

## **Vaccines**

### **Q2 2020**

Slide 13 gives you an overview of Vaccines performance with sales down 29%. As expected, Q2 revenues were impacted by containment measures, informing customers' ability and willingness to access immunisation services across all regions.

*Shingrix* declined 19% globally, primarily reflecting lower vaccination rates in the US, which was partly offset by favourable return and rebate movements.

The meningitis portfolio declined 29%, impacted by lower demand across all regions. In the US, *Bexsero* maintained and *Menveo* grew market share.

Hepatitis vaccines declined 62%, primarily reflecting travel restrictions.

DTP-a containing vaccines declined by 43% as vaccination rates fell. Sales of *Infanrix/Pediarix* were also impacted by unfavourable year-on-year US CDC stockpile movements and supply constraints in Europe.

One should also note that divestments of the travel vaccines *Rabipur* and *Encepur* resulted in a drag to vaccines sales in the quarter of around 3%, and will have a similar drag on vaccines sales growth this year.

The operating margin of 23.4% reflected the impact of reduced sales in the quarter.

In the first half Vaccines revenues were down 6% CER, and adjusted operating margin was 38.2% CER.

## Consumer Healthcare

Turning to slide 14, revenues in Consumer Healthcare on a proforma basis were flat, excluding brands either divested or under review, reflecting the unwind of increased COVID-19 demand we saw in Q1. Including those brands, turnover declined 6% proforma.

At a regional level, China returned to growth as mandated retailer shutdowns were lifted, however this was more than offset by declines in Europe and the US as a result of the pantry loading unwind.

The vitamins, minerals and supplements category continued to grow strongly, with sales growth in the high teens on a proforma basis, this higher demand reflecting an increased consumer focus on health and wellness.

In Pain relief, sales benefited from the continued strong performance of *Panadol*, and the successful Rx to OTC switch, and launch, of *Voltaren* OTC in the US. This was offset by an adverse impact on *Advil* due to initial market misinformation relating to COVID-19 ibuprofen treatment, which has since been corrected. We are also excited about the launch of *Advil Dual Action*.

Sales also benefited from increased retailer stocking ahead of a systems cutover in North America as part of Pfizer integration activities, which added two percentage points of growth in the quarter, largely in the Digestive health and Pain relief categories. This benefit is expected to reverse in Q3.

We are close to fulfilling our commitment to divest £1 billion of non-core brands in order to refocus our portfolio, as well as funding integration and restructuring activities within Consumer Healthcare.

Operating margin for the quarter was down 120 basis points year on year.

In the first six months Consumer revenues increased 2% CER proforma and 7% excluding the impact of divested/under review brands; proforma adjusted operating margin was 24.5%.

With the integration on track, we are delivering synergies as anticipated, and continue to maintain strong cost control while investing behind our brands.

## Sales and Adjusted operating margins

On slide 15 we summarise the sales and adjusted operating margin for Q2.

As I have mentioned, our group operating margin was down 530 basis points on a proforma basis, and was informed primarily by the sales impact in the quarter, while we continue to invest in R&D behind priority assets.

SG&A for the quarter was down 5% on a proforma basis, reflecting integration savings and reduced promotional and variable spending across all three businesses as a result of this pandemic. This is partially offset by targeted investment in customer-facing activities focused on growing the top line.

We continue to maintain a sharp focus on cost management and are on track to deliver, firstly, synergies from the Consumer integration, achieving £500 million savings between now and 2022; secondly, benefits from the Separation Preparation programme across multiple activities including supply chain, Development in R&D, commercial operations and our global support functions resulting in efficiencies which will deliver £800 million of savings by 2023, and will contribute to meaningful margin expansion from 2022 onwards. Thirdly, savings from learnings over the past four months, with opportunities initially across travel and entertainment, conferences and meetings, commercial real estate and through finding new ways of engaging with our customers, HCPs and other stakeholders.

We have included in the appendix this analysis covering the year-to-date information.

### **Adjusted operating profit to net income**

Moving to the bottom half of the P&L, I would highlight that interest expense was £227 million. The increase primarily reflects reduced swap interest income on foreign currency hedges and lower interest income on reduced overseas cash, post the close of the divestment of *Horlicks* and other Consumer Healthcare nutrition products in India. This was partly offset by favourable refinancing of term debt.

The effective tax rate of 20.5% reflected delays in the settlement of open periods and an updated forecast profit mix. We now expect full year effective tax rate of around 16%, and non-controlling interests reflected Pfizer's share of profits of the Consumer Healthcare JV.

### **Free cash flow of £2.5bn**

We have delivered cashflow of £2.5 billion in the first half of the year.

The increase primarily reflected a reduction in trade receivables as a result of collections following strong sales in Q1, beneficial timings of payments for returns and taxes, a lower seasonal increase of inventory, and disposals of intangible assets. These were partly offset by higher dividends to non-controlling interests.

Recognising the lower Q2 revenues, and the H1 impact on timing of RAR and tax payments, we anticipate lower free cashflow in the second half. Overall, we still expect cashflow to be a step down from 2019.

As well as the positive cashflow we delivered in H1, we closed the quarter with strong cash balances, have 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.

We are maintaining our full year guidance of adjusted EPS down 1% to 4%.

Our performance for Pharma and Consumer in the first half of the year is in line with where we expected to be. We expect limited impact from COVID-19 related stocking patterns for the balance of the year in these two businesses.

However, there remain notable risks to business performance over the balance of the year, primarily in Vaccines. As evidenced in the second quarter, the pandemic's biggest impact has been here. The key variable in achieving adjusted EPS guidance in the full year is the timing of the recovery of vaccination rates.

Underlying demand for our vaccines portfolio remains strong, and we have put in place a range of actions to support the recovery of vaccination rates which we anticipate, and are seeing take place so far, in the third quarter.

Should we experience a delay in recovery of vaccination rates of, say, three months, for example, this would adversely impact full year adjusted EPS by up to five percentage points.

As we move into the second half of 2020, there is no change in our capital allocation priorities. These are: investing in R&D behind priority pipeline assets and delivering returns to shareholders, and as noted in our earnings release, we have declared a 19p quarterly dividend in line with expectations we set out earlier this year.

With that, I will hand over to Hal.

## **R&D update**

**Dr Hal Barron (Chief Scientific Officer):** Thank you Iain, and good afternoon, everyone.

It has been two years since I shared our new approach to R&D and I am very pleased with the progress we are making.

Today I will review this progress and then discuss several very exciting medicines and vaccines in our pipeline.

And with that, I'll begin my presentation.

## **In July 2018 we committed to strengthening the pipeline**

Let me start with a brief reminder of our approach to R&D which I outlined in 2018, that is to strengthen our pipeline through a focus on the science related to the immune system, and to use human genetics and advanced technologies, such as functional genomics and machine learning to enable us to identify novel targets that have a higher probability for success and a robust lifecycle potential.

To achieve this, we have focused on four key strategic levers. First, to drive organic growth by focusing our Research organisation on human genetics and on both the adaptive and innate immune system. In Development, we have removed numerous projects from the portfolio to enable us to design and execute robust clinical trials on the more promising programmes.

Second, to effectively leverage business development to augment our pipeline.

Third, to improve how Commercial and R&D work together to maximise the lifecycle of our medicines and vaccines.

And lastly, to shift our culture in R&D to one that embraces innovation by focusing on smart risk-taking, single point accountable decision-making, and hiring and developing outstanding people.

## **Over the last two years we have made significant progress**

I believe we have made significant progress over the past two years.

Over 70% of the targets in research are now genetically validated, with nearly 30 therapeutic targets originating from the 23andMe collaboration.

We have exceeded industry averages for success in proof of concept studies, enabling us to initiate nine potentially registrational studies. In addition, we have had 17 positive read-outs from pivotal studies.

Lastly, we are on track to achieve 14 approvals since July 2018, with potentially five new molecular entity approvals this year alone.

The last three months have seen particularly strong pipeline delivery including, first, FDA approval for *Zejula* in first-line ovarian cancer based on the outstanding PRIMA data, which resulted in a uniquely broad label.

Second, the first regulatory approval for daprodustat in Japan.

Third, terrific PrEP data with cabotegravir that could redefine the management of HIV and, most recently, receiving a 12-0 positive vote from the FDA's ODAC on belantamab mafodotin that was further endorsed by last week's positive CHMP positive opinion in Europe.

## **We now have a biopharma pipeline of 35 medicines and 15 vaccines**

We now have a biopharma pipeline of 35 medicines and 15 vaccines with 39 of these 50 assets having a direct effect on the immune system.

I would now like to discuss several of these programmes in a little more detail.

### **Three new vaccine candidates starting Phase 3 studies**

Starting with the vaccines on Slide 23, I am very pleased to be able to share some great news on three of our vaccine programmes.

First, RSV. Scientists have been pursuing RSV vaccines for more than 50 years but have only recently gained a fundamental understanding of how to induce protective immune response by immunising with the pre-fusion protein. This was used in both our maternal and older adult vaccines.

It is important to note that 50% of infants are infected with RSV before they are one year old, and virtually everyone gets an RSV infection by the time they are two. In children, RSV can cause an acute bronchiolitis which can lead to respiratory distress, hospitalisation and even death. In addition, RSV is an important pathogen in the elderly and high risk adults. Although paediatricians are aware that RSV may cause serious illness in their patients, most internists are less familiar with the morbidity and even mortality associated with RSV in patients over 60. Given the lack of treatment options, this lack of awareness is understandable. In older adults, the infection can cause pneumonia, which can lead to hospitalisation, and it has been observed that the one-year mortality in these patients following RSV infection may be as high as 25%.

Our older adult vaccine not only capitalises on the pre-fusion antigen but it is also combined with our AS01 adjuvant to optimise the immune response, as we did with *Shingrix*. We hope that, if successful, this vaccine will have a meaningful impact on people over the age of 60 who are at the greatest risk from this high disease burden infection.

I am excited to share that we have had positive readouts for both of these RSV vaccines and we are moving both into Phase 3. We hope to share these data with you in more detail at a medical congress later this year.

In addition, we are moving our 5-in-1 meningococcal vaccine, combining serogroups ACWY and B, into Phase 3 trials this year. This will allow us to target the five serotypes that cause most cases of invasive meningococcal disease in one single vaccine.

## **Redefining HIV PrEP with long-acting cabotegravir**

Moving on to HIV, for me, one of the most exciting pipeline data readouts this quarter was the cabotegravir PrEP study, which we announced had been stopped in early May. These impressive data were presented at the AIDS 2020 conference a few weeks ago and demonstrated that long-acting injectable cabotegravir, administered every two months, is 66% more effective than daily pills at preventing people from developing HIV. We look forward to discussing these data with regulators and are working with them on a path towards registration.

In addition, *Cabenuva*, our first long-acting injectable, has been resubmitted to the FDA for approval and we anticipate the response in early 2021.

Lastly, *Rukobia*, our first-in-class attachment inhibitor, was approved at the beginning of the month for heavily treatment-experienced adults who are living with HIV.

## **Developing solutions to help prevent and treat COVID-19**

Now focusing on the pandemic, I am proud of GSK's contribution to developing solutions for COVID-19 and the breadth of the response is summarised on Slide 25.

As already mentioned by Emma, we have progressed a number of adjuvant collaborations to support the development of vaccines for COVID. We believe that by improving the immune response, both cellular and humoral, our adjuvant will have a clinically meaningful impact on the COVID pandemic. In addition, by reducing the amount of protein needed for a vaccine, we will be able to increase the number of doses that can be delivered to those in need.

I believe that our adjuvant may be under-appreciated and may, ultimately, enable antigen-based vaccines to have a superior profile to other approaches.

Two such programmes have moved into the clinic and we expect preliminary data in August on the Clover project. Additionally, our collaboration with Sanofi is on track to move into the clinic in September.

We are also working towards advancing therapeutic solutions for COVID via our collaboration with Vir Biotechnology, which we announced last quarter to accelerate the development of monoclonal antibodies directly to neutralise the virus. We shall be starting the first of these clinical studies with GSK'136 next month.

This quarter, we also started the proof of concept study OSCAR with otilimab, our anti-GM-CSF antibody for the treatment of severe pulmonary COVID-related disease. GM-CSF can act as a pro-inflammatory cytokine that induces survival activation and polarisation of

monocytes and macrophages, which are thought to be implicated in the cytokine release syndrome which occurs in severely ill COVID patients. We believe this is an exciting programme and we anticipate receiving data in the first quarter of 2021.

### **Our focus on immunology is resulting in a world-class Infectious Diseases portfolio**

The next slide underscores that, when looked at in totality, the medicines and vaccines we are developing to combat HIV, COVID, urinary tract infections, hepatitis B and many other infectious disease, as a result of our focus on immunology, have resulted in a world-class ID portfolio with 24 medicines or vaccines in clinical testing, of which more than 80% are immune modulators.

In fact, infectious disease now accounts for almost half of our pipeline. This pipeline of 24 programmes complements our existing marketed portfolio of more than 20 infectious disease therapies that, together, delivered almost \$17 billion in revenue for GSK in 2019.

Analogous to the declared war on cancer which has resulted in a marked increase in investment by the pharma/biotech sector on discovering and developing important medicines for cancer patients, we are optimistic that the world's experience with COVID may lead to an increased focus on the importance and value of developing new therapies to treat and prevent infectious diseases.

With that, I would now like to turn to another key portfolio within the R&D pipeline that has benefited from our increased focus on the science of the immune system – that is oncology.

### **We have built a strong oncology portfolio with 13 of 14 programmes modulating the immune system**

Slide 27 shows you how our focus on immunology has helped to strengthen our oncology pipeline where we now have 14 assets in development, 13 of which act by modulating the immune system.

I would like to briefly share some of the progress we have made over the last two years and flag key upcoming data we anticipate sharing with you over the next 18 months.

We expect data in the second half of next year on TSR-033, our LAG-3 antagonist which is currently being explored alone and in combination with dostarlimab in solid tumours. We also anticipate proof of concept data next year on our TIM-3 antagonist, cobolimab.

GSK'609, our ICOS agonist, is in a Phase 2/3 gated study for head and neck squamous cell cancer patients in combination with pembro, and we expect to see data in 2021.

Bintrafusp alfa, the TGF-beta trap/PD-L1 bispecific we are co-developing with Merck KGaA is on track to read out the pivotal study in second line biliary tract cancer next year. In addition, the lung studies remain on track.

Lastly, dostarlimab, our PD-1 inhibitor, has been submitted to the regulators for approval in second line MSI-H endometrial cancer.

In the next slide, I want to introduce you to the newest addition to our immuno-oncology pipeline.

### **Anti-CD96 (GSK'608) – a potential first-in-class antibody**

I am excited to announce that our anti-CD96 antibody, our first molecule being co-developed with 23andMe, has started Phase 1 this month. CD96 is an immune checkpoint receptor expressed on T cells and NK cells. It is part of the TIGIT, CD155/CD226 costimulatory axis as shown on this slide.

We are excited by this asset as blocking CD96 from binding to CD155 allows CD155 to interact with CD226 and importantly activate an immune response, analogous to how TIGIT induces its effect. This mechanism of action is distinct from, and possibly synergistic with, PD-1/PDL-1 inhibitors as well as possibly synergistic with TIGIT inhibition.

It is important to note that this axis was genetically validated by 23andMe via a proprietary algorithm using their unique dataset.

### **Belantamab mafodotin on track to be the first approved anti-BCMA agent**

Turning to Slide 29, we move from our newest to the most advanced asset that modulates the immune system – belantamab mafodotin – which, as you know, has four modes of action: blockade of the BCMA receptor; delivery of the cytotoxic MMAF conjugate; and importantly, enhancing antibody-dependent cellular cytotoxicity/phagocytosis due to afucosylation of the Fc receptor domain, as well as inducing immunogenic cell death.

We remain confident in the positive benefit/risk profile of belamaf in relapsed refractory multiple myeloma patients and we are pleased with the outcome of the FDA's ODAC hearing earlier this month and last week's positive opinion issued by the EMA's CHMP.

We take patient safety very seriously and are focused on helping physicians and patients understand and manage the corneal events, as well as aggressively looking at ways to reduce the ocular events, particularly in earlier lines of therapy.

Earlier this quarter we dosed the first patient in the DREAMM-5 study with belamaf and our gamma secretase inhibitor that we in-licensed from SpringWorks. I want to take a minute to share why I am so excited about this combination.

As you can see on the right-hand side of the slide, the gamma secretase inhibitor is responsible for clipping BCMA off the surface of the plasma cell. We believe soluble BCMA may act as a sink for our ADC, potentially compromising efficacy. As you can see in the panels at the bottom of the slide, the gamma secretase inhibitor blocks the shedding of BCMA, resulting in higher expression of BCMA on the surface of the plasma cells and as such you see greater cytotoxicity and an increase in ADCC.

If this effect translates into the clinic we may be able to lower the dose of belamaf and still have strong clinical activity.

In addition to the combination with a gamma secretase inhibitor, we are exploring lower doses and less frequent dosing in earlier lines where belamaf will be given with other effective therapies.

We are cautiously optimistic that these approaches will enable us to successfully develop belamaf in earlier lines of treatment.

I would now like to speak about the most advanced of all of our cancer medicines - that is *Zejula*.

### **In July 2018 we said we were going to be a leader in synthetic lethality**

Despite having no synthetic lethal drug targets in 2018, we committed to becoming a world leader in this exciting field. Our first step was to acquire *Zejula* based on the functional genomics studies that suggested PARP inhibitors should be effective beyond those women who have a BRCA mutation.

We were pleased that the PRIMA study bore out this hypothesis, showing that the treatment effect in HRD-positive patients was similar to that observed in women with the BRCA mutation.

In addition, because of its unique tumour concentrating effect, *Zejula* actually exceeded our expectations and demonstrated benefit in all-comers, which has translated into a unique and differentiated label.

As such, the TESARO acquisition validated our belief that functional genomics can be used to identify exciting, under-appreciated targets and we hope to expand this technology to find novel targets for patients with specific alterations in their tumour.

### **Building a world class synthetic lethal pipeline and unit**

Slide 31 shows what has been achieved towards this vision since PRIMA has read out.

Based on the PRIMA and other preclinical data, we are excited about the potential for *Zejula* to work in other tumour types, such as lung cancer and, given its unique PK property,

such as tumour accumulation and ability across the blood-brain barrier, we believe we have the best-in-class PARP inhibitor. We will start a Phase 3 study in first-line non-small cell lung cancer later this year.

Our confidence in the concept of synthetic lethality has led us to build out our pipeline in this key emerging area of science. We now have five new synthetic lethal assets, with one being our home-grown, Type 1 PRMT inhibitor, three are coming from a partnership with IDEAYA that we just announced earlier in this quarter and, of course, *Zejula*.

We have also established a new research unit in Boston with a new leader in place. I am pleased to share with you today that we have agreed to a five-year collaboration with one of the world's leading functional genomic centres, the Broad Institute, to help us advance our mission.

Taken together, I believe we have made excellent progress on our goal to build an industry-leading pipeline in synthetic lethality.

### **A stronger pipeline with a clear focus on immunology**

Not only has our focus on immunology resulted in a strong Infectious Diseases and Oncology pipeline, but we also have 10 other immunomodulatory drugs that are targeting diseases such as osteo-arthritis; systemic lupus erythematosus; rheumatoid arthritis; Duchene muscular dystrophy; ulcerative colitis; systemic sclerosis; asthma, and COPD.

I am particularly proud of the team working on *Benlysta*. We announced positive headline results from the BLISS study in lupus nephritis in December last year and we expect that these data will be published in a top-tier journal very soon. Furthermore, we anticipate approval of this indication early next year. In addition, the BLISS-BELIEVE study of *Benlysta* in combination with rituxan for SLE, will read out in a similar timeframe.

We have also made excellent progress on *Nucala*. We have recently generated positive pivotal data in nasal polyps, filed for approval for hyper-eosinophilic syndrome and resumed our pivotal study in COPD. We are also exploring a long-acting anti-IL5 which, if successful, will potentially transform the respiratory market in a manner similar to the way in which cabotegravir may disrupt the treatment of HIV.

### **BD has been key to augmenting our pipeline and providing access to differentiating technologies**

Building on the previous slide, I will briefly highlight the important impact that business development had in supporting the transformation of the R&D pipeline of GSK. The various deals outlined on Slide 33 will deliver significant value to GSK, either by adding strategically targeted assets to our pipeline or by providing access to world-leading technologies and

outstanding scientists who will help us to progress the next generation of transformative medicine and vaccines to patients.

**This strengthened pipeline is being delivered by a more engaged, focused and collaborative organisation**

Lastly, before I close with our upcoming pipeline milestones, I wanted to discuss culture. Two years ago, I spoke about the importance of culture to an organisation and how we were going to focus on creating the right culture within the R&D organisation at GSK.

I am delighted to share with you some of the results from the most recent GSK employee survey that demonstrate the progress we are making across R&D. Most importantly, we had an 8% increase in the engagement score for R&D employees, and a 20% increase in employees' belief in our commitment to scientific expertise.

We were also pleased that our focus on innovation was acknowledged by *SCIENCE* magazine, where we were ranked as one of the top 20 companies to work for, for the first time.

We have also worked to simplify the governance model across our pipeline, to improve our agility. This improvement in our agility is best illustrated by Vir and the otilimab OSCAR study in COVID-19. The Vir deal took less than three weeks to pull together and announce, and the Phase 2 OSCAR study took less than 10 weeks from the idea to the first patient being dosed.

Another great example is the speed with which the team took belamaf from essentially 35 patients in Phase 1, to the 10 study DREAMM development programme and, hopefully, approval in just over two years.

As I mentioned earlier this year, I am excited that we are combining our Vaccines and Pharma Development organisations into one single group because I believe that the opportunity for increased exchange of scientific ideas and expertise will greatly benefit our pipeline.

Finally, we are seeing much closer working between R&D and Commercial, to improve our focus on lifecycle management. This has resulted in many expansion indications under investigation for *Zejula*, *belamaf*, *Benlysta* and *Nucala*.

**Our upcoming R&D milestones**

Moving to my final slide, 35, I want to look forward over the next 18 months, where we have a number of important milestones. We have a great deal of work to do but I would particularly like to highlight four areas as a priority.

First, maximizing the patient impact of our marketed medicines, such as *Zejula*, *Benlysta*, *Nucala*.

Second, bringing the transformational impact of cabotegravir to prevent and treat HIV.

Third, advancing our Oncology portfolio by achieving approvals for belamaf and dostarlimab, while building a pipeline of future indication expansions, and of course delivering proof of concept for a number of exciting earlier assets.

Lastly, delivering a robust Phase III pipeline, including three new pivotal studies I mentioned earlier, with our RSV and meningitis vaccines.

In closing, let me say I am extremely pleased with the progress we have made over the last few years. I am confident that the approach we are taking is delivering. We will continue working to build a stronger, more productive and more innovative R&D pipeline.

With that, let me now hand back to Emma.

**Emma Walmsley:** Thanks, Hal. In summary, we are confident in the underlying demand for our portfolio, despite short-term quarterly impact.

GSK has been resilient and agile in its response to the pandemic and we are successfully navigating the crisis and meaningfully contributing to solutions while, at the same time, making sure that we are delivering our long-term priority of Innovation, Performance and Trust, and on our 2020 areas of focus.

We are building on the significant progress Hal has spoken to, and strengthening our pipeline further. We are driving improvements in our operating performance, we are progressing the Consumer JV integration at pace, including the reshaping of our brand portfolio, and we have started our programme to prepare the Group for separation into two new companies with relevant and competitive purpose, portfolios and strategies: one, a biopharma company focused on the science of the immune system and genetics, the other dedicated to everyday Consumer Health.

Ultimately we remain confident in the resilience and sustainability of GSK's business and our ability to deliver very successfully on our strategic goals.

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

## Question and Answer Session

**Matthew Weston (Credit Suisse):** Two questions, please. Firstly for Emma, President Trump has proposed a number of executive orders on US drug pricing, including international best price. As one of the first CEOs who is able to comment immediately after those announcements, I'd be interested in what is GSK's view on the proposals and what you would expect to shake out as we approach the election.

Secondly, probably for Luke, given the need for a vaccine rebound in the second half, can you talk about this year's flu season. How many doses are GSK targeting to ship versus last year, and should we assume price improvements given, I presume, high government demand for immunisation across the board. Thank you.

**Emma Walmsley:** I'll hand over to Luke in a second but just to comment on the executive orders which as you said have just come out. We're reviewing that and monitoring how things evolve, obviously being conscious and thoughtful about what can actually happen ahead of the election. These are all topics that have previously been raised, and our position, frankly, is maintained as the same, which is, we very much support any shift that continues to drive access and support innovation that the world has never seen more than now and is required for all of the unmet need, and we're very supportive of programmes that lower out of pocket, particularly for patients that are under economic pressure, and likewise, due governance around access to 340B.

We do, however, have concerns about international pricing indices and importation, because global systems are not comparable, and the focus should be on maintaining safety and quality of products and also incentivising innovation. Nonetheless, our No. 1 priority is continuing to focus on quality, needed, differentiated medicines. You all know that GSK has a strong track record in terms of responsible pricing, and actually, we have continued to innovate for access, and that is visible when you think about three-in-one respiratory with *Trelegy*, the fact that *Zejula* is a single treatment, or indeed the whole growth we are seeing and investing in two-drug regimens, and of course our commitment to price responsibly for any COVID solutions.

Luke, do you want to comment, please, in terms of the focus on the flu season, which we know is very important.

**Luke Miels:** In the US we expect to ship around 50 million doses in the upcoming season. The manufacturing team has done a great job and we expect those to be in the market shortly. This is a critical part of our acceleration programme for *Shingrix*, and

that's up from 46 million in 2019, which back then was about 19% of market share, and the US is where we send two-thirds of our supply.

**Louise Pearson (Redburn):** I have a couple of questions on the RSV programme please. Firstly, in terms of revenue opportunity in the older adults, do you see this as a vaccine that could potentially support a premium price point, like a *Shingrix*, should this programme ultimately be successful? Secondly, specifically on the maternal vaccine, is there any reason to believe your vaccine will be differentiated from the Pfizer maternal vaccine, which also recently came through proof of concept?

**Emma Walmsley:** Thanks very much, Louise. I'm going to turn to Roger, but absolutely, we do think that the RSV portfolio has tremendous potential, both in terms of unmet need and our competitive position, not least by the way, with our differentiated adjuvant, which is proven to work on older people. Roger, perhaps you would like to give a bit more detail on that?

**Roger Connor:** We are completely delighted with the positive data that we saw in the two RSV assets that Hal mentioned. I suppose it's worth pointing out both have Fast Track Designation from the FDA also.

Just on RSV older adults, we really think we are likely to be uniquely positioned here because of the pre-F antigen and the adjuvant that Emma referenced as well. This is the adjuvant system in *Shingrix*. It is the ASO1 adjuvant, which created greater than 90% efficacy in *Shingrix*, so, again, that's creating a level of excitement where we really believe that that could offer potentially wider and longer protection.

On your pricing point, I think if we do create that level of differentiation and protection that level of pricing is appropriate, but, obviously, that is to be determined as we run through the trials.

We are moving into Phase 3 in early '21 with this one. We are excited about older adults.

On the maternal side, it is the same antigen as the older adults vaccine. It moves into Phase 3 in the second half of this year.

Two points I would really note here. No. 1, this is likely to complement other CDC recommended maternal vaccines that we have in our portfolio as well. We have experience in terms of how we operate in this maternal vaccinations base. That will be the first one. I do think a vaccine offers potentially also polyclonal coverage, versus in the competition we know also we will be up against monoclonal competition, and I think that could offer broader strain

protection, which protects you against virus mutations, or if viruses or strains actually escape the monoclonal, so, yes, excitement in both of those.

The good news is we will share the data on this in Q4 later this year.

**Keyur Parekh (Goldman Sachs):** Good afternoon, thank you for taking my questions. I have two, please.

First, just on the cost trends that we have seen this quarter. Emma and Iain, I would love your thoughts on how do you see the sustainability of the growth and the costs as we go through the rest of the year. I think a lot of your peer groups seem to be reporting margins meaningfully better than expected, so I would be keen to hear your perspectives on how long do you think the need for reinvestment continues to be? That's question number one.

Then, question number two on *Zejula*. I think numbers are a bit below expectations for the quarter. Clearly, some stocking, more in from Q1 to Q2, or likewise, but Luke, I would love your thoughts on how you think you are doing in the real market place, if you can refer to some market share trends, and when do we anticipate a real pick-up that justifies the value you paid for Tesaro? Thank you.

**Emma Walmsley:** Thanks, Keyur. Let's go to Iain first and then over to Luke.

**Iain Mackay:** Okay, thanks, Emma. Keyur, thanks very much for the question.

With costs, I think one of the differentiating aspects of our focus around capital allocation is investment behind R&D pipeline. Key assets in the pipeline is absolutely key priority for us and you continue to see a cost increase in that regard as we invest behind those priority assets.

In the second quarter, Pharma R&D up 13%, and year-to-date overall for the company up 11%. That will remain a focus for us.

On the other hand, on the SG&A front, in the quarter down 5%. A very, very strong focus on all non-customer focused activities, so we continue to invest in terms of supporting new product launches and completion of the build-out in terms of speciality, but if you think about the programmes that we are delivering savings against, integration of the Consumer Healthcare business, Brian and the team now beginning to deliver savings from that integration very much in line with the £500 million we expect to deliver between now and 2022. The Future Ready programme, Separation Preparation programme by another name, beginning very, very early stages of delivery, but, again, between now and 2023 £800 million

of savings with the lion share of that delivered by the end of 2022 with meaningful margin improvement.

Then, in addition to that, just the day-to-day tactical management of costs in the second quarter, we have managed T&E down to a very, very small number. As you would imagine, conferences and meetings down to a very small number. We have found ways to continue activity with our customer, with our healthcare professionals, through virtual means. That's been particularly noted in the US, which, again, takes costs out of the travel and entertaining, the fleet expenses for the salesforce, for example.

There's a very strong focus across non-customer-facing activities, as well as just continuing to deliver productivity through the supply chain and the commercial organisation.

We are happy with the progress in terms of 5% down on SG&A in the quarter, continued focus in that area, but we will continue to invest behind priority assets and R&D.

**Emma Walmsley:** Thanks, Iain. Luke, *Zejula*?

**Luke Miels:** Sure, thanks, Keyur. I will add to this in a few pieces Iain's covered the inventory effect, which was the plus-5 in Q1 one and then we had a change of wholesale and delivery from Monday and Thursday to Wednesday and Thursday, which was £5 million in Q2, so that's £10 million between there.

In terms of operational, I guess I will split this into two parts: things that we can control and things that we can't.

In terms of things that we can control, I think we are doing well. First-line market share jumped 14% to 21%, and, again, if you look at the class it's up 100% or close to 100% in 12 months. We still only have 15% of women in first line getting a PARP.

We had the leading share of voice averaging at around 39%, reaching a peak of 49%, because we rapidly changed our model when COVID hit. Then, as soon as we had state level clearance and government clearance, we got straight back out there.

If we look at message recall tracking, this is translating into strong and clear recall for our key messages, which again is encouraging.

Then if we look at probably the most dynamic measure, which is the average new patient starts in the US, this is at an all-time high. If you look at Q1 versus Q2, it is up 58% and that's despite a big drop in late March and most of April.

Finally, on things we can control, we have seen over the last month more than 400 new unique writers' since green light. These are the things that are within our gift and we are competitive there.

In terms of what we cannot control, what is very clear when you look at the Oncology market is that there is a dynamic trend here. If you have slow progressing tumours, the referrals, the new patient starts and the in-office treatment rates are lower and ovarian is in that category. If we look at new patient diagnoses, they are down about 10% in April. Debulking surgeries are around 25% in the last data that I saw, so these factors are out of our control but, in the end, we launched PRIMA bang in the middle of COVID and now our focus is to keep executing as we are, growing the class and making sure we are getting our fair share.

**Richard Wagner (Wolfe Research):** I am speaking for Tim Anderson. I have a question on the COVID vaccine. It is commonly understood that there are three major diversified vaccines players - GSK, Sanofi and Merck - and yet all of the vanguard COVID-19 vaccine initiatives are by none of the three biggies. Instead, they are led by companies that do not at all have the same level of experience in this space. How did we end up in this place? I appreciate that GSK has multiple vaccine collaborations underway but these are not commonly described as one of the leading programmes. Was it because of the traditional vaccine companies feeling that vaccine development would be on the usual protracted timeline or something like that? That is my first question.

On belantamab, I know GSK doesn't give single product guidance but can you at least tell us whether you think this product has the potential to achieve blockbuster levels of sales, meaning crossing the £1 billion or \$1 billion threshold at some point?

**Emma Walmsley:** Thanks, Richard, and I can just say, yes, to your second question, subject to the programme of work that Hal outlined, and maybe I shall ask Luke in a moment to comment a bit further as we prepare for the launch on that.

In terms of vaccine, it is interesting that you describe the leading programmes - and I understand why - being not from the largest vaccine manufacturers today. I would qualify that by saying "the first".

All of us across the industry, both large and small, believe that more than one vaccine will be required to address this, and that is exactly why our decision, right from the beginning, was that a vaccine is the priority exit here, but treatments will still be required. As you know, the FDA have also said that they will consider approving vaccines with 50% efficacy and even for an extraordinary vaccine, it still means we are going to require treatments, not just in the near term, but for the long term. This is why we are investing in the areas that Hal talked about and are excited about our prospects there.

It is also why the choice we made in terms of technology play was to bring an adjuvant, which is important because it is proven at scale, it is safe and we know that it can add both efficacy and antigen-sparing benefits, as well as allowing us to have multiple shots on goal, if I can call it that. You can see that evidenced by the way governments are engaging in contracting now, in that there is still a lot of uncertainty about what is going to play out in terms of results.

We should all be encouraged by the early readouts, but these are often on totally new technologies that have never been licensed yet. They are encouraging but there is still a lot to see on duration of response and, particularly, on efficacy in different cohorts. One of the big outstanding questions is what is going to happen with the older cohort and the readouts there.

Therefore, we, alongside others across the industry, are still very much engaged with the programmes we are in. As Hal said, we have two already in the clinic with another just about to start, and we are very confident in being able to supply, subject to positive results, a billion doses of the adjuvant, importantly while still continuing and accelerating our existing pipeline and indeed investing in the exciting new technologies that are becoming more visible, be that in-house or with our CureVac deal, so I think a lot more to come in terms of where the vaccine solutions will conclude.

But Luke, is there anything else you would like to add in terms of how you think about the upcoming commercial execution and prospects of bela?

**Luke Miels:** Look, I think the key thing to anchor on here is that there is striking single agent activity and we believe that the side effect profile is manageable and it's an attractive infusion regimen.

I think we can execute a good plan in terms of optimally managing corneal events, and I think also just when we talk to physicians that use the drug, again the efficacy is attractive. In terms of managing the tox profile, let's see how that evolves and whether that's consistent with what we see with investigators once they get the drug in their hands and use it in patients and understand how it works.

I think also you can see with programmes that Hal has highlighted like DREAMM-5, we are also seeing pluses and minuses in terms of the pathways for this drug in earlier lines, so the short answer is we remain very confident about the asset.

**Emma Walmsley:** Thanks Luke The next question, please.

**Andrew Baum (Citi):** Thank you – a couple of questions. COVID-19 is obviously going to have lots of impact on industry but one that seems obvious to us is the importance of the government as a stakeholder is going to be materially greater going forward than it has been historically.

With that in mind, to what extent does that influence your capital allocation? I'm obviously thinking of areas that you are already in, such as vaccines, but in addition areas where you have been in historically, maybe thinking antimicrobials and anti-infectors more broadly? Is this a driver for you to increase your investment there?

And then second, on the announced deal in relation to vaccines, thinking about your pricing strategy for your COVID-19, there is obviously a diversion between the AstraZeneca approach being *pro bono* during the pandemic period and obviously Pfizer and BioNTech going for profit. How are you thinking about pricing your vaccine for the pandemic period should the safety and efficacy meet approval? Thank you.

**Emma Walmsley:** Thanks, Andrew, and I would definitely concur that the world and many governments have recognised the strategic importance of our industry and innovation within that and all in the context of the geopolitics that we know.

I think in terms of how it's influencing our capital allocation choices, Hal laid out very clearly in his presentation the mix of the portfolio of our pipeline, but also it's worth underpinning GSK's strength in infectious diseases, be that prevention, which frankly, if there is one thing despite any quarterly impact that we should all believe in, it is that fundamentally we should be absolutely confident in the strategic relevance and prospects of vaccination which is an area that GSK has tremendous strength, a growing pipeline and increasing competitive capabilities, but we also do have a broad infectious disease portfolio continuing to pioneer in HIV innovation. I think it's really important to underline the opportunity we see with Cab both in prevention and treatment, but also there is growing focus on antimicrobial resistance and we have, again as Hal mentioned, an asset in gepotidacin there as well which we believe does have appealing economic returns, so that has been clear.

In terms of the pricing of vaccines, this is a business that we have long led in and understood, both the responsibility to drive access and the necessity to drive profitable returns and therefore to keep funding innovation and our position - there is no publication from the Government in terms of the specific detailed terms of that - is that any short-term profit generated during the pandemic period would be reinvested in pandemic preparedness and those donations for access and pandemic preparedness is a combination of technology, support for new pathogen work but also the funding of ever-warm capacity, very much with

thoughtfulness to your first comment of the global footprint in terms of manufacturing and supply.

The next question, please.

**Laura Sutcliffe (UBS):** Thank you, I have two questions on RSV vaccines. Firstly, what sort of timeline do you think you might be looking at for Phase 3 read-outs for both of your assets that you are taking forward?

And secondly, your older adult vaccine is obviously adjuvanted. I think previously the evidence has suggested that there is little to no benefit from adding an adjuvant to vaccines that are going into this setting. Should we assume that since you are going forward you have seen something remarkably different here? I know that the data will be presented later this year, but any colour you can offer us will be very helpful. Thank you.

**Emma Walmsley:** I'm not sure you're going to get a huge amount of preview of data that's later to be presented, but Roger, would you like to follow up for Laura, please, on those questions?

**Roger Connor:** I'd say just on the older adult I won't share the data we will publish and present later in the year, however what I would say is that we have seen AS01 obviously in Shingrix performing incredibly well in the older adult population where we know the age-related decline in the immune system is critical, so that's all I would say on that.

In terms of timing, we are going to take RSV older adult into the clinic early in '21, maternal will be going into Phase 3 in the second half of this year, and these are going to be quite large trials, we would expect them to take a few years to complete, with regulatory approval to follow on from that if it's positive.

What I would say is that, certainly in the COVID environment, we are looking at clinical trial execution approach, regulatory engagement, and we will be taking any learning, in terms of how we do this effectively and efficiently, into these priority programmes.

**James Gordon (JP Morgan):** Thanks for taking the questions. Two questions: the first one was that your 2020 guidance is now caveated around recovering vaccination rates, and depending on what we see in Q3, we are a month into the quarter, so can you talk about how much better things are looking for July and what the exit rate is towards the end of this month? Is *Shingrix* a good proxy for what's going on overall with vaccines, or do we need to be careful reading through from that.

The second question was just the Consumer spin-off. I think when the spin-off was first announced there was a plan for four times levered, and the base case was that you dividend the whole company to GSK and Pfizer shareholders in '22. Is that still the concrete plan or the default plan, or might you do some other creative stuff like IPO-ing part of the business? Might you consider not putting quite so much debt in the business? Are there any other things being considered there?

**Emma Walmsley:** Thanks, James. I'll ask Iain to unpack the guidance and assumptions, a bit more for you, but just to say there is no change in terms of our position on Consumer separation, be that performer leverage or timing.

**Iain Mackay:** Thanks, Emma, and maybe, Luke can add some colour on this. I think as Emma mentioned, what we are seeing through July is a significant recovery of paediatric vaccinations back pretty much to pre-COVID-19 levels. Certainly in the adult and adolescent vaccinations we're seeing encouraging activity, it's not back to the levels that it was pre-COVID, but as we've pointed out in our guidance, that is the recovery that we are beginning to see, and we need to see that happen in the third quarter, with a very strong performance coming through in the fourth quarter.

So we are encouraged by what we see so far and our very strong view is it's not a question of *if* this demand comes back, but *when* the demand comes back. Certainly what we've seen through 24 July, which is the data that we've seen most recently, we are certainly encouraged by what we've seen.

**Emma Walmsley:** Luke, do you want to talk a bit more about the activity that's ongoing?

**Luke Miels:** Just to build on Iain's point, there is a clear difference when you look at the US, and Europe, and in Europe, the bulk of our business is paediatric vaccines and that rebounded relatively quickly. In the US, paediatrics. If you look at the industry as a whole, in February it was about 500,000 a week, and that dropped by 50% in the four weeks in March and April, then it rebounded pretty quickly, so that was a V-shaped recovery. It was about minus-40% in late April, and minus-10% in June, so it came back quickly, whereas adults dropped the same way but it's been slower to recover. In early May it was around minus-50% plus overall for adult vaccinations, whereas paedics at that point was minus-30, so it's just a longer area of the curve.

In terms of wellness as well, which is where we've seen the same pattern, a very strong rebound amongst paediatrics and 11 to 12 year-olds, and 13 to 18 year-olds. It's a slower recovery for older people. I think also when older people are going back in to their physician,

there's going to be a hierarchy that the physician is going to focus initially, so blood pressure, etc., for the more acute admissions.

In terms of what we're doing about it, again, we've not sat and been passive, so there's a series of things we've done. Firstly we've linked it to the early flu doses, as I mentioned earlier, because people come in for the flu shot, that's a prime opportunity for the pharmacists to bring up *Shingrix*. We have also, the field activity with our retail customers is back to pre-COVID levels, and with retail we have a lot of signage, volume goals, and some other things that I don't want to disclose, and we've also been chasing people for their second dose, and getting them back, and that's holding up quite well.

We are also doing DTC at point of sale, and there are some other things again that I won't cover, but we are doing everything we can, including targeted TV and some branded digital and print-based media as well, and, as Iain said, we now need to see how that goes with the dynamics in the US.

**Geoffrey Porges (Leerink):** Thank you very much – and I apologise for jumping in so late on the call that I may ask a question that you have already answered. First on flu, could you just give us a sense of your timing for shipment to the US market, the volume change you expect compared to last year and, most importantly, where do you see any of net positive drive due to the mix or contract?

Just to follow up on the COVID programme, when can we expect publication of your preclinical data, particularly primate data? Could you comment on the mix of CD8 and CD4 responses that you've seen with ASO, in your other studies rather than COVID.

**Emma Walmsley:** Thank you. Luke, we had the question on flu before and perhaps we could just repeat what we are aiming for in terms of volume. Then Roger or Hal, I don't know whether there is any further disclosure you want to bring on the COVID programme.

**Roger Connor:** I can make a very quick comment, Emma, if you come to me.

**Luke Miels:** Jeffrey, there is shipping in July, linking and lining it up with the *Shingrix* acceleration programme. We are targeting 50 million doses and also getting them in earlier, which is something I didn't say earlier – it is very important. It reduces the return rate that you see later in the year, because physicians tend to over-order. That is up from 46 million in 2019, which is just under 20% of the market. We sell two-thirds of it in the US.

In terms of pricing flexibility, it is very limited for this year in the US.

**Emma Walmsley:** Roger, is there anything else?

**Roger Connor:** I won't go into any of the detail in terms of the data that we have seen. I would make more of a generic comment around it. One of the things that is to play out in COVID-19 is this idea of immune response and T-cell contribution to the performance of the vaccine then having potentially an impact on the population, and the reaction of the vaccine in the population. What I would say is that adjuvanted vaccines have got that historic delivery and track record of delivering both humoral and cellular immune response, which we think could be very important for COVID. It is too soon to tell, though, and that will all play out over the coming months as more data on our vaccines and on the other vaccines come to light.

**Emma Walmsley:** Hal, do you have anything else to add from your point of view on that?

**Hal Barron:** No, but I would just highlight something Roger has said. The cellular response could very well be important in the success of vaccines. In addition to measuring some of the classic markers that you referred to, GSK's Vaccine research organisation has put a great deal of effort and innovation in what to measure, and what is actually predictive in the clinic as to what you want to look for, for surrogates for that. It is not only when, but the quality of what you might see, which will be interesting.

**Emma Walmsley:** Thanks, Hal. We can take one more question.

**Kerry Holford (Berenberg):** Thank you very much – I have a couple of questions. Just quickly on the flu vaccine, I am interested to know whether there is any upside to your ability to deliver more than 50 million doses into the US market. Sanofi is committed to ship, I think, 80 million and I was interested to know whether there was any upside to that capacity for you?

Then, just more broadly on the pipeline refresh, this is for Hal: is this something that we should now expect to continue to see from you on a six-monthly basis going forward? I wonder if you could talk to the reasons why you elected to de-prioritise certain assets in the portfolio, this TLR4, PI3 kinase, and the HIV entry. Thank you.

**Emma Walmsley:** Thank you, Kerry. Roger, quickly from you in terms of capacity on flu, and then Hal to complete, please.

**Roger Connor:** Yes. I think 50 million will end up being one of our highest volumes – the highest volume in the US. We are very close to maximum capacity here and so there is limited upside going forward in terms of this egg-based technology, because it is

not somewhere to which we have allocated a great deal of our capital. You will not see much more in terms of upside above the 50 million number within the US supply.

**Hal Barron:** Thank you, Kerry. Yes, the answer is that we will continue to focus our efforts in R&D on the most promising assets. Sometimes, the science will translate out nicely and we will double down and be aggressive about developing efforts, but sometimes the data will emerge to suggest that we should abandon projects. Of course, the risk is very high in the industry: 10% of the projects that enter the clinic will ultimately succeed. We think the most important thing is to follow the science and rigorously evaluate what the data in the clinic tells us. We think that this focus on human genetics, functional genomics, machine learning, and particularly a focus on immunology, will allow us to develop a portfolio that has a higher probability of success and, of course, by focusing, we have the opportunity to be developing and designing robust clinical trials to give us insights, so that we are not faced with the deep uncertainty that sometimes bugs the industry at the end of Phase II. I think the refresh is just our attempt to deliver scientifically and focus on the most promising asset.

**Emma Walmsley:** Thanks, Hal, and thank you to all of you for dialling in. We will look forward to talking to you soon. Thank you very much.

[Ends]