# GlaxoSmithKline 2020 Full Year Results Wednesday, 3 February 2021

lain Mackay (Chief Financial Officer): Good morning and good afternoon. Thank you for joining us for our full year 2020 results which were issued earlier today. Normally Sarah Elton-Farr, our Director of IR would lead this call, but unfortunately Sarah has been out ill for a couple of weeks and this is literally her first day back, so she is in listening mode only today.

You should have received our press release and can view the presentation on the GSK website. For those not able to view the webcast live that accompanies 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 our cautionary statement.

#### Agenda

Our speakers today are Emma Walmsley, myself, Iain Mackay, Luke Miels, David Redfern, Brian McNamara, Dr Hal Barron with Roger Connor joining us for the Q&A portion of the call.

We request that you ask a maximum of two questions so that everyone has a chance to participate. Our presentation will last for approximately 45 minutes, slightly longer than usual to allow time for Hal's extended fourth guarter R&D update.

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

### **Emma Walmsley**

#### **Chief Executive Officer**

Thanks, lain.

# Strong progress on our priorities in 2020

2020 was an extraordinary year for all of us; another year of strong progress for GSK and we are very confident in building on it in '21 for successful separation into two new companies with strong performance trajectories in '22 and beyond.

2020 was always planned to be a year of investment in our pipeline and new launches and in preparing to be two companies, but we also had to respond rapidly to mobilise through the pandemic and I am extremely proud of the agility and resilience our teams have shown in the face of this challenge.

We have remained firmly on track with all our strategic goals. We delivered strong performance in our growth drivers and disciplined cost controls to offset the unexpected impact in Vaccines and so delivered our guidance for the year, which was set before the pandemic with reported sales up 3% CER and earnings down 4% to £115.9p

I am especially pleased by the strong commercial execution in our New and Specialty products with sales of £9.7 billion, now more than half of our Pharma business and up 12% which reflects the impact of the changes we have been making to compete more effectively and generate greater share of voice across our growth drivers and you are going to hear more about this from Luke shortly.

Consumer JV integration is substantially complete and separation preparation is progressing very well, delivering efficiency in our support functions, simplifying our site network and further building world-class brands.

We also achieved an important milestone with the launch of our One Development organisation in R&D. This is already improving agility, decision-making and scientific collaboration between Pharma and Vaccines as well as the cost base.

We are transforming the pace and delivery on innovation, as Hal will talk to. We had nine major approvals in 2020 and it was great to see the FDA recently approve our long-acting HIV treatment, *Cabenuva*. We now have over 20 assets in late stage development, many of which could be transformational for patients and deliver significant commercial value. These products could all launch before 2026 and we believe more than ten, if successful, will have the potential to be blockbusters.

And across R&D we completed over 20 business development deals during the year, strengthening our capabilities with the acquisition of new antibody mRNA and genetic platforms and technologies amongst others.

We continue to contribute to the COVID response on multiple fronts. I am delighted that this morning we announced the deepening of our strategic partnership with CureVac with a new, exclusive agreement to research and develop next generation mRNA COVID vaccines which have the potential to address multiple emerging variants.

In addition, 100 million doses of CureVac's current COVID vaccine candidate and this is alongside our work with our other partners on adjuvanted vaccines and we are looking forward to more progress here in the coming months and to data coming very soon on our therapeutics as well as the longer term opportunities for further strengthening of our global leadership in infectious diseases.

Building trust with all our stakeholders remains of critical importance and in November we set ambitious, industry-leading environmental targets to have a net zero impact on climate and a net positive impact on nature by 2030. I was also delighted that last week for the seventh time in a row, when global health has never been higher on the agenda, GSK topped the Access to Medicine Index for the industry once again.

# High confidence in competitive growth outlook for 2 new companies

For 2021 we have been clear that this would be the second of a two-year transition period, with further investment in our pipeline and that we expect a meaningful improvement in operating performance from 2022 onwards. This remains the case, although the short-term disruption from the pandemic to our Vaccines business, as COVID immunisation is now prioritised, has impacted our guidance for 2021. Assuming that healthcare systems and consumer trends return to more normal conditions later in this year, we would expect to see the strength of each of our businesses come to the fore, supporting our high confidence that we will deliver improved growth and margin expansion from 2022.

Looking at our priorities ahead of separation, this year will be focused on continued investment and innovation to support sustained, long-term growth from 2022 onwards. We expect to deliver further progress in R&D and we will update you in June on our plans to advance and commercialise our high-potential late-stage assets and the significant value creation we now see as we develop a pipeline based on the science of the immune system, the use of genetics and advanced technologies.

Our performance focus is on growth driver execution and completing our Future Ready programme, to set competitive operations for both companies. In June, alongside our R&D update, we will set out the positive growth outlook we see for this new biopharma company from '22 onwards, together with our expected capital allocation priorities and the new distribution policy that supports investment in sustainable growth and attractive shareholder return.

On trust, we are committed to retaining our leadership in ESG, in global health, and to being a modern employer, to attract and retain the very best talent. Never has being a purpose and performance-driven company mattered more and ESG will also be a part of the Biopharma Investor

update and we will provide news on progress here alongside that of innovations and performance throughout the year.

An investor update for the new consumer company is also expected in the first half of 2022.

I will now hand over to lain, to take you through the detail of this year's results.

#### 2020 Results and 2021 Guidance

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

#### **Headline results**

On Slide 8 there is a summary of the Group's results for 2020, showing that we delivered within our guidance range. 2020's performance demonstrated continued execution on our strategic objectives. Reported turnover growth was 3%, down 2% on a proforma basis. Total operating profit was up 15%, with total earnings per share up 26%. On an adjusted basis, operating profit was up 2% and declined 3% proforma. Our adjusted EPS was down 4%. I will go through the drivers behind these in more detail in a moment.

We delivered another good year with regards to free cash flow, generating £5.4 billion. On currency, the strengthening of sterling against the US dollar, and weakness in emerging market currencies relative to 2019, resulted in a headwind of 2% on both sales and adjusted earnings per share.

# Results reconciliation - 2020

Slide 9 summarises the reconciliation of our total to adjusted results. The main interesting items in the year were: in disposals, which reflected the disposal of Horlicks and other Consumer Healthcare brands; in major restructuring, which reflected continued progress on the Consumer Healthcare integration and separation preparation programmes; and in transaction-related, within which the main contributor was a charge relating to the re-measurement of the contingent consideration liability for ViiV Healthcare, including the increased forecasts related to strong cabotegravir PrEP data.

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

#### Pharmaceuticals - 2020

Slide 10 summarises the pharmaceuticals business where overall revenues were in line with expectations, with a slight decline, down 1% for 2020. Excluding established Pharma, revenue grew 12% in the year, reflecting strong commercial delivery of our New and Specialty medicines. Respiratory was up 23% with strong growth, mainly from *Trelegy* and *Nucala*, with favourable RAR adjustments benefitting *Relvar/Breo*.

You should note that we will in future be reporting *Relvar* along with the smaller *Incruse* and *Arnuity* within the Established Pharmaceuticals, and we will give you the statement information ahead of Q1 so that you can update models.

Moving to *Benlysta*, sales were up 19%, with subcutaneous formulation up 33%. In Oncology, sales were £372 million, up 62%. *Zejula* sales were £339 million in the year, up 48% and *Blenrep*, which was approved in August, had sales of £33 million.

HIV revenues were up 1%. The dolutegravir franchise grew 2%, with the combined performance of *Dovato* and *Juluca* more than offsetting the decline in the three-drug regimens. Luke and David will provide more details on commercial performance shortly.

The Established Pharma portfolio declined 15%. Within this, Respiratory was down 15% reflecting generic competition for *Advair*, *Seretide* and *Ventolin*, plus price pressure for *Flovent* in the US. The rest of the Established Pharma portfolio was down 14% with COVID-19 impacting performance, particularly in antibiotics. Additionally, we have seen increased government-mandated use of generics in certain markets. We continue to review opportunities for divestments in this portfolio.

The Pharma operating margin was 24.5% in 2020 and the 150 basis points decrease primarily reflected increased investment in the R&D pipeline and with the impact of lower revenues largely offset by the continued benefit of restructuring and tight control of ongoing costs.

#### Vaccines 2020

Slide 11 gives you an overview of Vaccines performance, with sales down 1% in 2020. Generic sales grew 11% driven by good growth in Germany and China and a stronger performance in the US in Q4. Influenza sales grew 37% and primarily reflected robust demand across all regions resulting from the strong Government recommendation to prioritise flu vaccination during COVID-19 pandemic conditions, together with the reverse of a prior year returns provision in the US.

Meningitis sales grew 3% and in the US both *Bexsero* and *Menveo* grew market share. However, the meningitis market share was impacted by the disruptive back-to-school season in the US, which resulted in *Bexsero* sales declining 2%. This was more than offset by growth in *Menveo* and *Menjugate*.

Established vaccines were most impacted by the pandemic environment and declined 14%, notably in Hepatitis where the impact of lower demand in older adult populations and travel restrictions was further impacted by the return of a competitor to the market. Our DTPa-containing vaccines and *Synflorix* were also significantly affected. Partly offsetting this, *Cervarix* more than doubled to £90 million in China.

The operating margin was 38.9% in 2020, the 190 basis points decrease reflected negative operating leverage from the COVID-19-related sales decline and increased investment behind key brands.

#### **Consumer Healthcare 2020**

Turning to slide 12, 2020 revenues in Consumer Healthcare on a proforma basis grew more than 4%, excluding brands either divested or under review. Including those brands, turnover declined 2% proforma; reported growth was 14%.

Oral Health grew 6% at CER, including *Sensodyne* growing double digits, reflecting underlying brand strength and innovation.

Vitamins, Minerals and Supplements grew high teens, driven by increased consumer focus on personal health and wellness and strong commercial execution. There was continued growth in Pain Relief driven by the successful Rx to OTC switch for *Voltaren* in the US and *Advil* returning to growth.

However, this growth was partially offset by weaker performance in Respiratory health, with a weak cough and cold season in Q4.

Operating margin for the year was 22.1%, 22.3% at CER, up 30 basis points, benefiting from integration synergies which more than offset the expected significant impact on the margin from divestments in the year.

There is no change to our previous guidance for Consumer margins of mid to high 20s from 2022.

# Sales and adjusted operating margins 2020

On slide 13, we summarise the sales and adjusted operating margin for 2020. Our Group operating margin was 26.1%, down 40 basis points on a proforma basis at CER. Increased investments in R&D, up 6% for the Group and up 9% in Pharma, along with negative sales operating leverage, was partially offset by ongoing tight control of costs across the Group and the continued benefit of restructuring.

Looking at margins on a pre-R&D basis, the increase was 50 basis points on a pro forma basis at CER, which underscores the progress we are making in efficiencies across the Group.

# Adjusted operating profit to net income

Moving to the bottom half of the P&L, I would highlight that interest expense was £844 million, slightly below our expected range, and we expect interest expense to be in the range of £850-900 million in 2021, similar to 2020.

The effective tax rate of 16% was in line with expectations. We expect the 2021 tax rate to increase to around 18%, in line with what we have previously indicated, and continue to expect the effective tax rate to step up again over the medium term, excluding any potential impact from changes to US tax policy.

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

#### Free cash flow of £5.4 billion

We had a good year of positive cash flow performance, delivering free cash flow of £5.4 billion in 2020, up from £5.1 billion in 2019. Key drivers of this year over year improvement are set out in the slide. Q4 performance was mainly informed by strong working capital performance.

Improving cash flow is a constant focus for our team. We however anticipate lower free cash flow in 2021, informed by less cash from asset divestments, which was particularly strong in 2020, less favourable RAR timing compared to last year, along with continued investment in R&D-focused business development and higher outflows from restructuring, which we will largely complete this year.

### 2021 guidance and 2022 outlook

In 2021 the Group will continue the strong progress made during 2020 in delivering our strategic objectives and readying for separation. With regard to turnover for 2021, there is no change to expectations we previously set out for Pharma and Consumer, with 2020 performance reinforcing our confidence in their outlook.

Across the Group, our turnover comments assume that healthcare systems and consumer trends approach normality in the second half of the year. For the full year, we expect flat to low single-digit percentage growth in Pharma revenues excluding divestments, which will be a balance of continued strong momentum from our New and Specialty medicines, largely offset by decreasing revenues in established pharma.

In Consumer, excluding brands divested or under review, we expect low to mid-single digit growth, outperforming the market.

In Vaccines the 2021 in-year COVID-19 impact on our portfolio is uncertain, the pace of mass vaccination programmes being a key factor, notably in the US. Overall, for this business we expect flat to low-single digit percentage revenue growth.

With respect specifically to Shingrix, Luke will provide more detail shortly, but broadly we anticipate deferral of strong growth in revenues into the second half of the year, and increasing contributions from markets outside the US. Across the rest of the Vaccines portfolio, we expect to deliver a similar volume of flu doses, but for sales to be under pressure due to favourable RAR in 2020.

We expect meningitis to be broadly flat, informed by the continued impact of the pandemic, including COVID-19 vaccination programmes. Our Established vaccines portfolio will experience similar pressures than 2020, again largely informed by pandemic dynamics.

The key factors that will influence our 2021 outturn in Vaccines, in addition to the pace of deployment of COVID-19 immunisation programmes, include the trend of infection rates, the extent of recovery in international travel, and back to school patterns, particularly in the US, and how health systems around the world prioritise resources between COVID-19 response and other infectious diseases.

Across the three businesses, it's worth noting that comparisons to the prior year will be influenced by stocking patterns experienced in 2020, notably in 1Q when turnover grew 10% proforma, and adjusted EPS was up 26% in the prior year. This volatility in comparisons is amplified in Consumer, with a weak cough and cold season continuing into the start of 2021. To assist analysis we have included an appendix showing 2020 quarter-by-quarter performance.

We will continue to grow R&D investment in low double-digit percentage terms, and expect an effective tax rate of around 18% for the full year.

Taking these factors together, we expect a decline of mid to high-single digit percent in adjusted EPS. For 2021 we expect to pay a dividend of 80 pence per share for the full year.

Importantly, our operating performance outlook for 2022 and beyond remains unchanged. Our focus on delivering our strategic objectives in 2020 and 2021 lays the foundation for a meaningful step-up from 2022 onwards, with an advancing pipeline, further growth in New and Specialty Pharma, normalisation in Vaccines following the short-term COVID impact, and ongoing Consumer sales growth and margin expansion. Savings from largely complete restructuring programmes and resulting synergies will underpin our improved Group operating performance.

Our Biopharma Investor update in June will set out details of progress in the R&D pipeline and key growth drivers, medium-term financial outlooks and capital allocation priorities.

We intend to implement a new distribution policy for dividends from 2022, the year of separation into two new companies. The new policy will ensure we have the right capital structure for each business, and the capacity to invest so that we can deliver growth and long-term shareholder value. We expect to implement the new policy from Q1 2022, and that the distribution will be lower than the 80 pence per share currently paid. The new policy will target a progressive dividend informed by appropriate earnings payout ratios through the investment cycle and will be well covered by free cash flow.

With that, I will hand over to Luke.

**Luke Miels (President, Global Pharmaceuticals):** Thank you, lain, and hi, everyone! 2020 was a transformative year for GSK in terms of our commercial execution capabilities and despite the challenges brought about by the pandemic, during the year we benefited from a number of important changes to our HCP engagement policies and salesforce incentives.

In addition, we invested in expanded digital capabilities to complement our traditional detailing approach. The result of these changes was that we were able to compete more effectively in our key markets and to win greater share of voice across key drivers in our portfolio.

The momentum we now see behind our new and specialty products is really encouraging and I just wanted to spend a few minutes highlighting some of the important examples.

### Strong contribution from key respiratory growth drivers

Starting with key respiratory drivers which you'll find on Slide 18, *Trelegy* had a tremendous year with sales up nearly 60% to over £800 million in just its third year on the market.

*Trelegy* continues to lead the inhaled triple category for COPD in the US, Europe and Japan and is growing the overall market. In the US, the FDA approval announcement in September had a hugely galvanising effect with two-thirds of HCPs recognising the uniqueness of our dual indication and we have seen the prescribing by allergists soar. As a consequence, *Trelegy*'s market share has continued to build and in fact has now more than double the share of its nearest rival and closing on it 50%.

While we expect asthma to help drive momentum in the US, it's also important to stress that we still have a major opportunity for growth in COPD as a little more than a quarter of patients receive triple therapy, despite an addressable patient population in which up to two thirds of sufferers are at risk of exacerbations.

If I move to *Nucala*, we had another strong year delivering close to £1 billion in sales and growth of 30%. *Nucala* has maintained its category leadership in the US and other key markets based on its precision targeting of IL-5 to reduce eosinophils to normal levels which differentiates it from other biologics.

Looking ahead, we continue to see significant growth opportunities in asthma, given that only 28% of eligible patients in the US currently receive a biologic.

In addition, we are confident of extending *Nucala*'s leadership through expansion into other eosinophilic-related conditions, including EGPA, HES and potentially nasal polyps and COPD.

Last, but not least, we want to capitalise our learnings with *Nucala* and deliver a new level of patient convenience through our novel, long-acting IL-5, GSK 294. This potentially transformational asset will be dosed as a convenient subcut injection once every six months and we are moving into Phase III this month. With positive in-house data and a validated mechanism of action, we believe it has a high probability of success and the potential to deliver blockbuster sales.

# Benlysta: first and only biologic for SLE and LN

Switching on to Slide 19 to *Benlysta*, we have now seen nine successive years of double-digit growth and this is a testament to the unique value this product brings to lupus patients.

In 2020 growth of the product was driven by convenient at home administration with a subcut which has brought in new patients, and by the success of our IV launch in China.

At the end of the year *Benlysta* received FDA approval for use in lupus nephritis which affects around 40% of patients with SLE and can lead to end-stage kidney disease and in doing so, *Benlysta* became the first and only drug to be indicated for both indications.

This slide shows that the lupus market is a substantial upside potential as more than 80% of eligible patients remain untreated with *Benlysta* in the US and of course even more around the world.

The number of untreated patients has increased further with the lupus nephritis indication, so we remain very optimistic that this is a major growth opportunity ahead to help these patients.

But it also highlights the expanding market opportunity in China where we have filed for the subcut formulation in the lupus nephritis indication. Taken together, we expect *Benlysta* will continue to surpass forecasts on the upside.

### Strong launches driving uptake in Oncology

On Slide 20, we continue to make great progress in building our Oncology business. With *Zejula* we were able to drive a substantial increase in market share. In particular we have been very successful in using the FDA approval of PRIMA which resulted in *Zejula* having the best in class label as the only PARP inhibitor for all-comers in the first-line maintenance setting.

As a consequence, our overall share in this setting continues to grow.

In the BRCAm population we are up to a 27% share, but the real uplift has come in the wild-type population where we have overtaken Lynparza as the category leader and we now have over 50% share, again a direct result of execution on the PRIMA study.

Looking ahead we know there is a significant opportunity to penetrate the market given that watch-and-wait is still unfortunately being used in the majority of women in the first-line maintenance setting in the US and only one guarter of patients receive a PARP.

We are addressing this through carefully targeted medical education programmes and through DTC. Beyond first-line ovarian maintenance, we have a robust development plan in different settings and other cancer types, including non-small cell lung. In the short-term though, we need to navigate the impact of COVID lockdowns which continues to materially disrupt debulking surgery and treatment rates. We remain confident on the potential of *Zejula*.

I will now turn to *Blenrep* which we launched in the second half of 2020 to heavily pre-treated multiple myeloma patients in the US and Germany. It is still early days but we are pleased with the solid demand we have seen which reflects the high unmet need in later lines of disease. Response from physicians, patients and advocacy groups has continued to be excellent, based on the potent efficacy of the drug in the approved setting and on positive clinical updates in other settings, such as we saw at ASH. To date, more than 1100 ACPs and 700 patients have enrolled in our US REMS programme. We are supporting the launch with a highly experienced salesforce and our share of voice is almost at the level of Darzalex.

We are also focused on the continued development of this practice-changing medicine through alternative doses, scheduling and combinations to improve the safety profile, and to potentially extend approval into earlier lines of therapy. Later in the presentation, Hal will discuss the significant potential for *Blenrep* in the earlier lines of therapy, highlighted at ASH. Consequently, we are optimistic that *Blenrep*, like *Zejula*, has the potential to deliver blockbuster type sales and to be a cornerstone of our fast-expanding oncology business.

### Shingrix: strong underlying demand with likely short term pandemic disruption

Shifting to *Shingrix* on Slide 21, we saw a strong recovery in sales growth to more than 20% in Q4. This was driven by increased wellness visits in the US, higher demand in Germany, and the phased launch in China. For the year as a whole, *Shingrix* moved back into double digits. Critically, for the long-term output for this key growth driver, we made good progress on our planned capacity expansion, inventory on hand and our approved production plans for 2021 and beyond, should allow us to fully meet demand until our new facility comes online in 2024. At that point, we will benefit from a further step-up in capacity amounting to tens of millions of doses over time, supporting our multibillion sales expectations.

In the near term, however, we expect to contend with some further disruption in the US. The resurgence of the pandemic is already resulting in double-digit reductions in well visits in January, which is impacting our Vaccines business more broadly. In addition, the prioritisation of vaccine resources towards COVID-19 immunisation is likely to have a significant impact on older adult vaccination, including *Shingrix*, especially given the recommended 14-day window either side of mRNA vaccine shots.

The slide you can see shows a couple of scenarios of how the phasing of *Shingrix* could be impacted for several months in patients who are receiving COVID vaccines. Of course, we could see similar disruption in other key markets, including Germany and China. I do, however, want to stress that the extent to which *Shingrix* is impacted, the fact is that this is a timing issue and the underlying demand remains strong since we are expecting sales to be deferred, not lost.

What does this mean for the 2021 outlook? Taken together, we are anticipating broadly similar volumes in the US for *Shingrix*, with growth weighted to half-two, and increasing contributions from markets outside the US. Assuming progress towards more normal operating conditions, we expect a significant step up in *Shingrix* sales in 2022.

With that, let me now hand over to David.

David Redfern (Chief Strategy Officer, Chairman ViiV): Thank you, Luke. Hello everyone.

#### HIV: Dovato and Cabenuva to accelerate growth outlook

This HIV business grew 2% in Q4 and 1% for the year. Within this, we achieved a noticeable acceleration in our dolutegravir regimen, with growth reaching 4% in the US and 8% in Europe in the fourth quarter. This growing momentum is the result of strong execution – strong *commercial* execution – behind our two-drug regimen, and *Dovato* in particular. We now have the leading share of voice in the US and Europe and this helped sales of *Dovato* and *Juluca* to more than double in 2020 to over \$1 billion.

A key driver for *Dovato* has been the inclusion in mid-2020 of the TANGO switch data in the US. This has helped to drive dolutegravir share of the NBRx switch market in the US to

approximately 31.5%, well above our TRx share of just over 25%, therefore supporting our growth expectation over the coming year.

We have also seen a positive start for *Rukobia* with more than 300 patients now on this potentially life-saving therapy.

Turning to our injectable portfolio, on 21 January we received FDA approval for *Cabenuva*, the world's first long-acting injectable for the treatment of HIV. This followed European approval in December. *Cabenuva* is the first and only once-monthly regimen shown to have non-inferior efficacy and comparable safety to a daily oral three-drug regimen. For many people infected with HIV, the stigma is a daily reminder of their HIV status and, as a result, up to two-thirds expressed interest in a long-acting therapy and, in our pivotal studies, nearly all patients preferred *Cabenuva*.

We also see a significant opportunity for cabotegravir in the PrEP setting and we will be presenting the detailed superiority data versus daily oral PrEP at CROI next month. We intend to file this product to global regulators in the first half of this year.

We believe *Cabenuva* and cabotegravir for PrEP will both provide significant benefits to patients as well as having blockbuster commercial potential.

In summary, we are very confident in the outlook for ViiV. We expect a progressive acceleration in growth, underpinned by the continued expansion of the two-drug regimens, noticeably *Dovato* and the launch of *Cabenuva* and, in due course, cabotegravir in the PrEP setting.

With that, I shall hand you over to Brian to talk about Consumer.

#### Brian McNamara (CEO, GSK Consumer Healthcare): Thanks, David.

#### Integration update

In a year where consumer health has been more relevant than ever, our results today reflect the strength of our portfolio, the benefits from successful integration to date and our investments in Digital and Innovation paying off. This has been despite the challenges of the pandemic and the need for more agility than ever in managing through the crisis.

I would like to start by sharing an update on integration: the positive momentum I shared at Q3 results has continued with a number of milestones achieved to date. The commercial integration is now largely complete with the manufacturing integration under way. 97% of Pfizer Consumer Healthcare revenue is now on our systems, with 74 markets having transitioned since the start of the pandemic, and 100% of co-locations are now complete.

At the time of the transaction, we provided synergy and financial guidance for 2022, that remains unchanged.

On divestments, we completed transactions in 2020 delivering on our £1 billion proceeds target. The divestments of more than 50 growth dilutive brands has helped strengthen our portfolio.

Our separation programme is also on track with work around the future organisational structure and systems separation under way.

# **Consumer Healthcare FY20 performance**

In 2020, pro forma revenue at CER, excluding brands divested and under review, grew over 4%, supported by healthy brand growth and overall share growth. Our business continued to benefit from the consumer focus on health and wellness, the strength of our brand portfolio and successful execution.

Vitamins, Minerals and Supplements remained a stand-out performer, with *Centrum*, *Emergen-C* and *Caltrate* all up double digits and our category performed ahead of the market. We also saw double digit growth in the final quarter in China and in our retained business in India.

E-commerce was strong across all categories, growing around 70% for the year and now at around 6% of sales, up a few percentage points on last year. In key markets such as US, China and the UK, where our e-commerce shares are ahead of this level, we out-performed. Importantly, we grew significantly ahead of the market gaining overall share.

Turning to our power brands, we saw six of the nine power brands in growth, four of these brands growing double digit and with seven out of nine gaining or holding share.

We saw strong performance from our innovation and examples during the year include: Sensodyne Sensitivity and Gum, which is now in over 50 markets and continues to help drive overall brand share. In the US, the Voltaren Rx to OTC switch was a key growth driver, and the brand accounted for 79% of pain relief category growth in the adult pain segment.

Finally, our *Advil Dual Action* launch in the third quarter, the first ever ibuprofen/acetaminophen combination, helped *Advil* return to full year growth.

Looking ahead, we have a strong pipeline of exciting innovations for 2021.

# World-class portfolio with category-leading positions

In 2020, our portfolio strength helped us deliver over 4% revenue growth CER, excluding brands divested and under review, for the full year.

Finally, it is important to note that on the back of all that great integration work to date, we start 2021 with a fantastic portfolio of category-leading brands with a strong geographic footprint positioned in the sector which is now more relevant than ever. With that, I'll hand it over to Hal.

Dr Hal Barron (Chief **Scientific** Officer & **President** R&D): Thanks, Brian, and good afternoon everyone. Today, I shall spend the next 10 minutes or so summarising the JP Morgan Healthcare Conference last month and highlighting some of the assets believe transformational medicines we have the potential to be and vaccines.

### Building a sustainable pipeline of transformational vaccines and medicines

Let me start by reminding you that in July 2018, I introduced our new R&D approach, focused on Science, Technology and Culture. Our goal was, and still is, to build a high value, sustainable pipeline to have focus on the science related to the immune system and to use human genetics and advance technology such as functional genomics and machine learning to help identify novel targets with a higher probability of success and a robust life-cycle potential.

Two and a half years into this new approach, I believe we have made significant progress. Across our pipeline, we have seen the benefits of our commitment to immunology and genetics. In Oncology, our focus on immunology has resulted in numerous novel immuno-oncology medicines and several innovative cell therapies being added to our pipeline.

Our focus on human genetics and functional genomics has led to the acquisition of Tesaro, the formation of the Synthetic Lethal Research Unit and through business development a growing portfolio of programmes and important collaborations.

In Infectious Diseases, this has led to a significant number of opportunities across both Vaccines and Pharmaceuticals, including solutions to the COVID-19 pandemic. Our focus on human genetics and functional genomics has resulted in more than 70% of the targets in research now being genetically validated.

We are also delivering value from our commitment to life-cycle innovation due to closer collaborations between the Commercial and R&D organisations. A good example of this is the number of new launches for *Nucala* that Luke discussed and, most recently, with the advancement of our long-acting IL-5 programme that we plan to move into pivotal studies this month.

# 2020 delivered significant progress in strengthening and advancing our pipeline

This slide summarises the significant achievements R&D delivered in 2020. During the year, we received nine major approvals, including the approval of four new molecular entities. We delivered positive data and multiple high-value programmes, leading to the initiation of nine pivotal studies. We continued to augment the pipeline through business development, with more than 20 deals executed in 2020, including important new collaboration with both Vir and CureVac.

### Strong R&D pipeline

The next slide shows a snapshot of our current pipeline of 57 vaccines and medicines which are focused predominantly on infectious disease, oncology and other immune-mediated diseases. 23 of these assets are in Phase 1, 12 in Phase 2 and 22 in potentially pivotal studies, with the vast majority of these assets likely being either first or best in class.

# High value late-stage pipeline; >10 potential blockbuster launches by 2026

Based on our current projections, by 2026 we have the potential to launch numerous new vaccines and medicines, as well as new indications for existing assets. Given the probability of success associated with drug development, we don't expect all of these assets to succeed and reach

patients. However, if all were successful we believe that more than 10 vaccines and/or medicines in our late stage portfolio could significantly change medical practice and thus have peak annual sales potential in excess of \$1 billion, and a number of these assets, such as our RSV vaccine in older adults, could have multi-billion dollar potential.

Given time constraints, I cannot discuss all these programmes today but will have an opportunity to provide more information in June.

### Innovative oncology portfolio

The next slide shows the significant progress we've made in oncology, where we now have a development portfolio of 15 potential medicines. We took a smart bet with the acquisition of Tesaro, and this was validated by the PRIMA data. As you heard earlier from Luke, we are pleased with the position response we are seeing to *Zejula* as we continue to grow market share for this potentially best in class PARP inhibitor.

I'd like to take a moment to talk to you about bintrafusp alfa, the TGF-beta trap PD-L1 antagonist, and the recent news about the 037 lung study. Given an industry average success rate of about 25% for Phase 2 studies, the high-risk nature of IO studies, and the high bar we set with the head-to-head study against pembro, Merck's announcement that the study has been discontinued is disappointing, but not completely unexpected, and I still believe this was a smart, though risky, bet to have taken.

Another IO programme where we made substantial progress was *Blenrep*, which I'll cover on the next slide.

# Blenrep: opportunity in earlier lines of multiple myeloma

Blenrep is the first approved BCMA-targeted therapeutic, and our most advanced immune-modulating asset. In addition to blocking BCMA and delivering a potent drug toxin, it has enhanced ADCC activity and induces an immunogenic cell death, both of which we believe are important for its impressive efficacy.

As many of you are aware, keratopathy is a side effect that some patients experience when receiving *Blenrep*, and we are focused on reducing the risk of this occurring. One of the approaches I am particularly excited about is the novel combination of *Blenrep* with SpringWorks' gamma secretase inhibitor, which inhibits the cleaving of BCMA from the cell membrane. This could result in higher expression of BCMA on plasma cells, which could enable a lower dose to be used and still preserve the impressive efficacy. We should have some preliminary data on this combination from the ongoing DREAMM-5 study by the end of this year.

There is significant potential for *Blenrep* in earlier lines of therapy and this was highlighted at ASH in December, where compelling data from the Phase 1/2 ALGONQUIN study in the second-line setting were reported. The key message from this study was that deep responses are being seen with *Blenrep* when given in combination with PomDex. Across two different dose regimens, the combined overall response rate was 88%, and there was a 100% response rate in patients who were refractory

to an IMiD, PI, and daratumumab. Additionally, the overall incidence of corneal events was reduced with the lower dose regimen. These data give us increased confidence in our ongoing second-line pivotal DREAMM-7 and DREAMM-8 studies.

# Feladilimab, ICOS receptor agonist: several near-term catalysts anticipated

I'd like now to highlight another potential medicine in our IO oncology portfolio: our unique first in class ICOS agonist antibody called feladilimab. ICOS is a receptor on T-cells that stimulates T-cell expansion. Feladilimab is an IgG 4 antibody designed to stimulate and grow cytotoxic T-cells without the depleting effect seen with other antibodies.

We are developing our antibody in combination with pembro for patients with first-line relapsed/metastatic head and neck squamous cell cancer, in two ongoing Phase 2 studies, INDUCE-3 and INDUCE-4, both of which, if the interim data is encouraging, will ungate the Phase 3 component of these studies. INDUCE-3 is enrolling well and we expect to have data to enable this interim analysis from the first half of this year.

ENTRÉE lung is our other randomised Phase 2 study looking at overall survival in non-small cell lung cancer patients, which should read out in the first half of the year. We also intend to share new data from the INDUCE-1 study in various different tumour types by the end of the year.

So, as you can see, there are a number of upcoming data readouts which will clarify the path forward for this potentially transformative medicine.

# **World Leader in Infectious Diseases**

Switching from oncology to infectious disease, where we have a world-class pipeline of 30 vaccines and medicines and a market portfolio of 22 vaccines and medicines which had revenue of approximately \$16 billion in 2020. A number of these programmes have the potential to transform patients' lives, and we plan to cover these in more detail at the June event. These include our antisense compound, GSK'836 which may provide the first functional cure for people with chronic hep B, and gepotidacin, which could be an important new treatment option to combat antimicrobial resistance and potentially be the first new antibiotic in 20 years to treat patients with uncomplicated urinary tract infections and urogenital gonorrhoea. And as David mentioned, an impressive HIV pipeline.

Lastly, given recent advances in vaccines majoring in the pandemic, it's important to highlight our exciting, early stage vaccines pipeline that leverages our extensive portfolio of platform technologies such as mRNA, both non-replicating and self-amplifying as well as viral vectors and adjuvants.

Several of these candidates are actually expected to move into the clinical over the next 18 months. Additionally, as Emma mentioned, we announced today a new agreement with CureVac to develop a next generation mRNA COVID vaccine which complements our previously announced collaboration with CureVac on mRNA technology more broadly.

Today, however, I want to focus on two programmes that I am particularly excited about – our RSV vaccine candidate for older adults and the highly promising COVID-19 antibody, VIR-7831.

# RSV older adults: major opportunity with high unmet need

One of the highlights of 2020 was the exciting Phase 2 data we shared on our RSV vaccine candidate for older adults and mothers at the ID Week in October. Both vaccines are based on a recombinant subunit prefusion RSV antigen which is believed to trigger the required immune response. For older adults, we combined this with our proven AS01 adjuvant to enhance the immune response. The Phase 2 data in older adults showed our vaccine induced a near ten-fold increase of protective antibodies. Importantly, T-cells were boosted to a similar range to that observed in younger adults given non-adjuvanted vaccine. And importantly, the vaccine was well tolerated.

Clearly this is highly encouraging data and we expect to move into Phase 3 this month and anticipate receiving initial pivotal data in the second half of 2022. Vaccinating the elderly against RSV represents a major unmet medical need with RSV infection resulting in over 170,000 hospitalisations and unfortunately 14,000 deaths a year in people over 65 in the US alone.

Not only could this vaccine have profound clinical benefit, but we also believe that it represents a significant commercial opportunity.

### VIR-7831: potential best-in-class COVID-19 antibody

We have also been active in the search for solutions to the COVID global pandemic and I want to focus today on the VIR-7831 which we, along with our partners at Vir, believe has the potential to be a best in class antibody for COVID. This is due to 3 unique characteristics.

First, this is a very potent neutralising antibody and by binding to a unique and highly conserved epitope, it is expected to confer a high barrier to resistance. Two recent publications have supported this hypothesis which we believe could become extremely important given some of the recent reports of emerging mutant strains.

Second, this antibody was designed to have increased effector potency, potentially allowing for greater efficacy and this is in part why the NIH chose it for the ACTIV-3 in-hospital study.

And finally, VIR-7831 has been engineered to have an extended half-life with the so-called LS mutation which should enable us to observe efficacy at a lower dose, possibly enabling intramuscular dosing.

We have a number of ongoing and planned studies with VIR-7831 including the recently announced BLAZE-4 study in combination with Lilly's CoV555 antibody which we expect data from in the first half of this year.

Before I move on to my last slide, I would like to make a comment about our randomised Phase 2 study called OSCAR, a trial evaluating otilimab, our anti-GM-CSF antibody as a potential treatment for patients with severe COVID-related pulmonary disease.

The pathophysiology that underlies severe COVID is only just now being unravelled. The emerging science supports a maladaptive innate immune response associated with actually increased GM-CSF expression, particularly in older patients where COVID-19 is particularly severe.

We remain cautiously optimistic that our Phase 2 study which will read out this quarter could demonstrate a benefit in patients whose disease is driven by GM-CSF, enabling us to move to Phase 3 with this potentially important medicine.

#### Multiple important catalysts in 2021

Now moving to my final slide and our key catalysts for 2021, this year we have already received US approval for *Cabenuva* for the treatment of patients with HIV. Later in Q1 we could have data on the pivotal study of VIR-7831 and the Phase 2 data of otilimab.

In Q2, we should have the feladilimab data I referenced earlier and in the second half of the year more data on *Blenrep* as well as data on daprodustat.

I will close by reiterating and I believe we have made significant progress over the last two and a half years in building a high value, sustainable R&D pipeline which we expect to strengthen further with continued delivery in 2021.

With that, I will hand it back over to Emma.

# Emma Walmsley: Thanks, Hal.

# High confidence in competitive growth outlook for 2 new companies

To summarise, 2020 was a year of great progress as we approach separation into two new companies and we remain fundamentally on track to deliver all our strategic priorities. Our pipeline is stronger, our commercial execution is sharper, our cost base leaner and our confidence higher in our ability to deliver sustainable long-term growth post-separation into two companies.

In terms of our priorities for the year, we will retain our execution focus on innovation and performance and expect another year of investment behind our pipeline and new product launches. We will continue our work on optimising our cost base across the Group and setting up the Consumer business as a standalone entity, and with our long-term focus on trust, we will work to deliver on our public commitments and maintain our sector-leading ESG performance.

All of this aims to support future growth and the significant value creation we expect to deliver with the formation of two new leading companies, each with the opportunity to improve the health of hundreds of millions of people.

Finally, and very importantly, I would like to recognise the enormous contribution of our people and all the partners we have worked with in 2020 under extraordinary circumstances. Without them we wouldn't succeed and we count on them now as we prepare for our very exciting future.

With that, Operator, the team on the line is ready to take questions.

#### **Question & Answer Session**

James Gordon (JP Morgan): Thank you very much for taking my questions: I have two, please. The first question is about Vaccines and the CureVac deal and mRNA vaccine. The release says that as well as looking COVID-19, you will also look at other respiratory vaccines, so could that include something like RSV for instance? More generally, how are you thinking about a vaccine in terms of the mRNA space? Could you see a lot more competition coming in there? I know that our conference last month, Moderna and Biontech were talking about going after flu, amongst other diseases. So, could mRNA vaccines be a serious threat to GSK's existing protein-based vaccine business? Is it also a big opportunity for GSK? That was my first question.

My second question is about the EPS growth rebound in 2022. I assume you regard it as a meaningful improvement in revenues and margins but the question is, how meaningful could the rebound be in 2022? If Vaccines rebound and there is some catch-up, and the rest of the business is doing better and opex grows slowly, could 2022 be a year of double-digit EPS growth? Could 2022 earnings be above 2020 earnings power? How should we think about that, please?

**Emma Walmsley:** Thank you very much, James. In terms of the CureVac deal, I will ask Roger to comment on how strategically this impacts our portfolio, and the enormous opportunities that we see here, and why we think that GSK is very, very well-placed.

Obviously, we were delighted to make the announcement this morning because it allows us to contribute to COVID. We are all learning and it continues to evolve, and it is becoming increasingly clear that there are opportunities both in Vaccines, endemically, but also – as Hal has alluded to – in terms of our therapeutic treatments. It is very important for that but it is also additive to the very exciting platforms that we are taking – and we see this as a second generation mRNA that can be combined with some of our other platforms.

Roger, it would be great to hear from you, about how this fits in more broadly, and then we will come back to your guidance question after that.

Roger Connor: Thank you very much for the question, James. Specifically on combinations, I think we will share more later in the year in terms of our overall pipeline, but it is obvious that getting access to the COVID second generation is a big opportunity for us. We have been looking at combinations and certainly, looking at the flu asset that you referenced as well, is there potential for a combination in the future? There will be more coming on that.

As you step back and look at the CureVac relationship, we are delighted. We are delighted to add what we have just announced today to a very strong strategic relationship already, bringing together two companies – CureVac with their platform and us with the technical expertise. The deal we have is one which we really think will make a difference.

Specifically on the COVID-19 vaccine and this particular deal, this idea of getting multi-valent protection, we think, will be critical. You will have seen that data from recent clinical trials certainly

shows that the level of protection from some of the licensed vaccines can potentially fall as these new variants evolve. mRNA is a proven platform now and there is one which we feel is a real strategic strength of ours: applying it to COVID brings breadth of coverage, we think, to the multi-valent approach, and speed of reaction because of the very nature of reprogramming an mRNA vaccine. We will also be working with CureVac on how we store and distribute this in an optimal way.

Just on your broader strategic question around the opportunity threat of the technology, my headline here is that it is an exciting time to be a global leader in vaccines. We feel very well positioned, particularly on mRNA-2 programmes, which Hal referenced, internally, self-amplifying, and then also the relationship with CureVac, which is a non-replicating mRNA. We have very strong optionality here, too, and we see far more opportunity than risk. We would never be complacent but, from an mRNA perspective, it can't be applied to all disease areas. When we add this, we think it really complements our technology portfolio: when you add it to viral vectors, add it to adjuvant, if you add in an mRNA – we did a portfolio, a deck of cards here that we can select from, to make sure that we get the best vaccine for each disease that we are developing.

You just have to look at our pipeline. If you look at our therapeutic hepatitis B vaccine, that is an example of a combo technology, where we think we will be able to plug and play some of these for the best vaccines, going forward. We will share more of that as we go through the year. The headline is that I think we are very well placed.

**Emma Walmsley:** Thank you very much. James, in terms of your guidance question, obviously we are really pleased with the progress we are making. We have reiterated several times today that despite the impact of the pandemic, which we see as short-term, there is absolutely no change to our ambitions and confidence in 2022. We will give you more precision about that in our update for the Biopharma group more broadly, in terms of growth outlook and the medium term.

lain, would you like to add any more details?

**lain Mackay:** We will certainly provide lots more detail in terms of what supports our optimism around the outlook for 2022 and beyond, James. Importantly, there are building blocks here: 2020 was a tough year, but we delivered in our guidance range, and, as you know, that was informed well before we started living with the pandemic.

2021 the in-year impact is very much about Vaccines. We see the progress in our Pharma business and in our Consumer Healthcare business: again, very much in line with what we saw at this time last year, and we made great progress in 2020 which will continue through 2021. The work we are doing around the cost base, the restructuring of the Group and the readiness for separating the Group all gives me a great deal of confidence around that progress as far as meaningful growth and the top line expanding growth in adjusted EPS from 2022 onwards.

**Emma Walmsley:** Luke cut out from Australia at exactly the moment when he was giving precision on the *Shingrix* outlook, so I shall repeat what was said. We really do see the impact on *Shingrix* being about a deferral of sales. We have made great progress in manufacturing capacity

and our expectation is for broadly similar volumes in the US, recognising the uncertainty that lain introduced, with growth weighted more to the second half and more of a contribution from other countries ex-US, before we then see, assuming a return to a normal healthcare operating system, some good, strong growth in 2022.

Next question please?

James Quigley (Morgan Stanley): As a first question, I would like to get your thoughts on any of the other levers or mechanisms in order to recognise the cash flow to be able to invest in Pharma innovation. Clearly, the dividend cut will unlock some cash for you to invest and you guided for the Pharma business excluding any divestments, so should we expect some more divestments and cash realisation this year to invest in other areas, or in 2021, or is that a sort of beyond strategy?

You announced the extended CureVac collaboration this morning and you have lots of collaborations, as Roger highlighted, in other areas. More broadly, how are you taking the earnings from your Vaccines work and looking to apply that into immunology, immuno-oncology and use mRNA in a broader sense as a therapeutic? Thanks.

**Emma Walmsley:** As far as divestments, the short answer is, yes, and I'll ask lain to comment. We are constantly looking at the portfolio and we do have further plans for this year but I shall ask lain to comment on that and the broader cash flow discipline. I am very pleased with the progress we are making overall on operating delivery there. Then I shall come to Hal. This is really the great, strategic benefit of the new Biopharma company, being focused on driving second vaccines and specialty, all around the science of immunology. We are seeing this great convergence and we now have one development organisation, so after lain, let's come to Hal to talk a bit about how we are thinking about that with the Vaccines and Pharma R&D team.

**lain Mackay:** Thanks, Emma. James, a really strong performance from the team this year in terms of free cash flow. Obviously, it was a year that was supported by really, really good work by Brian and the team across the tail brands within the Consumer Healthcare portfolio, reaching - surpassing in fact - the billion sterling net proceeds in that regard.

What continues, as I mentioned in the script, on the established Pharma portfolio where David Redfern and his team continue to work very closely with Luke on where the opportunities are and the right inflection points for divestments from that portfolio. There are a number of targets that we are working on presently and we shall keep you informed on that as we make progress.

I believe it is fair to say that in the Pharma space, for divestments in 2020, it was a somewhat more difficult year from a valuations perspective and our focus on divestment is doing it for the right reasons and at the right valuation. There is a good focus around that and we would certainly expect to see proceeds supporting free cash flow as we work through 2021 in that regard.

Beyond that, it continues to be a really sharp focus on improving our management of working capital in which we have done a lot of really good work over the course of the last two years but, as ever, there is more to be done in that area.

Then when you look forward - and we shall provide a lot more information about this at our Biopharma update in June - it is very much about establishing the right capital structure for each of these two new companies going forward. You will recall from earlier conversations that there is a significant deleveraging opportunity for GSK on the separation out of the Consumer Healthcare business, which clearly continues to support our ability to do business development and invest in the strength of our pipeline.

Emma Walmsley: Hal, over to you on the scientific synergies in immunology?

Hal Barron: We are very excited about the advances that mRNA have provided as it relates to COVID but, as you see, the collaboration with CureVac is not only focused on that but, potentially, broader. We believe there are opportunities for mRNA to provide benefit to patients in other infectious diseases and possibly even beyond infectious diseases. It is also important to note that our focus on the immunology really helps us understand what kinds of immune responses are needed for every different type of infection, allowing us to leverage mRNA in some instances, self-amplifying in others, the other platforms that I mentioned. I think that our focus on immunology will fit very nicely with our deep successes we've had in vaccines, to allow us to really bring benefit to patients in a much more effective way.

**Laura Sutcliffe (UBS):** First question is on your existing flu sales drive. I think you've indicated that volumes in the US will be pretty flat this year, should we take that as a sign that you have gone as far as you can with your existing flu set-up, or is there any scope to grow again beyond this year?

Then secondly, on *Cabenuva*, are you going for a full US launch immediately, or are you thinking waiting until later in the year, when the environment for launching drug like this is maybe a bit easier? And perhaps you could give us a picture of what market access is looking like over there as well. Thanks.

**Emma Walmsley:** Let's come to David about *Cabenuva*, because this really is a very important, pioneering medicine, leading the way for patients living with HIV, and can be a foundation in many ways for the pathway forward for, as David said, accelerating growth. We're really looking forward to that, but as you've said, it is a new paradigm in behaviours in a not simple environment.

On flu, I think Roger alluded to this as well – well, Iain covered it in some of the forecasts, which you picked up. It was a tremendous year in 2020, we are expecting volumes but some pricing pressure for 2021, just due to phasing of RAR, but I think if your question underlying that is old technology versus new, I don't think we should walk away thinking mRNA is going to be the solution to all vaccines, as Roger said. There are some disease areas where it's not relevant, there are others it's going to be very important to bring combinations. It is probably highly relevant for flu, and indeed

potentially with combinations of respiratory infectious diseases, so this is an area where we will be looking at new technology platforms, in terms of any other future plans, but more of that later.

Let's come to David in Cabenuva plans and access question.

**David Redfern:** I think the short answer is yes, we're going for a full launch of *Cabenuva*, and in fact we are shipping this week in the US, the first oral lead-ins and then the injectible will be shipped in the very near future. The reason we're doing that is this is the first long-acting therapy for HIV, and there is definitely pent-up demand for it. As I said in my remarks, two-thirds of HIV patients have expressed interest in long-acting treatment, we saw from the clinical trials that recruitment went very fast, adherence was very high and patients wanted to remain on the medicine. There's definitely a pent-up demand, and a very passionate group of patients who for all sorts of different reasons can't plan, but often the stigma and the emotional burden of taking daily oral pills, want access to *Cabenuva*, so we are launching.

As always, it will be a build: there are some set-ups for physicians who have to get used to giving injections, but we've been working with practices across the US to set that up, there are always the early adopters. We have to go through reimbursement, as always, for different formularies and so forth, that normally takes a quarter or so, but nothing particularly unusual here versus any other launch.

We will be launching it, we will build momentum, and in the very near future, or in the next few weeks, we will also file in the US for the eight-week data, so every two months, based on the eight-week data that we already have, and that will go in. We're really excited to get going with *Cabenuva*, and we know patients are waiting for it.

Geoffrey Porges (SVB Leerink): I'd like to ask a question about the future and COVID, and it's nice to see GSK really getting engaged with the response to COVID now. Normally I would ask Luke to answer it, what the future looks like in a COVID-free world, but perhaps I will direct my question to Hal.

Hal, I'm getting mixed signals from GSK. On the one hand your financial commentary suggests that you expect medical activity and particularly *Shingrix* to return towards normal by the end of the year and then be more or less normalised with catch-up next year, but you are still committing to developing a COVID vaccine, and more engaged with developing a COVID antibody, despite that outlook. Could you help reconcile those signals, and particularly, you mentioned these variants and I think there is near panic about them now. Do you think that the so-called South African variant with the triple mutation at the receptor binding domain is a terminal adaptation of the virus ,or do you think that this is going to be a whack-a-mole, every six to 12 months the virus is going to mutate to an immune escaped variant that we will have to continue to iterate against?

**Emma Walmsley:** We will come to Hal in just a second, but just to repeat, the assumptions in the outlook that we have given and that lain laid out is that we would expect, and this is really in our large developing markets, that healthcare operating systems return to verging on

normal in the second half of the year. This is because we are assuming, in this scenario, successful deployment of the vaccination of COVID.

As lain said very clearly, the variants in that will depend on the pace of that and the infection rates. At the same time - and Hal should certainly comment on this scientifically and epidemiologically - it is clear that this virus is continuing to mutate and we do expect some kind of endemic market, although as you have all seen, the data is showing in different degrees under different vaccines, the degree of protection on certain mutants today. I just wanted to clarify what the assumptions are and what we have laid out and then Hal perhaps can comment on the ongoing opportunity for COVID, not least with the hesitancy rates in some countries of vaccination anyway. Hal.

**Hal Barron:** Yes, thanks. I think it's pretty clear despite the robust reduction in symptomatic disease with the vaccines that we have seen that we are really just beginning. There is already evidence, as Roger mentioned, from vaccine trials that the protective immunity from some of the vaccines is lower in certain patients with the virus that has mutated and these variants of concern that are emerging are probably not going to end. There will probably be more variants.

I think that our approach is very consistent with that. From the very beginning we were worried about mutations and hence did the deal with Vir for a monoclonal that was binding to an epitope that we believed was very unlikely to mutate because of how it was discovered to have been both observed and effective in Sars-CoV-1 patients, but also highly neutralising in the current COVID-19 epidemic. We were from the beginning imagining these variants coming out and developing this monoclonal which we think will have significant benefit for those patients unfortunate enough to contract the virus.

We are also not resting on that. We do have, as I mentioned, the combinations with the lowering antibody should mutations emerge even more robustly than we expect and of course from a vaccine perspective, given these mutations, whether it becomes another pandemic or more likely an endemic sort of state with the multivalent mRNA vaccine potential that we have with CureVac. I think our strategy from the beginning has been very consistent that that is likely an outcome and now we are moving forward.

I should also say that in addition to being able to prevent the hospitalisations with the VIR-7831, we do have a trial with the NIH looking to see even if you can reduce the morbidity of patients being treated within the hospital as well as our otilimab therapy, as I mentioned, which I think leverages our really deep understanding of the immune system and evolving understanding of how the COVID pulmonary syndrome evolves and are cautiously optimistic that that could potentially be a treatment option for those patients whose severe pulmonary COVID symptoms are GM-CSF mediated.

It's a bit of a three-pronged, maybe even four-pronged approach, and I think it has been relatively consistent from the beginning.

**Graham Parry (Bank of America):** Thanks for taking my questions. The first one is just going back to follow-up from James Gordon's question at the beginning just about the recovery rate into 2022. You are flagging the '21 hit from COVID is temporary and then strong recovery in 2022. If you look at the consensus EPS at the moment, it's about 120p, so that would be about 20% EPS growth in 2022 over what your guide is implying for 2021, so could you help us with your level of comfort with where that is or perhaps which variables consensus should be thinking about for their 2022 forecast.

And then secondly, you talked about giving dividend policy for the BioPharm business as well as an outlook over the mid-term in June. Do you expect to give a range for payout ratio or cover or even declare a very specific what the 2022 dividend would be as a base early to give the market some sort of certainty?

And when you are saying about factors that go into, or having an appropriate dividend through the cycle, can you just help us understand what factors go into that? Are you benchmarking against other companies and which ones would you consider to have an appropriate dividend policy? Thank you.

**Emma Walmsley:** Yes, okay, two important questions. Iain, do you want to pick up both on outlook and clarity of what is coming on the dividend or distribution policy versus dividend value?

lain Mackay: Absolutely. Thanks for the question. As you might imagine, Graham, we are not providing 2022 guidance today, but what we are doing is revisiting what we expected this time last year around attractive revenue growth and adjusted EPS growth from 2022 onwards. With the exception of the in-year impact that we see for 2021 in our Vaccines business, and fairly clearly our assumptions and some of the factors that will influence that outcome, the progress that we are seeing in our Consumer Healthcare business and our Pharmaceuticals business remains very much on track. A key signal in that, within the Pharma business, is the growth that we see coming through from the new and specialty medicines in 2021. We saw that in 2020 and we very much expect that to continue in 2021 and in to 2022.

Without confirming or denying any of the guidance, we are very confident with the progress we are making across the businesses and we are very confident in the prospects for the Vaccines business beyond the impact of COVID-19, for all the reasons that Emma and Roger have set out. In June, we will set out in considerable detail those medium-term financial outlooks that inform the top line, our margins, our adjusted EPS, balance sheet structure and the like. What we will also do in June is to set out the key factors that inform the dividend policy and the dividend policy for that new GSK – the new biopharma business.

You obviously already have a possible payout range, a probable payout range, for the Consumer Healthcare company post-separation, but we will set out those factors – I think you answered the question yourself – which are the comparison to our peer groups, what is appropriate through the investment cycle? By that, I mean that we obviously have variability in earnings per share

on an ongoing basis but just looking at the appropriate payout ratios through the investment cycle, and appropriate and robust coverage from a free-cash flow perspective and, importantly, the propensity to grow from the point at which we reset it in 2022.

I think we have been clear today that we would expect the aggregate distributions for the biopharma business and the Consumer Healthcare business, standalone, to be less than they presently are today but that, importantly, they will have the propensity to grow and be progressive dividends from that point onwards. We will provide the information that helps everybody to model this through and think about the investment case in the round, and not just on the basis of a specific context of a dividend policy, which is principally why we are not giving you the full detail on the policy today.

**Emma Walmsley:** Fantastic, and I hope that is clear for everybody. Next question, please.

Jo Walton (Credit Suisse): I have two questions. If we look at the guidance for 2021, at the sales level for the divisions, they are flat to growth. At the Group level for earnings, it is mid- to high-single digit decline. There is clearly an increase in cost coming through here. I think we understand that R&D is rising as one of the main elements of that but I wonder whether you could take us through some of the other aspects of the cost structure that we should expect for the Group for 2021.

My second question is just looking at the older, established products. They were down 15% on a constant currency basis for the full year, 18% in the fourth quarter. Do you have any help on how we should be looking at that block, going forward, because you have not made any disposals from it yet? Should that decay rate be easing as we begin to see the impact of *Advair* generics and the price erosion in the respiratory market, which is obviously a big part of that, beginning to ease? Or, with a new entrant coming in for generic *Advair*, could that whole respiratory price still reset further in that £3 billion-plus portfolio that you have?

Emma Walmsley: Great, thanks, Jo. Iain will add more colour to this, particularly on the established products dynamics, although I would repeat that we are looking continually at the portfolio there. That is obviously where we target selective divestments, too. However, the headline – and Iain alluded to this – is that with pre-R&D we have already made progress and we expect to continue to make progress there. There is also an element of tax and revenue mix as well in the EPS outlook. The only difference from where we were previously is the Vaccines contribution to total growth, which is quite different from what we might previously have expected. However, I keep reiterating that that is a short-term effect, and if you ever needed to believe that having the kind of strength in vaccines and infectious diseases was relevant, important and created significant long-term growth opportunities and resilience for the new GSK, now is definitely a time to have conviction.

lain, I don't know whether there is anything I missed on the guidance.

lain Mackay: Yes, the mix is important. You certainly got the dynamic on the top line right but the mix of those revenues, clearly with some COVID-19 pressure on the Vaccines business, has had something of mixed effect on margins, as you can well imagine. Then there is the continued double-digit investment in R&D and the pipeline which is a key focus, with an effective tax rate of around 18%, being a step-up of two percentage points from this year. Those are the key factors that translate from the top line outlook through to the adjusted earnings per share outlook.

Reflecting your question on the established Pharma, and as I mentioned earlier, David and the team are focussed and active on a number of transactions in the established Pharma portfolio. We obviously aren't comment on the detail on either or which parts of that portfolio, but it is an area where, with Luke and David, we spend a good deal of time looking for when the right time and the right value is to exit certain medicines within that portfolio because they are reaching frankly an NPV inflection point from a GSK valuation perspective. Particularly when we get to the point where Luke and the team are no longer investing behind a particular product in terms of promoting a product, we start to think very actively about the opportunity to exit those portfolios. But it is very disciplined in terms of how that balances out from an economic perspective and NPV.

More specifically around the pricing dynamics, particularly in ICS-LABA class we have seen certainly through 2019 continuing in '20, and frankly no reason to expect that it wouldn't further continue to some degree, although probably a little bit more muted than '20 and '19, pressure in that class and very much driven in our experience by the genericisation in *Advair/Seretide*. If anything we saw that influence a little bit muted in 2020 where we saw those medicines being possibly prescribed either in larger prescriptions or more so in terms of response to respiratory health in a COVID-19 setting. But in terms of the trajectory for that medicine over time, our outlook on that has not changed from when we first announced generic competition in that space, but what we have seen and we have been clear about is the pricing pressure in the ICS-LABA class and as we would expect, it has been pretty severe. The discounting in that space is very marked and we wouldn't necessarily expect to see that abate but nor would we necessarily expect to see it exacerbate much further.

**Louise Pearson (Redburn):** Hi and thank you for taking my questions. Firstly for Luke on daprodustat with data due later in the year and, given some recent developments in this space, could you remind us of how you are thinking about that asset and the options you might have on the table should the trials read out favourably.

And then one for Roger on the RSV older adult programme; this was Phase 3 design I assume pre-COVID incidence of RSV, i.e., is there a risk to the programme that social distancing affects this to some degree, meaning that there is less RSV going round and maybe a signal might not be seen. Thanks very much.

Emma Walmsley: Okay, so straight to Luke and then Roger.

**Luke Miels:** Sure, thanks Louise. Increasingly positive about daprodustat for a couple of reasons which I will go through now. Just as background for everyone, we have five studies

with about 9000 patients and two of them are MACE studies and are fully recruited. The patient population in the US and the EU is about 2.7 million patients, so a sizeable population.

I think what has changed if you go back 24 months ago, even 12 months ago, our assumption always was that you would have seen roxadustat on the market relatively early followed by daprodustat, both of them having non-dialysis and dialysis indications. I think the increased likelihood, we know that roxa's PDUFA is on 19 March this year, our assumption is that they get non-dialysis and dialysis. Vadadustat is in Q3 '21 with the PDUFA and our assumption is that they only get dialysis if approved, so with our timeframe towards the end of the year we expect to get non-dialysis and dialysis so a competitive profile.

I think the third thing is we have seen the class in Japan launch different labels but our partner actually has 42% market share, so roughly the same as the nearest competitor in a very, very heated market. So yes, I think we are more optimistic about daprodustat than we were even a few months ago.

**Emma Walmsley:** Thanks, Luke and then over to Roger on RSV. I know we are targeting a readout in the second half of '22 – anything to add, and then we will come to the last question.

**Roger Connor:** Yes, exactly. We are obviously watching this very carefully in the trial design. Just to reiterate, we think there is a major opportunity in RSV older adults just because of our ability to be the first and best in class.

One element of modelling that we are doing obviously and I won't go into the detail of the trial design, is looking at the populations, geographies and numbers that we want to make sure that we select. That is going to be very critical in the trial piece.

One important assumption is that where we see the bulk of the population, of the affected population here being vaccinated in the first six to nine months of this year, which I think is important because then you have that vaccinated population. That is the at-risk group that we will be studying through the study, so we think that as we get through that mass vaccination we will see less impact in terms of overall risk of the COVID circulation as well.

Emma Walmsley: Thanks, Roger. Last question, then, please.

Andrew Baum (Citi): Thank you. The question won't come as much of a surprise given our research, but you have outlined the separation as most likely taking place as a demerger. Given the demand from GSK Pharma to future-proof their outlook, specifically be aware of the dolutegravir/cabotegravir loss of exclusivities and why not a partial IPO in order to increase your fire power for M&A? Is it because the tax considerations or your own risk that it makes this less attractive if you and lain could comment on that, that would be interesting.

Then a second to Hal. Perhaps you could update for the durability of response that is seen with your ICOS agonists in INDUCE-1? I think the last update you gave was at six months all patients

who had a response have maintained their response. Maybe you have updated us since then, but if you could update us further, that would be helpful in just thinking about whether we are seeing additive or some logistic efforts here in the head and neck setting, thank you.

**Emma Walmsley:** Thanks, Andrew, so we will come to Hal in a second. You set the mechanism for separation in the context of dolutegravir. We are all more than familiar with the requirement for replacement rates in the face of patents, and I just really want to emphasise our confidence in the progress under Hal's leadership, and ever more so in the prospects of our Vaccines' portfolio on developing a strong pipeline, including in long-acting in HIV, and all of that will bring more visibility over coming months and years. But it is very important that we reiterate the confidence there, and as lain also referred to, one of this benefits of this separation does allow for the deleveraging of the Biopharma business, which in all worlds is going to continue to prioritise from a capital allocations point of view the pipeline, including business developments.

We remain, we hope, strategic, selective and disciplined on the way that we pursue that, but we are thoughtful about continuing to create capacity and that is also where we want to give a holistic view of this new company. Its correct capital structure, the ability to support investment in all the growth opportunities we see inside and outside the company, and competitive, appropriate returns.

The technical mechanism of the separation will be confirmed later this year. You will imagine that we are with the Board and in on-going dialogue with our partners, really thoughtful about what's in the best interests of shareholders and we will confirm the specifics of that later in the year.

lain, before I hand to Hal on ICOS, anything that you would add to that?

lain Mackay: No, that's it, Emma.

**Emma Walmsley:** Okay, so, Hal, over to you for the last response for the day on ICOS until tomorrow's discussions.

Hal Barron: Thanks, Andrew. We have a lot of catalyst events for the ICOS programme in the next six months, as I mentioned in the INDUCE-3 interim analysis, the ENTRÉE lung randomised Phase 2 data and also some updates from INDUCE-1. I am hoping that we will have more updated data on duration of response from the INDUCE-1 studies when we provide that, which we hope will be somewhere around mid-year, so I don't want to comment on any numbers yet, but as I mentioned, we are excited about the data regions that we will have for those three programmes and we will share more that data with you soon.

**Emma Walmsley:** Thanks, Hal, and a big thank you to everybody for the slightly extended discussion today. We look forward to further conversations – actually, some today and tomorrow and in the weeks and months ahead for a very exciting next 18 months for GSK and future two new companies. Thank you, have a good day.

[Ends]