

GSK
Half year and Q2 2022 Results
Conference call and webcast for investors and analysts
Wednesday, 27 July 2022

Nick Stone (Head of Global Investor Relations): Hello, everyone! It's Nick, as mentioned. Welcome to our first half in Q2 2022 conference call, and to our investors and analysts.

This is our first quarter as the new biopharma company, and earlier today, the presentation was posted on GSK.com. It was also sent by email to our distribution list.

Cautionary Statement regarding forward-looking statements

This is our usual safe harbour statement, and we will be making comments on our performance using constant exchange rates, or CER, unless otherwise stated.

As a reminder, GSK has satisfied the formal criteria according to FRS5 for treating Consumer Healthcare as a discontinued operation effective from 30 June 2022. The Consumer Healthcare business was demerged on 18 July to form Haleon, and as a result, we are presenting continuing operations for GSK.

Earlier today, Haleon also published a trading update and will be announcing its Q2 results in September.

Agenda

This is today's agenda where we plan to cover all aspects of our half-year in Q2 2022 results. The presentation will last approximately 35 minutes, with a further 40 minutes for questions.

For those on the phone, please join the queue by pressing #1, and we request that you ask a maximum of one question so that everyone has a chance to participate. We can always come back for a second round.

Today, our speakers are Emma Walmsley, Hal Barron, Luke Miels, Deborah Waterhouse, and Iain Mackay. The Q&A portion of the call will be joined by Roger Connor and David Redfern.

Half year and Q2 2022 Delivering a landmark year

Turning to Slide 4, I will now hand the call over to Emma.

Emma Walmsley: Thanks, Nick.

A warm hello to everybody joining our half-year and Q2 conference call today.

A new focused biopharma company

I'm pleased with the momentum we are announcing today. We are delivering a landmark year, the most significant corporate change for GSK in 20 years, and a new chapter of competitive and profitable growth.

GSK is now a focused global biopharma company with the ambition and purpose to unite science, technology, and talent to get ahead of disease together. It's a company focused on the science of the immune system, human genetics and advanced technologies, with world-leading capabilities in vaccines and medicines development across four therapeutic areas.

In delivering our strategy, we have made – and will continue to make – significant improvements in both R&D productivity and operating performance, unlocking the potential of GSK. Our bold ambitions are reflected in commitments to growth and a significant step-change in delivery.

Through the demerger, we have also strengthened our balance sheet, creating new flexibility to invest in sustaining growth and innovation. These bold strategic steps enable us to deliver for patients, shareholders and our people on our five-year ambitions and beyond.

I am delighted by today's first half results. They demonstrate that our strategy is delivering the step-change in performance we committed to, with double-digit sales growth of 25%, adjusted operating profit growth of 26%, and adjusted EPS growth of 27%. This performance supports my strong confidence in our medium-term outlooks.

The first half sales growth was driven by strong commercial execution across the whole portfolio and, alongside this excellent performance, we continue to invest in R&D with further strategic business development to support our pipeline momentum. Given our momentum and these very encouraging results, we are increasing our full-year guidance, excluding COVID solutions, to between 6-8% sales growth and 13-15% adjusted operating profit growth.

Q2 2022: turnover increased +13% (+10%¹)

Q2 was another strong quarter of growth. Sales increased 13% to £6.9 billion, adjusted operating profit grew 7% to more than £2 billion, an increase of 21% excluding COVID solutions, and adjusted EPS grew 6% to 34.7p.

Specialty Medicines grew 35% to £2.7 billion, benefiting from strong demand for *Dovato* and *Cabenuva* in HIV. Excluding *Xevudy*, sales increased 13%.

Vaccines sales grew 3% to £1.7 billion, driven primarily by *Shingrix* which delivered another quarter of record growth, with sales more than doubling to £731 million and, excluding pandemic vaccines, sales grew 24%.

General Medicines also increased 2% to £2.5 billion, reflecting the strong growth of *Trelegy* in Respiratory.

In SG&A we continued disciplined cost control while prioritising investments in growth to support launches in Specialty Medicines and Vaccines, particularly *Shingrix*, as we accelerate international expansion and invest for further growth.

In R&D we increased investment in Specialty Medicines to support our early-stage HIV portfolio, while also investing in our late-stage Vaccine portfolio and mRNA tech platform. You will hear more about our commercial and financial performance from Luke, Deborah and Iain in just a moment.

Turning to slide 8 and our pipeline headlines.

H1 2022: continued strengthening of late-stage R&D pipeline

Our focus on the science of the immune system, human genetics and advanced technologies is reflected in the excellent progress and strength of our late-stage pipeline. We were the first to announce positive Phase 3 results with our RSV vaccine candidate in older adults, demonstrating statistically significant and clinically meaningful efficacy and exceptional protection.

We also announced encouraging Phase 2b data for bepirovirsen in chronic Hep B. This is a disease with a very significant unmet medical need and is responsible for over 900,000 deaths each year. In a moment, Hal will provide more detail on these and our broader pipeline momentum.

This quarter, we also completed the acquisition of Sierra Oncology and announced the proposed acquisition of Affinivax. Both of these transactions are excellent examples of strategic business development to develop a strong portfolio of innovative vaccines and specialty medicines that will deliver sustained growth through the decade and beyond.

This is an exciting year with strong momentum and I am pleased with the progress we are delivering. Now over to the Team, with Hal first to you on slide 9.

Dr Hal Barron: Thank you, Emma.

Innovation: pipeline progressing as planned

I will take the next few minutes to review the recent progress in our pipeline and key expected news flow over the next 12-18 months. This slide updates one that we presented in June 2021 at our Investor Day. Based on assets launched between 2017 and 2021, our R&D performance was top quartile relative to industry peers. Furthermore, these launches are expected to contribute over 60% of the 2021-2026 sales CAGR for GSK. In addition, the balance of the sales growth on a risk-adjusted basis is expected to come from anticipated approvals for medicines and vaccines in the pipeline.

As you can see here, I am pleased to say we have made tremendous progress against these commitments. Based on the robust results of the ASCEND Phase 3 programme, we completed both US and EU regulatory submissions for daprodustat in the first half of 2022, and we now look forward to a decision from the FDA by February 2023.

During the first half of this year, we also received approval for *Apretude*, the world's first long-acting injectable for the prevention of HIV.

The biggest news from our pipeline, of course, was the exceptional Phase 3 data we announced last month from our RSV vaccine trial for older adults, which Emma just mentioned.

We also presented impressive data for bepirovirsen which I am going to call "bepi" from now on, in the treatment of Hep B. I shall touch on both of these assets later.

Looking ahead, we remain on track to report pivotal data for several assets on this list with several potentially important readouts in the second half of this year. Importantly, as you know, we have been very active on the business development front, augmenting our pipeline with two important deals. First, the acquisition of Sierra Oncology, which includes momelotinib, a potential new treatment for symptomatic myelofibrosis patients with anaemia.

Our proposed acquisition of Affinivax will provide us with the next generation 24-valent pneumococcal vaccine candidate, as well as access to an innovative MAPS technology which may generate vaccine candidates with higher valency and higher immunogenicity compared to existing options.

Finally, I want to mention our early-stage pipeline activity. We have initiated 10 Phase 1/2 studies in the first half of 2022 alone, including our PVRIG antibody in oncology and capsid inhibitors in HIV.

Importantly, I am also pleased to report that interim data from our Phase 1b randomised control study of anti-CCL17 in osteoarthritis was positive, demonstrating a

reduction in knee pain intensity compared to placebo at the end of the eight-week dosing period.

We are proceeding with discussions with regulators to inform our future development of this molecule.

Innovation: a potential new vaccine to prevent respiratory syncytial virus (RSV)

In June, we were excited to announce positive pivotal Phase 3 data for our RSV vaccine candidate for older adults. RSV remains one of the few major infectious diseases without a vaccine, and RSV infections are associated with around 360,000 hospitalisations and over 24,000 deaths worldwide each year.

Our vaccine candidate contains a prefusion RSV F glycoprotein antigen combined with our proprietary AS01 adjuvant. The adjuvant was designed to address the natural decline in the immune system linked with ageing, and the vaccine is the first to report statistically significant and clinically meaningful efficacy in a Phase 3 trial.

Importantly, the magnitude of effect observed in this trial was consistent across both RSV A and RSV B strains, and across key secondary endpoints, including people aged over 70 and patients with comorbidities and in the prevention of severe respiratory disease.

The trial will continue to generate data for three years following a single and annual re-vaccination schedule. We look forward to sharing these exceptional data with regulators in the second half of this year. We believe this puts our RSV older adult vaccine candidates on track to be considered at the June 2023 ACIP meeting.

Innovation: bepirovirsen B-CLEAR phase II end of treatment data

Last month we were also excited to present interim end of treatment data from the 457 patient bepi monotherapy trial B-CLEAR at the EASL International Liver Congress.

The current standard of care for Hep B patients includes anti-viral plus interferon therapy. Existing treatments rarely result in a functional cure and, as a result, hepatitis B remains a significant unmet medical need with 300 million people worldwide living with Hep B, which is responsible for approximately 900,000 deaths each year.

Our ambition is to develop a functional cure for patients with Hep B eliminating the need for prolonged therapy and, by doing so, reducing the long-term risk of developing cirrhosis and liver cancer.

The data presented at ESAL demonstrated that bepi was effective in lowering Hepatitis B surface antigen below the lower limit of quantification. This is the first time that any

monotherapy agent has been shown to reduce Hep B surface antigen below the lower limit of quantification in more than a handful of patients.

What appears to be driving this unique effect is bepi's novel mechanism of action. As described in a poster at EASL, in addition to lowering HPV surface antigen, bepi appears to uniquely activate the TLR8 pathway in the liver. This activation appears to stimulate an immune response which helps clear the virus, which we hope will result in functional cure for some of these patients.

We will continue to monitor the patients in the B-CLEAR study to assess the durability of this remarkable response, and we expect to present this data later in the year. However, based on the strength of the B-CLEAR data set to date we plan to initiate a Phase 3 monotherapy programme in 2023.

Additionally, we expect to report the data on the B-TOGETHER trial which looks at bepi followed by PEG interferon. While interferon has a well-known tolerability burden, we are cautiously optimistic that this study will augment the data scene in the monotherapy setting.

Innovation: 2022 ASCO Annual Meeting Research advances demonstrate the strength of the Oncology pipeline and portfolio

This year's ASCO meeting saw an increased cadence of presentations on our growing oncology pipeline, including data from six potential new medicines within our portfolio. In particular, I want to highlight the pivotal data MOMENTUM from momelotinib, the groundbreaking data from *Jemperli* in rectal cancer, and the first publication of data from our *Blenrep* plus GSI combination setting, DREAMM-5.

I want to briefly review the latter two datasets on the next slide.

Innovation: *Blenrep* and *Jemperli* at ASCO 2022

While *Blenrep* continues to deliver strong activity as a single agent, we are investigating how to advance this important medicine into earlier lines of therapy using different dosing schedules and combinations. The GSI combination is one potential solution because it may allow a marked reduction in *Blenrep* dose, while maintaining a similar efficacy rate. This in turn brings a potential for reduced ocular toxicity.

We were therefore pleased to share the preliminary data from the GSI combination cohort of the DREAMM-5 sub-study at ASCO. This showed encouraging signs of activity with an overall response rate of 38%, similar to that of the DREAMM-2 study, but with lower rates of ocular adverse events and only 7% of patients reporting a Grade 3 or worse ocular event.

Subsequently, at EHA, data were presented by Terpos et al in the front-line setting, using an eight-week dosing schedule with lower doses of *Blenrep*. This regimen resulted in a

very high response rate with much lower rates of ocular side effects than has been seen with the standard three-week dosing schedule.

I also want to briefly mention the extraordinary trial of *Jemperli* or dostarlimab in patients with DMMR locally advanced rectal cancer in the neoadjuvant setting. This trial, which is awarded the coveted Best of ASCO data, showed an unparalleled response rate with each of the first 14 trial participants, who had completed six months of therapy, reporting a clinical complete response.

These data suggest the potential for a chemotherapy-free treatment with curative intent for this difficult-to-treat population, and we look forward to working with regulators to identify a path forward for registration.

Innovation: 2022-2023 key news flow

My final slide lists a number of the key clinical and regulatory events expected over the next 12 to 18 months. As I noted, we will see data from across the portfolio, with pivotal results anticipated for otilimab and our vaccine candidate, MenABCWY.

In addition, we hope to see data from *Blenrep* in third-line multiple myeloma patients and, potentially, an interim analysis for gepotidacin for the treatment of patients with uncomplicated urinary tract infections.

We also anticipate data from the head-to-head PERLA study, which looks at *Jemperli* plus chemo, versus pembrolizumab plus chemo, in the treatment of patients with non-small cell lung cancer. The PERLA study is not intended for registration but it will inform future development plans for our PD-1 antagonists.

Finally, this is my last quarter presenting our R&D progress, so let me close by saying how delighted and proud I am of the achievements of the R&D organisation since I joined in 2018. We have made considerable progress against our objectives to improve productivity in the pipeline and embed a significant cultural change across R&D. Assets within our development pipeline are now supported by genetic data, which we believe will increase the probability of success, and we expect to accelerate the cadence of new product introductions.

I am also incredibly proud of, and confident that my successor, Tony Wood, will build on these achievements and further accelerate our R&D delivery. Tony is an outstanding scientist and an inspiring leader and I look forward to contributing to the next chapter of growth for GSK as a non-executive director.

With that, I will hand this over to Luke.

Luke Miels: Thanks, Hal – and I will miss saying that!

Performance: Vaccines +24%: Shingrix delivers strong performance

I am pleased to say that Vaccines performance was very strong, with sales growth of 24%, excluding the impact of the prior year and the pandemic vaccines sales.

The growth saw continued recovery of *Shingrix*, where we delivered another record quarter of turnover. The strong *Shingrix* performance reflected good demand and a focused commercial effort in the US to extend shingles vaccination throughout the year, which led to steadier TRx volumes in H1, higher engagement in non-retail settings, and an earlier than anticipated channel inventory build.

In Europe, we continued to see strong demand in Germany and contribution from new launch markets as *Shingrix* becomes more widely available. *Shingrix* is now in 23 countries globally and we are unconstrained on supply and remain on track to expand to more than 35 countries by 2024, making *Shingrix* available in around 90% of the global vaccine market.

We remain on track for a record year, with strong double-digit sales growth this year. Previously, we had expected sales to be weighted to the second half but, following the earlier than anticipated channel inventory build, we now expect slightly lower sales in half-two than in half-one, reflecting an anticipated 1 million doses of inventory burn. *Shingrix* is the key driver of this year's expected sales growth in Vaccines, excluding pandemic solutions, and we now expect Vaccines sales to grow by low to mid-teens, up from low-teens previously.

Performance: specialty medicines grew +13%, general medicines +2%

In Q2, our Specialty Pharma business, including HIV, continued to deliver strong performance, with 13% growth. Deborah will cover HIV momentarily. This excludes the pandemic solutions sales contribution from *Xevudy*, which delivered an additional £466 million during the quarter. *Benlysta* delivered another quarter of double-digit growth. Our market-leading lupus medicine in the US is also benefitting from increased contributions from China, Japan and the European markets, driven by our expanded indication for lupus nephritis.

For *Nucala*, our IL-5 biologic, which has a broad and differentiated indication approved across eosinophilic diseases, delivered strong growth as it remains the leading IL-5 in key markets like the US, Japan and the EU five. Our leadership in the IL-5 space is underscored by a lifecycle innovation commitment with Phase 3 trials for *Nucala* in COPD and our long-acting IL-5, depemokimab, ongoing.

In Oncology, sales increased 23% and we are seeing signs in the US of ovarian cancer and surgery rates stabilising. We are well positioned, as the market recovers, with half of the new first-line ovarian cancer maintenance patients receiving *Zejula*.

Finally, I would also like to point out that our GenMed portfolio delivered a fifth consecutive quarter of growth, up 2% in Q2, with strong growth from *Trelegy* across all regions, which more than offset the decline of older, established products in the quarter. *Trelegy* is the No. 1 triple therapy in COPD and asthma in the US, with market shares above 50% in each.

I will now pass this to Deborah with slide 19, to review the performance in HIV.

Deborah Waterhouse: Thanks, Luke.

Performance: HIV growth accelerating

Our Q2 performance demonstrates a progressive acceleration of growth, underpinned by our oral two-drug regimen, *Dovato*, and our cabotegravir-based long-acting injectable for the treatment and prevention of HIV. HIV sales were £1.4 billion, with growth of 7% in the quarter and 10% in the first half.

Performance benefitted from strong patient demand for our innovation portfolio, which comprises *Dovato*, *Cabenuva*, *Juluca/Rukobia*, and *Apretude*, and a favourable US pricing mix. This was partially offset by the unfavourable phasing of *Tivicay* tenders. Momentum is firmly behind our innovation portfolio, which delivered more than £1 billion in the first half of the year and now accounts for 41% of our sales. Our ambition for the year is to deliver mid-to high-single digit sales growth. Our business delivered strong growth in the US and in Europe, growing at 13% and 17% respectively. This growth was underpinned by strong commercial execution across the portfolio.

Dovato continues to perform, delivering £320 million of sales in the quarter, which represents 66% year-on-year growth. Market perform firmly reflects prescriber belief and we were delighted to see that through this quarter, *Dovato* reached the milestone of £1 billion of rolling annual sales with further significant growth potential beyond.

Performance in Europe is particularly strong with market share for *Dovato* at around 13% and the leading position in switch.

Turning to our injectable portfolio, *Cabenuva*, also known as *Vocabria* or *Rekambys* in Europe, is the best-in-class long-acting treatment regimen for HIV. Sales almost doubled in the quarter delivering £72 million. 11,000 patients are now taking *Cabenuva*, an increase of 5,000 through this quarter and around 12,000 HCPs are prescribing the medicine.

The approval and launch of the every two-month dosing in the US in February and the removal of the oral lead-in requirement in the US has simplified and improved patient

experience and delivered a significant inflexion for this injectable therapy. Underlying patient demand is high and we are therefore very confident about the potential of this medicine to transform the treatment paradigm of HIV.

Moving on to prevention, *Apretude* is the world's first long-acting injectable for the prevention of HIV dosed every two months. It was launched in the US in January 2022. This quarter we received the J code for *Apretude* which is an important step because it enables prescribers to buy and bill and simplifies reimbursement for the medicine. With around 1700 patients already taking *Apretude* in the US, we have high levels of ambition for this medicine and launch activity continues to centre on building awareness and access.

I am pleased with the progress we have made in negotiations with the Medicines Patent Pool to enable access to CAB LA for prevention in resource-poor settings. We look forward to providing further updates at the International AIDS Conference which is taking place in Montreal in a few days' time.

I will now hand over to Iain.

Performance: financial results

Iain Mackay (Chief Financial Officer): Thanks, Deborah and as I cover the financials references, references to growth are at constant exchange rates unless stated otherwise.

Performance: Q2 2022 results and total to adjusted reconciliation

Firstly this presentation is based on the continuing operations of GSK, as Nick noted earlier.

For the second quarter of 2022, commercial operations turnover was £6.9 billion, up 13% and adjusted operating profit was £2 billion, up 7%. Total earnings per share were 17.5p, down 58% while adjusted earnings per share were 34.7p, up 6%.

The main adjusting items of note between total and adjusted results for Q2 were in transaction related which primarily reflected the ViiV contingent consideration liability movements, the majority of which related to foreign exchange and in 'other' which reflected an unfavourable comparison of a £325 million credit in Q2 of 2021 resulting from the valuation of deferred tax assets following the enactment of the proposed change in UK Corporation Tax from 19% to 25%.

Pandemic solutions reduced growth of adjusted operating profit by approximately 14 points and growth adjusted EPS by around 18 points.

The Q2 currency impact was a favourable 6% on sales and 17% on adjusted earnings per share.

Performance: Q2 2022 turnover £6.9bn, +19% at AER, + 13% at CER

My comments from here onwards are on adjusted results unless stated otherwise. Total sales growth was 13% driven by strong performance across commercial operations as all product areas benefitted from increased demand. Excluding pandemic-related sales, growth was 10%.

Luke and Deborah have taken you through the commercial performance in the quarter and the key turnover dynamics and I'll make comments on sales outlook shortly.

Performance: Q2 2022 adjusted operating margin

Adjusted operating profit +7% at CER

The second quarter margin of 29% was slightly higher as margin benefitted from operating leverage driven by strong sales growth, product mix excluding *Xevudy*, higher royalty income and favourable currency movements which were 2.4 percentage benefit in the second quarter.

These factors were partly offset by the impact of lower margin sales of *Xevudy*. COVID solutions reduced adjusted operating profit growth by approximately 14 percentage points and reduced the adjusted operating margin by approximately 4.4 percentage points at constant exchange rates.

Within cost of goods sold, the increase primarily related to sales of lower margin *Xevudy* which increased the cost of sales margin by 4.7 percentage points, mainly reflecting the profit share pay-away to Vir.

Excluding *Xevudy*, COGS were a 60 basis points benefit to margin driven by favourable business mix with 61% of commercial operation sales ex-pandemic being from Specialty Medicines and Vaccines compared to 57% in the second quarter of last year. This mix benefit was partly offset by a modest increase in commodity prices and freight costs which we continue to manage closely.

SG&A increased at a similar rate to sales in the quarter which reflects an increased level of launch investment in Specialty Medicines and Vaccines. This was particularly focussed on HIV and *Shingrix* to drive post-pandemic demand recovery and support market expansion.

The growth also included some increased freight and distribution costs. These factors were partly offset by continued delivery of restructuring benefits. Taking into account the

commercial investment to date, we now expect SG&A to increase slightly above the rate of sales growth this year.

R&D was broadly stable in the second quarter, which primarily reflected the ongoing benefit of efficiencies from the One R&D restructuring programme, the benefit and the comparator with regard to the timing of completion of several late-stage programmes, including COVID-19 investments in 2021. These factors were largely offset by increased investment in Vaccines across mRNA technology platforms, ongoing late-stage trials and the acceleration of several early-stage programmes. There were also increases in early-stage HIV programmes.

In the remainder of the year, we would expect the R&D run rate to increase in part reflecting phasing and in part reflecting incremental investment following the Sierra Oncology acquisition and the anticipated Affinivax deal.

For the full year, given the dynamics we have seen in the first half, alongside our upgraded guidance for the full-year sales growth, we now expect R&D to increase at a rate slightly below sales.

Royalties benefited from the contribution of *Biktarvy* and higher sales of *Gardasil*. In the first half, adjusted operating profit grew 26% to £4 billion, an operating margin of 28%, reflecting strong operating delivery.

The commercial contribution of COVID solutions reduced adjusted operating profit growth by around 1 percentage point, and I shall cover the outlook in a moment.

Performance: Q2 2022 adj. operating profit to net income

Moving to the bottom half of the P&L, I would highlight that the effective tax rate of 15.2% reflected the timing of settlements with various tax authorities, and higher non-controlling interest charges related to an increased allocation of ViiV profits.

Performance: H1 2022 free cash flow of £1.7 bn

On this slide, I shall cover cash flow. In the first half, we generated £1.7 billion of free cash flow and cash generated from operations of £3.9 billion from continuing operations. The key drivers of higher free cash flow were as follows: a significant increase in operating profit, including the upfront income from the Gilead settlement in February; a favourable foreign exchange impact and favourable timing of collections and profit share payments for *Xevudy* sales. These factors were partly offset by lower proceeds from disposals, increased contingent consideration payments reflecting the Gilead settlement, higher capital expenditure and a higher seasonal increase in inventory.

Performance: increasing guidance for sales and adj. operating profit

GSK has delivered first half performance ahead of its existing full-year guidance as expected, based on strong business delivery and the dynamics of prior year comparators. As Emma outlined earlier, with that performance to date and the momentum it provides, we are raising our guidance for sales to increase between 6-8%, an adjusted operating profit increase between 13-15% excluding COVID solutions.

For both sales and adjusted operating profit, we would expect Q3 growth below full-year expectations given the stronger comparator of last year, and our Q4 growth to be higher than Q3 given the more favourable comparator in 2021.

With regard to phasing considerations for the year to go, there are several factors that will influence the out-turn. These include sales delivery within the upgraded range, given the more challenging second-half sales comparator. This includes the *Shingrix* stocking effect that Luke covered earlier, as well as ongoing generic competition in General Medicines; product mix; phasing of R&D spend as we step up investments, strengthening our pipeline and technology platforms; continued investment through SG&A and supporting new launches, and broader targeted business improvements such as further investment in Data & Analytics; the continued risk from COVID dynamics as we head into the northern hemisphere Autumn and Winter seasons and any possible developments in the current uncertain global macroeconomic environment.

As far as our expectations for adjusted earnings per share, both including and excluding COVID solutions, we would expect growth around 1 percentage point below adjusted operating profit, reflecting lower associate profits.

On COVID-19 solutions specifically, the majority of expected sales for 2022 have been achieved in the first half of this year. Based on non-binding agreements with governments, we expect that sales will be substantially lower in the second half. Compared with 2021, sales will be at a reduced profit contribution due to the increased proportion of lower margin *Xevudy* sales. Given more than expected sales to date, we now expect this to reduce overall GSK adjusted operating profit growth by between 4-6 percentage points.

With respect to dividends, dividends declared in Q2 and those expected for the remainder of the year are in line with existing expectations, adjusted for the impact of the share consolidation completed on 18 July. Accordingly, GSK will pay 16.25p per share for Q2. For the second half, GSK expects to pay a 27.5p per share dividend, which is equivalent to 22p per share previously indicated before the share consolidation. For 2023, we expect to pay a 56.5p per share dividend.

Turning to the balance sheet, with the demerger of Haleon completed, we have now received the £7.1 billion demerger dividend and half our 13.5% retained stake in Haleon that we intend to monetise in an orderly manner. This strengthened balance sheet supports our clear capital allocation priorities of further strengthening the pipeline, investing in new product launches and delivering dividends to shareholders.

Taking all of this together, we remain firmly on track to deliver the step-change in performance for 2022 first referenced at our Investor Update in June last year, and this sets us on the right trajectory for our 2026 outlooks.

With that, I'll turn it back to Emma.

Trust: delivering health impact and shareholder returns

Emma Walmsley: Thanks, Iain, and turning to slide 28.

Trust: ESG is integral to GSK's overall strategy and performance

Delivering health impact and shareholder returns

At GSK, we are guided by our purpose to unite science, technology and talent to get ahead of disease together, and we deliver this purpose considering the environmental, social and governance impacts across everything we do. Running a responsible business is integral to our strategy and future performance. It's how we build trust, deliver health impacts at scale and reduce risk.

We have prioritised our resources to focus on six material areas: the environment, global health and health security, diversity, equity and inclusion, pricing access, product governance and operating standards.

We are focussed on maintaining sector leadership in ESG with our No. 1 ranking in the Dow Jones Sustainability Index and our long-standing leadership in the Access to Medicines Index.

Looking ahead we are also on track to deliver our ambitious environmental commitments with targets of net zero on carbon and net positive on nature by 2030.

We are proud of our track record but there is always more to do and this quarter we continue to advance our global health and health security leadership with a commitment to invest £1 billion over ten years to get ahead of infectious diseases in lower income countries. As part of this commitment, we also formed a new Global Health Unit under Roger Connor's leadership which will be measured by its human health impact.

Trust: committed to delivering health impact at scale

GSK is committed to delivering health impacts at scale reaching more than 2.5 billion people worldwide over the next ten years.

In this landmark year, GSK has delivered another quarter of strong performance and momentum and I am very confident that as a focussed global bio-pharma company we will deliver our bold ambitions for patients reflected in our commitments to growth and a step-change in performance.

With that, operator, can we please move to the Q&A for the team.

Question & Answer Session

Emmanuel Papadakis (Deutsche Bank): Thanks for taking the question. I was once with Barclays and I'm with Deutsche Bank now.

Emma Walmsley: Emmanuel, hi!

Emmanuel Papadakis: Hi! Thanks for taking the question. I'll stick to one on RSV, please and maybe a question on pricing strategy, so if you can help us there. We still don't know durability of course so I would love to hear your latest perspective on where you think that's likely to land.

Presumably that's an important input in the pricing calculation and give us some kind of yardstick between the boundaries of 'flu and *Shingrix* what we should be thinking about and some of the considerations you are thinking of. Thank you.

Emma Walmsley: Thanks, Emmanuel, but it won't surprise you to know that in a commercially competitive environment we are not going to give very many indications around pricing.

I will let Luke add to this, but we are extremely excited about bringing forward further data on this and there is just no debate in an environment for governments under the inflationary pressures they are with, that prevention of disease is always a good investment for healthcare systems and we are confident that payback for this, especially across multiple endpoints, will be a good one.

I don't know if there is anything you want to add on.

Luke Miels: I would just say you have the bookends right, Emmanuel, but we can't give you whereabouts it would sit between those two bookends between 'flu and *Shingrix*.

Emma Walmsley: Thank you.

Emmanuel Papadakis: Sorry, can we just go back to this durability question and also any comments around efficacy, Hal?

Hal Barron: We are going to be looking at the data to assess the durability. Of course, the reason that we in part used the ASO was to assess whether that would increase the durability both within a given season to see if the treatment effect is actually preserved during what can sometimes be a long season, which could have really significant implications in terms of the timing of the vaccine as well as the potential for being even super-seasonal. That's why we have the extended study where we are looking at additional vaccinations or annual.

I think in terms of the effect, what we have said and I think it's very clear, is it is exceptional data, and it's not just exceptional on the primary endpoint but what we have said is this is a really exceptional data package which includes both the effect on the primary endpoint as well as a myriad of secondary endpoints, including examining whether the effect was maintained in those over 70 versus those under, which it was, whether the effect was maintained in both the RSV A as well as RSV B, and it was, as well as the effect in patients with comorbidities and even reductions in severe disease. Overall a very exceptional data package and we look forward to being able to present that to the community soon.

Emma Walmsley: Yes, so lots more to come in due course.

Laura Sutcliffe (UBS): Hello, thank you. I have a question on *Shingrix* for you. I know that you have a doubling of sales goal to 2026 but do you have any sense of where the peak sales year sits for *Shingrix*? Thank you.

Emma Walmsley: Thank you, Laura. I will come to Luke in terms of overall outlook but it is fantastic to see this momentum coming back. It was a record quarter, it will be a record year and a really important move, going back to this durability question on de-seasonalising – if that is English – *Shingrix*, which is important, as this move towards more and more adult vaccination comes in. The opportunity for us and for retailers is very interesting and that quarter smoothing.

Amazing moves on geo-expansion. Luke, would you like to comment further?

Luke Miels: Sure. Laura, that is a great question and the main swing factor is probably China. You can imagine that the US, at some point, will exhaust the population – and, of course, our intent is to do that before any competitor would arrive, or likely to do it before any competitor could arrive. We are learning a great deal from the launches in Europe,

and you can see that performance coming through in the results, which has just been reported. We are now launching in emerging markets – we have just started in Brazil and a number of other smaller markets. The speed of the uptake there will really guide that but, because of the conditions on the ground in China right now, that is the main swing factor for us – even though the growth, in absolute terms, is quite strong.

Emma Walmsley: This is why it is very exciting to see the pipeline building through in our adult vaccination portfolio. There is *Shingrix*, with lots of great growth prospects ahead, and we will add to that, hopefully, in due course with the launch of RSV and of course the Affinivax portfolio, later in the decade.

Keyur Parekh (Goldman Sachs): Hal, first of all, thank you very much for all your help and support over your multiple innings in the biopharma industry – I am sure all of us really appreciate it. Good luck in your non-executive role, but thank you very much for the multiple years of help.

I have a couple of questions, please. One is just a broad one on RSV. I know that Pfizer, at least in clinical trials, seem recently to have changed the primary and secondary endpoints on their RSV study. I was wondering whether you might be able to share your perspectives on what that means and why that might be the case.

Linked with that, for Luke, from a commercial perspective, how should we think about the demand trends. When you launch the product, should we think of this as a *Shingrix*-like launch, or is this one where you might have to create a market, unlike the situation with Zostavax. That is on RSV.

Separately, as I look at your updated guidance for the full year, at mid-point, the operating profit growth range essentially implies little to zero growth in the second half of the year. My question is not whether that is conservative or not but, if you are going to exit the year doing 0% growth in the second half of the year, how should we feel comfortable with the double-digit operating profit growth for 2023, to which you have already guided? Thank you.

Emma Walmsley: Thank you, Keyur. I will obviously come in turn to Hal, then Luke and then Iain. You know that we are not about to give you 2023 guidance in Q2 of 2022, as Iain has already alluded to, but I am sure he will add to that after we have had a little more on RSV.

This is really a comparator question. We feel very good about the momentum on fundamental demand across the business. We feel very good about the outlooks overall, on the five-year outlook we gave you last year. We have always said that that was not a back-

weighted prospect, and we feel that we have all the fundamentals moving in the right direction – both on execution, on multiple core aspects across the portfolio, and on the progress we are making in terms of the launches that are coming through.

Let's come to Hal - we are very focused on our own results in RSV – and then we will hear from Luke. The only thing I would say is that the world has been waiting for 50 years for an RSV vaccine. Usually, when you have more than one competitor in a market, that bodes well for the size of the market, too. We feel extremely excited about our results – but I don't know what Hal would like to say.

Hal Barron: Thank you for the kind comments, Keyur – that's very nice of you. I would just like to say that it has been a real honour to work in the field, and particularly to work as Head of R&D at GSK with the incredibly amazing colleagues with whom I have spent the last four and a half years, transforming the R&D organisation and really getting to the incredible place where we are at GSK today. So, thank you for that.

In terms of the Pfizer change – yes, of course, we saw that. It is a bit unusual, but I will not comment on other companies' decisions on clinical trial design or regulatory involvement. I will say, however, that we have exceptional results. This was a very unusual RSV season but we do have exceptional results. We have seen the treatment effect, as I mentioned, maintained in both RSV A and B, and, very importantly, we specifically added the adjuvant because we observed in Phase 2 - and this was somewhat known - that the elderly T-cell response to viruses in general and RSV in particular is blunted, and we were able to show that with this modified dose of adjuvant, we can normalise that T-cell response. We did see in the clinical programme a treatment effect in the over-70 to be very similar to that in the under-70.

As Emma said, it is always terrific when you have outstanding data, this has been in the making for 60 years or so and it is very complicated. All of these scientific advances are now set to have a huge impact on the very large number whose lives we can hopefully save, and certainly hospitalisations we can avoid.

Luke Miels: It is very interesting, there has been no solution to this problem. You see high awareness among physicians because the numbers are quite striking with six million cases in the US, about 180,000 hospitalisations in an average year and 14,000 deaths. Physicians are aware of it but, as far as the number of people potentially impacted by it, there is not as great an awareness as you would imagine, because there is no solution but I would expect that changes quite dramatically. I don't think it is like Zostavax, I think it will be us creating the market. I think there are other variables. You should assume ACIP

recommendation. The question is whether the cut-off is 60 or 65, whether you have individuals with Type II and respiratory and CV comorbidities in there.

The other variable we have is will there be another company there? We compete against that other company right now in meningitis B: we have high respect for them but we get 77% of that market share, so I think we are ready for a dynamic contest. If there are two companies in there, I believe that the market will expand faster.

Emma Walmsley: Thanks, Luke. Iain, anything else to add?

Iain Mackay: I was given great advice by a colleague at HSBC many years ago never to try to out-analyse an analyst, so I am not even going to try, Keyur! Suffice to say the momentum we are taking out of the first half, the second half performance is very much influenced by the comps from the third and fourth quarter of last year with the pretty strong performance from *Shingrix* in the third quarter of last year being a key influence in that. Suffice to say we have a visibility to revenue performance in the second half of the year that we believe keeps us consistent with our longer-term/medium-term outlook, so more than 5% and more than 10% adjusted operating profit through to 2026. Although the second half will be a little slower than the first half in terms of growth of top line, we still see attractive growth coming through in the second half with momentum into next year. When we get to our full-year results, we shall be sure to give you a more specific view of what next year looks like both on top line adjusted operating profit and adjusted earnings per share.

Jo Walton (Crédit Suisse): Good afternoon. I shall respect the one question rule but ask for a clarification. My question is about the General Medicines business. It is about one-third of your business at the sales level and it is expected to decline. I wonder if you could tell us if there is any change in your appetite for potentially slimming that down, whether there is the opportunity to sell some of those assets and redeploy the cash in other areas?

As far as my clarification, I apologise that it might just have been Crédit Suisse telephony. The line went very crackly when Luke was talking about the *Shingrix* stocking, so I wonder if you can reiterate how much of the 2Q performance was effectively brought forward from the second half? Many thanks.

Emma Walmsley: Thanks, Jo, and I shall come to Luke to comment on both your clarification and your question. Just to say big picture, we have done an enormous amount of work over the last five years, as you know, on the portfolio of GSK in the broadest possible sense, including two weeks ago the successful execution of the demerger, and then

within Gen Meds as well. We always keep that as a watching brief but I want to emphasise that we said last year [broadly stable] on Gen Meds over the five-year horizon. That is a combination of the growth of some assets in some geographies and then, of course, as Luke mentioned, the digestion of some genericisations of parts of the portfolio. However, this is a nicely profitable business and we have parts of it like *Trelegy* that are growing extremely well.

We shall always keep a watching brief on that and continue to look from a capital allocation point of view at an overall level, as Iain reiterates, where we want to do BD. We shall continue to do more of that with a newly flexible balance sheet but no major initiatives. Luke, do you want to do the clarification and add on Gen Meds?

Luke Miels: Sure, Jo. On Gen Meds, we see opportunities to grow that portfolio. You see a surge in demand from *Augmentin* as things normalise. We have done divestments like Ceph's in the past but, if you take out pressure on products like *Seretide* and *Advair*, this is an outstanding portfolio and we see opportunities using non-manpower ways to grow growth.

In terms of your question around the inventory, if you will indulge me a little, I will just expand on the broader answer. In H1, we saw very good demand in the US and Europe, that is largely the comparator. If you look at Q1 and Q2 2021, it was very large – percentage-wise, it was a relatively generous comparator and that will not be the case in the second half of the year.

We also have the new launches that we talked about. Emma made the point earlier around us trying to expand vaccinations outside of the flu season: we are doing that to normalise but also, obviously, with one eye on RSV in our portfolio. Then the other Q1 trends are very much the same into Q2, around HCP willingness and pharmacists willing to rank. These actually improved.

The volume, with the wholesalers in the US, is a very good forecast: they have a good sense of demand. What we saw through Q1 was that it was within range. We talk about 1.1 being the normal range and, if it went up to 1.3 in Q1 and then it started to slide back down as we went into Q2 – so, 1.2, 1.1 - and sat there for a while. But in the back half of Q2, we started to see it climb. It softened, and then it went to 1.6, [1.8] and we finished at [1.8]. If normal is 1.1, then [1.8] seems to be a pull forward on the part of wholesalers, and that is certainly the feedback they are giving us.

Emma Walmsley: Thanks, Luke.

Seamus Fernandez (Guggenheim): We saw a good performance of *Cabenuva* in the quarter in the overall HIV portfolio. I was hoping to have a little more colour on the treatment versus PrEP utilisation, and then just conviction that this trend is actually accelerating at this point. It looks like strong results but I just wonder whether there was anything in the quarter that we should be aware of, from a stocking perspective, or a pull forward? Thank you.

Emma Walmsley: Thanks, Seamus. We have a great deal of conviction in this portfolio, but I will let Deborah explain.

Deborah Waterhouse: Great, thank you. In terms of the balance between treatment and prep, as you probably know, the PrEP market is much smaller than the treatment market. Treatment is currently at round about \$23 billion to \$23.5 billion, with \$2.5 billion for the PrEP market. Treatment versus PrEP is significantly different in size. The uptake of *Apretude* is limited as we said it would be all along, because we need to go through that process of securing access and also setting up the processes, building the market basically for an injectable in the PrEP space. However, the feedback we are getting from physicians and particularly patients, about the impact that this medicine will have, is phenomenally positive. I think you will see that translate into significant revenue next year.

In terms of *Cabenuva*, it was another strong quarter where we saw sales doubling. We simplified the process by which physicians can acquire and administer this medicine. Again, all the ATU work – the tracking of the opinion of physicians around *Cabenuva* – continues to strengthen. Confidence is high and we absolutely see ourselves as being on track to be able to deliver between *Apretude* and *Cabenuva* that \$2 billion worth of revenue that we talked about in the Business Investor Update last June, and which we reiterated in the investor session that we did in November which was solely focused on HIV.

Let's just talk a little about the break in the first half of the year. The first half-year is 10% growth. A vast majority of that is driven through volume uptake of our innovation medicines. We are really seeing strong underlying demand for *Dovato*, both in the US and in Europe, and, again, very strong underlying demand for cabotegravir in the US. That is the vast majority of why we are delivering that 10% growth. There is a little bit of net price mix in there, as we move from the older products, which have higher discounts, to the newer innovation products which do not, through the mandated channels or to a lesser extent. This is an incredibly positive story – a story of volume, performance and market share.

Thanks, Emma.

Andrew Baum (Citi): I have a couple of questions, please. The first one is to Hal, given that it is my last opportunity on a GSK call. You highlighted the CCL17 monoclonal: do you feel that you have a Sub-Q dose that is ready to be taken directly into Phase 3? Do you think that there is any role for this molecule to address the composite components of long-COVID, just given some of the recent pre-prints?

Secondly, for Deborah, our recent survey highlighted a shortage of nursing staff as a potential cap for the *Cabenuva* franchise to expand. Are you seeing this as potentially problematic in terms of administering *Cabenuva* to a broader patient population? Many thanks.

Emma Walmsley: Thank you. You just cut out in your question as you were bridging to the long-COVID piece. Would you remind repeating that?

[*Call cuts out*]

Emma Walmsley: I suggest we go to Deborah.

Nick Stone: I think what Andrew was asking if I caught it correctly, was Sub-Q for CCL17 and long-COVID.

Hal Barron: Thank you, Andrew if you can hear us. Yes, we are very pleased by the CCL17 mAb data in osteoarthritis for reduction of pain. As you know, that was based on a pretty compelling preclinical hypothesis that CCL17 may be involved in inflammatory pain, maybe neuropathic pain, lots of different preclinical models that have given us some confidence in that.

And of course that's what was, to some extent, behind the interest in anti-GM-CSF because GM-CSF is the proteins when you expose a PBMC to GM-CSF, CCL17 is the most overexpressed protein. Of course a mAb to CCL17 is going to be a much more effective way of reducing CCL17 levels, so we were pleased to see that in the randomised Phase 1b which is a pretty unusual design but we decided given that it's pain and all, the challenges with assessing the benefits of a drug on pain, that we would do a small but randomised Phase 1b study.

Now that data is positive. That is going to enable us to initiate a Phase 2 study. We are certainly not ready to move to Phase 3 with that so if there was any confusion, are we ready for Phase 3. No, we are going to be needing to do more dose-ranging, more durability ranging. This was an eight-week study and of course we will need longer and there may be the potential to see if there are biomarkers and subsets of patients, whether there would be other patient populations, patients with refractory pain that might benefit the most from that.

Yes, we are very excited based on the biology and the clinical data but we need Phase 2 data to optimise the programme.

In terms of long COVID, at this point we have not thought about CCL17 as an approach to long COVID. I think the definition, the epidemiology, the biology behind long COVID has really been challenging to understand and to elucidate the mechanism behind it but as you point out it does appear to be inflammatory, but at this point we are focussing our energy on developing CCL17 antibody for pain given the enormous unmet medical need that exists for patients with pain, particularly those who are needing narcotics and all the obvious problems with the opioid issues, so we are really excited about the role that could play in pain and maybe someday we will look to see if it has roles outside of pain.

Emma Walmsley: Right, thanks, Hal. Are there any quick comments on the nursing staff shortage?

Deborah Waterhouse: Yes, sure. We do a huge amount of research like you do, Andrew. Basically we are building a market and there are a number of things which in building that market can act as a barrier, so nursing staff is one, people within clinics that can actually manage the reimbursement process would be another and we are supporting clinics to work their way through all of that.

That is about helping with work flows within the physicians' offices themselves but also we are doing a huge amount of work to expand our alternative sites of care, so actually if physicians are struggling with nursing staff or they have such a volume of *Cabenuva* patients now that they don't want to handle it all themselves, they can now move their patients into alternative sites of care. Also we are doing a lot of work via a study called Glacier and working with the community to move the injection of *Cabenuva* and actually *Apretude* eventually we hope into pharmacies. That starts to unlock that bottleneck.

What I am struck by is all the physician visits I do, and I was in Los Angeles the other week and spoke to ten of the biggest prescribers of HIV medicine and PrEP is just the demand for this product. Both *Apretude* and *Cabenuva*, they have people waiting on lists to get this medicine and the unlocker is the process within the physician's office and the ability to refer people into alternative sites of care and eventually we hope to do the same in pharmacies. It's incredibly motivating to see the demand for these incredible medicines that will really revolutionise the lives of people who are living with HIV or who would benefit from PrEP.

Emma Walmsley: That's great, and the other only thing to add in terms of any suppressions, we are still set on it. I think the switch market is down 30%, isn't it, versus pre-COVID?

Deborah Waterhouse: Yes, exactly, so when the market continues to come back then we will continue to benefit from that.

Emma Walmsley: And then in our more outer stage pipeline, but an important one for later in the decade of course, as well as longer acting, longer acting, we are exploring self-admin, too which helps solve some of that challenge.

Simon Mather (BNP Paribas Exane): Thanks. Afternoon, all. Thanks for taking my question. I am just wondering, could you provide any comment on the ongoing Zantac litigation and potential liabilities and just generally your stance on the topic and whether or not you could quantify what portion of any liabilities, if any, have been transferred to Haleon as part of the spin. Just any information you can give us would be greatly received. Thank you.

Emma Walmsley: Thanks, Simon. It's a bit of a short answer to the question. I am afraid I am not going to comment, as we never do, on any legal matters like this.

Iain Mackay: The latest is in the earnings release, Simon, and any more detail beyond earnings release was prior the Annual Report and Accounts published a couple of months ago, and so the latest is in the earnings release.

Emma Walmsley: Thanks.

James Ridley (Morgan Stanley): Thank you for taking my question. I have a clinical one on otilimab. Looking at clinicaltrials.gov, contRAst-3 has completed, contRAst-2 will finish in October and contRAst-1 is expected to finish in September. Should we anticipate that the data will be ready to present at ACR in November?

ACR20 is the primary endpoint which is seen as a reasonably low bar, or more of a regulatory endpoint, so what would you say is a key endpoint that physicians are looking at, and what would be the bar for success across those endpoints?

Also on the last call, you mentioned that the Phase 2 study failed to meet the primary endpoint, which was DAS28 remission. Where would you say physician sentiment, knowledge and excitement is around the programme in the context of the Phase 2 data and the upcoming Phase 3 data?

Emma Walmsley: Great, thanks, so a variety of sub-questions around the otilimab programme, Hal?

Hal Barron: Thanks, James. The way I would think about the otilimab programme is to include in the programme the CCL17, so think of them as two molecules as part of a hypothesis that CCL17 may be driving the pain associated in the contRAst studies, rheumatoid-arthritis-induced joint pain. The basis for us moving forward despite, as you point out, a negative Phase 2 study was that there were, as I mentioned earlier, recently compelling preclinical models that suggested CCL17 was one of the most important proteins in creating this inflammatory neuropathy.

We did observe that anti-GM-CSF reduced CCL17 but to a smaller extent than, of course, would be seen with a mAb. That then gave us more confidence than one would have had in a negative Phase 2 study because we did see trends in improvement in symptoms.

The design of the Phase 3, as you point out, was to have ACR20 as the approvable endpoint and, given some of the safety concerns seen with some of the other rheumatoid arthritis drugs, we think that is a reasonable endpoint. Of course, if the medicine were to be successful both at ACR20 and reduce pain, that would be a very differentiated molecule, very high bar, and, as I point, one you should think of as being part of the CCL17 anti-GM-CSF programme. By the end of the year, I believe we shall have a much better sense of how to put both of those molecules into context and to think about how we can advance each.

Graham Parry (BSA): Thanks for taking my question. Hal, I have a question on the RSV vaccine, and I guess it is always good to go out on a high. You have mentioned many times that these are exceptional data. I believe you previously used similar language to describe potential vaccine efficacy of over 80% on your primary endpoint, so can we interpret the "exceptional" comments as referring to primary endpoint or to a more severe disease or secondary endpoint?

Given Pfizer is shifting to a more severe disease endpoint, does that match more closely your definition of the infection, so the three symptom definition? Your description in clinical trials is perhaps a little looser than that, so will we be able to compare their headline data or their primary efficacy data with yours?

Secondly, on momelotinib, are you expecting a priority review and how much physician education do you think will be needed at launch on this given there were two failed studies versus ruxolitinib and you are going into the more advanced setting, or is there an addressable pool of patients waiting for therapy here? Thank you.

Emma Walmsley: Hal, if you can do RSV and make comments on momelotinib and, Luke, I'll come to you to see if you have anything to add.

Hal Barron: Thanks, Graham, lots of really good questions embedded in there. Let me clarify two things because they were done very intentionally. It wasn't exceptional, we said outstanding was more than 75 and I specifically put into quotes "exceptional", so they are different. You will have to see why we use different words.

The exceptional data refer both to the primary endpoint as well as to the key secondaries. Remember, we have an antigen of RSV-A and we were confident from the Phase 2 data that the treatment effect would be preserved in both A and B but we didn't have the Phase 3 data. Now we do and we are very confident that the treatment effect is preserved in both RSV-A and RSV-B. The most important component of this is the treatment effect and, as I said, we are not going to give a point estimate but the data are exceptional.

The other really important point just to highlight again is that we believe that the adjuvant that normalises the T-cell response seen in the elderly compared to that which is seen in the young is really important as far as engendering a treatment effect in the over-70s where much of the morbidity exists. That is an incredibly important secondary endpoint for the programme and, as we said, the treatment effect in the under-70s and over-70s is very consistent. That is the package that is exceptional.

We shall be doing additional analyses on duration and durability, etc., as well as some other sub-groups, but those patients with comorbidities, as was alluded to earlier, benefit. I am not going to comment on Pfizer changing the primary endpoint, other than to say it is unusual that companies do that at the time of unblinding and we will have to look at all of the data very carefully but the over and under 70 and the durability of response are the two key attributes that one are going to need to compare. That probably will not be something that you can do from a press release but you should see the data from our programme within the next two or three months, so we are confident that a great discussion will ensue.

In terms of momelotinib, we don't really comment on regulatory interactions at this point. We are very confident in the data, the unmet need and the robust nature of the findings.

Luke, I don't know if you want to add anything.

Luke Miels: Graham, the deal was constructed on an assumption that we would have that second line block and so you should assume that at this point. I think at the recent conference where the Phase 3 data was presented people were raving about it. It was very positive, so we remain very excited about the potential and we have also just filed in the US as you know and then we will file in the second half of this year in Europe.

Emma Walmsley: Great. The next question, please.

James Gordon (JP Morgan): Thanks for taking the question. One on HIV, I think you have said before that *Cabenuva* plus *Apretude* could be more than £2 billion peak but based on this initial ramp, could maybe *Cabenuva* be a £2 billion-plus product by itself, even ahead of CAB 400 coming along, or do we need to be a little bit cautious that maybe there are some low hanging fruits, some warehoused patients and things then slow?

And then also *Apretude* next year, could *Cabenuva* be a good guide to what the ramp might look like for this product next year, smaller market but lots of weight-listed patients or do we need to be a lot more cautious in terms of taking a few years for the market to really build?

If I could also just squeeze in a clarification, *Blenrep* we heard the gamma secretase combo and the wider dose interval, they are two different ways you could deal with the ocular tox and both look promising, so have you now decided to go down just one of the routes or are you going to do both? When do you start more trials and when could the sales start to accelerate as a result?

Emma Walmsley: Alright, so now that you seem to have rebaptised questions as clarifications I am just going to ask my team to be as brief as possible, Deborah first, then Hal, so that we can get to as many clarifications left as possible.

Deborah Waterhouse: Thanks, James, so *Cabenuva*, we are still sticking with the £2 billion in 2026. The competitive landscape, you know there is a little bit of uncertainty in there at the moment, so how that unfolds could make a difference but for us fundamentally the £2 billion is what we'll do in 2026, so no change there.

Apretude, a similar journey to *Cabenuva*, so next year you will see a ramp up which is going to be quite significant on the basis that we will have solved all of the process and access issues in 2022.

Emma Walmsley: Thanks. The only thing that I would add to that as well is that we are very excited about the emerging early stage pipeline of how our longer-acting, longer-acting is going to be growing through the end of the decade, so I don't see that as a full stop.

Hal, anything to add on the DCMA?

Hal Barron: Yes, clearly your point is excellent. The GSI combination is a clear synergy and it is completely independent from the opportunity to improve the benefit-risk profile from a Q4w, six or even eight-week regimen, so yes, the answer is both of those will be advanced forward as we move to earlier lines.

We also of course have two other levers. That is the holding for Grade 2 ocular tox as well as the synergy we are observing with pomalidomide and other standard carrier agents, so all of those will enable us to have a much more robust profile and to enter into earlier lines.

I think you said what is the data coming out? We are going to have DREAMM-3 soon and DREAMM-7, both of those are in earlier lines, third-line and second-line respectively and comparator arm with PFS as primary endpoint, so we are going to be able to see how potentially effective these agents are compared to Velcade and other standard-of-care agents like Darzalex as well in third-line, so we are very excited about the molecule.

Simon Baker (Redburn): Thanks for taking the question. A big picture question on R&D for you, Hal. You talked about cultural changes that you have implemented during your time. I wonder if you could discuss what the most important cultural changes have been in the R&D organisation. And on the basis that the job is never truly finished, what are the key items remaining in Tony's inbox when he takes over? Thanks very much.

Emma Walmsley: I'll let Tony speak for his priorities. He is literally starting next week and you are all going to have a great chance to meet him in coming months and certainly he will be presenting next quarter, but Hal, I don't know if there is anything briefly that you want to say in terms of the biggest dynamics within the culture change you have been driving and as Hal concluded, there is always more to do and you remain very focussed on that.

Hal Barron: Yes. As I said at the beginning, the cultural change is incredibly important and one that actually will probably take longer than even revitalising the portfolio, so I think that there is a lot more work to do but the things I am most proud about the culture is we really did try to drive a culture where there is limited if no fear of failing, taking smart risks is the way we called it which is sort of knowing that in this business it's very risky. 90% of drugs that enter the clinic will fail and if one is trying to avoid failing you will never have innovation, so I think we've come a long way there.

The second thing, and I won't go through the rest, was that we have really tried to be very obsessive with something called single accountable decision-making models where we identify individuals who are accountable for decisions and not relying on consensus which I think can kill innovation.

I'm trying to be very brief but I think we have made a lot of progress on the cultural change but there is certainly much more to come.

Emma Walmsley: We are running a bit longer. I am going to take two more questions. That culture question, we could take up a whole hour and a half of presentations on and I do not want to take away from the enormous impact and momentum that has already been driven there, so the next question, please and then we will have one more after that.

Peter Welford (Jefferies): Thank you for taking my question. This is for Luke on *Shingrix*. If we go back to what we have seen, with the doses – thank you for the detail there – I wondered if you could talk a little about who it is that you are seeing now actually doing the administration. I think we talked about a shift previously, from retailers and more into the doctors. Has that shift moved back again? Are you still detailing actively to the doctors – I think you said it was with the *Trelegy* salesforce? Could you talk a little about how you are seeing that dynamic essentially evolving now in the second half of the year, I guess, as COVID truly unwinds with the vaccine.

Luke Miels: It stabilized around 55% retail/45% non-retail. About 60% of the non-retail is doctors. As I mentioned earlier, the trend rates are there: their willingness to recommend and strongly recommend continues to build. Having *Trelegy* – and, actually, we have expanded this to other teams globally - we have *Shingrix* in the P2 slot across a whole number of teams, including the *Nucala* teams globally, and it is working very well.

Emma Walmsley: Great, thanks. Final question, please.

Emily Silt (Barclays): Hi, thank you for fitting me in. On clarification: is 'exceptional' better than 'outstanding'?

Then I have a question on the guidance. The decision to maintain the growth rate for Specialty, given that the HIV guidance was nudged up a little – is there a deterioration in any other elements of the business there, or is it perhaps just a broader air of conservatism?

Then also, what drove the slight moderation in influenza guidance for the year? Was that share, or anticipated market pricing?

Emma Walmsley: Iain, perhaps you could comment on guidance and then we will come to Hal for the distinctions in his vocabulary.

Iain Mackay: That is a very good question. It's basically around proportionality – the comments that Deborah made earlier about the performance of HIV are particularly in the HIV context. When you put it in the context of the Specialty Medicines portfolio overall it

is not sufficiently material to lift up the guidance for Specialty Medicines overall. It is not as if it is offsetting something else within Specialty, but it is just in terms of proportionality, and it does not move the needle for Specialty overall.

Hal Barron: Let me just say, as my last comment on my last call, that it is a real honour to say that the question as to whether 'outstanding' or 'exceptional' is how you would define the Phase 2 results for one of the most important trials done in the last 60 years is incredibly inspiring. You can decide when you see the data!

Emma Walmsley: Perfect! Thank you, everybody. We are delivering, and I am absolutely delighted that we have been able to upgrade our guidance this year and demonstrate pipeline progress – including with Hal's concluding comment – as well as tremendous commercial momentum. We have delivered a successful separation and the biggest change for GSK in two decades, and created the capacity to continue to invest in future innovation and growth.

I would like to conclude with my own very sincere thank you to Hal for the enormous impact he has had on the momentum of GSK. We are really looking forward to his graduation to being a member of the Science Committee and a non-Executive director of the Board. I know he will continue to contribute wonderfully. I know how much Tony is looking forward to spending time with you all in the coming weeks and months, and we will look forward to seeing him in the days ahead.

Thank you very much.

[Ends]