# GLAXOSMITHKLINE Q3 2020 RESULTS Wednesday, 28 October 2020

Sarah Elton-Farr (Head of Investor Relations): Good morning and good afternoon. Thank you for joining us for our Q3 2020 results which were issued earlier today. You should have received our press release and you can view the presentation on GSK's website. For those who are not able to view the webcast, slides that accompany today's call are located on the Investor section of the website.

#### Cautionary statement regarding forward-looking statements

Before we begin, please refer to Slide 2 of our presentation for our cautionary statement. Our speakers today are Emma Walmsley, Iain Mackay, Luke Miels, David Redfern and Brian McNamara; Hal Barron and Roger Connor will join us for Q&A. We request that you ask only a maximum of two questions so that everyone has a chance to participate and with that, I will hand the call over to Emma.

**Emma Walmsley (CEO):** Thank you, SEF, and welcome everybody to today's call. I hope that you are all keeping well.

#### Q3 progress

2020 continues to be an extraordinary year. GSK has shown resilience and agility in tackling the challenges, while maintaining focus on our strategic goals which remain firmly on track. We continue to strengthen and advance the pipeline. In July, as mentioned at Q2, we received approval for *Rukobia* in HIV and this quarter we have also had first approval and launches for *Blenrep* in multiple myeloma, for *Trelegy* in asthma and new indications for *Nucala*. We have delivered positive data on our RSV candidate vaccines and GSK 836 in Hep B. Plans to progress these programmes are under way, both represent major opportunities for healthcare impact and have the potential to be significant future growth drivers.

We also initiated three major pivotal studies in meningitis vaccines, second line multiple myeloma and with our Vir antibody and COVID-19, a very exciting programme you are going to hear more on later.

Though there have been some short-term pressures as a result of the pandemic, especially in Vaccines early in the quarter, our performance fundamentals continue to strengthen. We are very confident that our Vaccines portfolio and pipeline will drive growth

for years to come. Brian will update you in more detail but the momentum we are building in our commercial execution is driving encouraging growth across our new products, setting the course for strong future performance.

And this has also been a quarter of disciplined cost control as we have made substantial progress on both our Consumer integration and company separation programmes. We continue to deliver efficiency in our support functions, further simplify our site network and we have achieved an important milestone on building one Development organisation in R&D for Pharma and Vaccines that will improve agility, decision-making and scientific collaboration, as well as our cost base.

Our pipeline includes several COVID solutions and we remain committed to building stakeholder trust as we deliver them. We have in place supply agreements with multiple governments for our partnered adjuvanted COVID-19 vaccines and have pledged to maintain our focus on safety and global access.

#### Q3 performance

Turning to the quarter, strong performance from our future growth drivers combined with a focus on costs has offset the ongoing pandemic impact. We have delivered margin and earnings growth this quarter and expect to deliver within our earnings guidance range for 2020. All numbers referenced are on a constant currency basis.

In Pharma, we are very encouraged by the strong performance of our New and Specialty products with sales up 12%. This was offset by a decrease in established Pharma of 18% and lain will go into that in more detail in a minute.

The greatest impact of the pandemic has been in our Vaccines business where sales were down 9% in the quarter. However, we are encouraged by the accelerated recovery towards pre-COVID level of immunisation as the quarter progressed and a strong performance in flu, up 21% in the quarter. Year-to-date, *Shingrix* sales are up 6%.

In Consumer, we continue to reshape the portfolio and pro forma growth in our ongoing business was 3%, driven by Vitamins and Oral Health. Overall, we are gaining share and our power brands are performing strongly. Group adjusted operating margin for the quarter was 30.8% with the impact of Vaccines more than offset by tight cost control and a realisation of restructuring benefits, with SG&A down 10% pro forma while we have continued to invest in our pipeline and our new product launches.

On a total basis, earnings per share were 25 pence and adjusted earnings per share were up 1% to 35.6 pence.

#### Progress on portfolio of COVID-19 solutions

Before I hand over to lain, I would just like to remind you of the great progress we are making on our portfolio of COVID solutions. Our aim is to develop multiple adjuvanted COVID-19 vaccines and we now have three different vaccine collaborations in the clinic that could move to pivotal studies by the end of the year. We also have two exciting therapeutic approaches in clinical studies through our collaboration with Vir, which Luke will speak to later, and our aGM-CSF antibody, otilimab.

Now, to lain, with more detail on the quarter.

# Q3 2020 Financial Results

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

# **Headline results**

On Slide 9 there is a summary of the Group's results for Q3 and the year-to-date. In Q3, turnover was down 3% CER, adjusted operating profit was £2.7 billion, up 4% CER. Total EPS was 25 pence, down 9% CER, and adjusted EPS was 35.6 pence, up 1%.

In the year-to-date, turnover was £25.4 billion, up 4% reported, down 2% pro forma. Adjusted operating profit was £7.1 billion, up 3%. Total EPS was 102 pence, up 55%, and adjusted EPS was 92.6 pence, down 4%.

We delivered over £2.3 billion free cash flow in the year-to-date and, in the quarter there was a 5% headwind in sales and 9% on adjusted EPS from currency movements.

#### **Results reconciliation**

Slide 10 summarises the reconciliation of our total to adjusted results. The main adjusting items in the quarter and highlights are major restructuring, which reflects continued on-track progress in the Consumer Healthcare integration, and transformation and separation activities.

In transaction-related, within which the main contributor was a charge relating to the re-measurement of the contingent consideration relating to ViiV Healthcare. The main component within this was an increase in our forecast for cabotegravir PrEP, following the very strong clinical data that was shared earlier in the year.

Comments from here onwards are on adjusted results on a constant currency basis, unless stated otherwise.

#### **Pharmaceuticals**

Slide 11 summarises the Pharmaceuticals business, where overall revenues were in line with expectations, down 3% in Q3, and down 1% in the year-to-date. Excluding established Pharma, revenue grew 12% in the quarter, and was up 12% in the year-to-date, reflecting our strong commercial delivery. Respiratory was up 26%, with continued strong growth from *Trelegy, Relvar/Breo* and *Nucala. Benlysta* was up 13%, extending its double-digit growth after more than nine years on the market.

In Oncology, *Zejula* sales were £92 million in the quarter, up 47%, reflecting excellent commercial execution. We remain very excited by the prospects of both *Zejula* and *Blenrep*, which launched in the quarter.

Our new products continued to perform strongly and Luke will comment on these momentarily.

HIV revenues were flat, with the dolutegravir franchise up 1%, with very strong performance from *Dovato*.

The Established Pharma portfolio declined 18%. Within this, Respiratory was down 18%, reflecting generic competition for *Advair/Seretide*, and *Ventolin*, plus accelerated brand erosion of *Flovent* in the US. The rest of the Established Pharma portfolio was down 19%, with COVID-19 impacting performance, particularly in antibiotics.

Additionally, we have seen increased government mandated generics in certain markets.

For the current year, we expect the total Established portfolio to be down mid-teens. Next year, we would expect the established portfolio to revert to its historical norm of mid- to high-single digit decline. We continue to review opportunities for divestments in this portfolio.

The Pharma operating margin was 28% in Q3. A 470 basis points increase reflected a favourable product mix that benefitted in the quarter from the recognition of pre-launch inventory and approval of *Blenrep* within R&D. There was a favourable comparison to 2019 pertaining to non-recurring manufacturing write-down and legal settlements, and tight control of costs and the benefit of restructuring actions. These were offset by increased investment in new product support in target priority markets and, in R&D, a focus mainly on oncology and COVID-19 programmes. The year-to-date margin was 26.3%.

#### Vaccines

Slide 12 gives you an overview of Vaccines performance in Q3, with sales down 9%, driven by the adverse impact of the pandemic. *Shingrix* sales were down 25%, reflecting lower adult wellness visits in the US, particularly through July and August. However, by the end of Q3, *Shingrix* weekly US prescriptions reached similar levels to the same time last year. *Shingrix* revenue has grown 6% year-to-date, and we have put measures in place to support further growth through Q4 and beyond. Recent trends are encouraging and demonstrate the strong underlying demand for this vaccine, and we continue to make progress in expanding supply capacity.

Flu vaccine has performed well with revenue up 21%, primarily reflecting strong execution on supply and sales. We expect the increase in flu immunisations, particularly amongst older adults to support further recovery in *Shingrix's* performance.

The Meningitis portfolio grew 1%, with the disrupted back-to-school season in the US affecting *Bexsero* performance.

The established vaccines declined 15%, reflecting lower demand due to the pandemic environment, particularly in hepatitis, as expected.

The operating margin of 44.2% was 500 basis points lower, primarily reflecting the negative operating leverage from COVID-19-related sales decline and investment behind key brands such as *Shingrix*.

In the year-to-date, Vaccines' revenues were down 7% and adjusted operating margin was 40.7%.

# **Consumer Healthcare**

Turning to slide 13, Q3 revenues in Consumer Healthcare on a pro forma basis were up 3%, excluding brands either divested or under review. Including those brands, such as *Horlicks*, turnover declined 6% pro forma.

Reversal of the Q2 systems cutover stocking benefit impacted overall growth by around 2 percentage points.

Oral health grew 5% at CER, with *Sensodyne* up 7% driven by strong global commercial execution.

The pandemic has had a sustained positive impact on Vitamins, Minerals and Supplements, which grew 18% driven by increased consumer focus on personal health. However, this growth was partially offset by weaker performance in Respiratory Health, with

a lower cough and cold season so far, and in Pain Relief, informed principally by *Advil* market share.

The RX-to-OTC switch of *Voltaren* in the US is performing very strongly.

Operating margin for the quarter was down 90 basis points year-on-year, mainly reflecting the impact of divested brands and increased brand investment, partially offset by synergy benefits from the Pfizer integration and tight control of costs.

There is no change to our previous guidance for Consumer margins.

In the year-to-date, Consumer revenues were flat pro forma and up 6% excluding the impact of divested or under-reviewed brands. Pro forma adjusted operating margin was 23.8%.

Brian will provide more detail on the Consumer Healthcare performance and an update on the business shortly.

#### Sales and Adjusted operating margins

On slide 14 we summarise the sales and adjusted operating margin for Q3.

Our group operating margin was up 240 basis points on a pro forma basis. Lower costs across the group offset reduced sales operating leverage, which was mainly in Vaccines.

Across the company we are beginning to realise restructuring benefits from programmes announced earlier this year. We continue to manage operating costs very tightly and have realised significant savings in categories such as T&E.

During Q3 in SG&A we realised a one-time benefit from restructuring of postretirement benefits, and the non-recurrence of high legal costs from Q3 '19.

We continue to invest in new product launches and our pipeline progress remains firmly on track with Pharma R&D year-to-date spend up 6%.

The lower R&D spend in the quarter was the result of a benefit from the recognition of pre-launch inventory upon approval of *Blenrep*, comparably lower spend related to niraparib and dostarlimab following their filings at the end of 2019, plus the realisation of transformations savings, synergies and efficiencies.

This was partly offset by increased investment in the progression of pre-key assets such as *Blenrep*, ICOS, otilimab for rheumatoid arthritis, and two key COVID programmes, being Otilimab COVID and the Vir Antibody.

R&D in Vaccines and Consumer was slightly down in the year-to-date, and with the realisation of noted transformation synergies and savings we now expect R&D for the group to increase mid to high single digits for the year.

All our pivotal programmes are on track. Pre-COVID-19 related delays initially experienced now recovering, with the exception of gepotidacin.

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

# Adjusted operating profit to net income

Moving to the bottom half of the P&L, I would highlight that interest expense was £197 million, mainly reflecting lower debt. The effective tax rate of 16.8% was in line with expectations, and we still expect a full year effective tax rate of around 16%.

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

#### Free cash flow of £2.3 bn

We have delivered cash flow of £2.3 billion in the year to September. The reduction primarily reflected higher dividends to non-controlling interests and adverse exchange impacts, partly offset by lower seasonal increase in trade receivables, beneficial timing of payments for returns and rebates, higher proceeds from disposals of intangible assets, and improved operating profits.

As we indicated at Q2, we expect free cash flow to be lower in the second half of 2020 than the first half, and we still expect cash flow for the year to be a step down from 2019. We closed the quarter with strong cash balances, have an effective approach to working capital management and maintain access to extensive undrawn committed facilities.

# 2020 guidance

We set a guidance range of -1% to -4% CER adjusted EPS in early February this year. I think it would be fair to say that quite a lot has happened since then, and I'm pleased that the group has responded with agility, and we are still on track to deliver within this guidance range, albeit at the lower end.

The performance for Pharma and Consumer so far this year is in line with where we expect it to be, with good commercial delivery in our New and Specialty products in Pharma and our Power Brands in Consumer Health.

We are encouraged by the Vaccines business recovery through the quarter, with a stronger performance in September, which has continued so far in October, compared to a year ago.

In Vaccines across the age categories this recovery is mostly complete in paediatrics, while slightly slower in adolescents informed by the return to schools disruption. In older adults, the increasing immunisation rates and uptake of *Shingrix* is encouraging, and demonstrates strong underlying demand.

Achieving our guidance does depend on sustaining this recovery of adult immunisation rates, particularly in *Shingrix*. We continue to make good progress in improving supply capacity for *Shingrix* ahead of our new facility coming online, and we will update you on the details behind this in Q1 next year.

There has been no change to our capital allocation priorities, we continue to advance the pipeline as noted by Emma earlier, we are making great progress with the integration of the Pfizer Consumer Business, are advancing the transformation across all aspects of GSK, and are confident in our preparations for the separation.

As noted in our earnings release we have declared a 19p quarterly dividend, in line with expectations set out earlier this year.

And with that, I will hand over to Luke.

#### **Commercial execution**

**Luke Miels:** Thanks lain. Hi everyone. As you know, we have been working hard on our commercial execution, to ensure that we are competitively resourced, with a particular focus on new product launches and our key markets, and the changes we have made are now starting to pay off. Sales in our growth areas of respiratory, HIV, immuno-inflammation and oncology are up 12% this quarter, at £2.5 billion.

Changes we have made include updated HCP engagement policies, and salesforce incentives, to allow us to compete more effectively and responsively in the key markets where we're driving growth.

We are also winning share of voice, with strong acceleration of our digital capabilities as well as increased face-to-face engagement where possible, and though the lockdown restrictions have, as expected, impacted on some of our portfolio, especially established pharma, we have taken the opportunity presented by the new ways of working to amplify our digital presence, complementing more traditional approaches very successfully. With these measures and the right investment we are seeing great momentum across our new product portfolio, which we expect to build further in the coming quarters as we bring our pipeline assets to market.

#### Nucala: market leadership with upside opportunity

Starting now with *Nucala*, we had another great quarter, delivering a strong, competitive performance, maintaining our leadership in the IL-5 class. This remains a market with significant growth opportunities, with unfortunately only 27% of eligible patients in the US receiving a biologic, and we're leading share of both new and total IL-5 with patients in the US, and remain the leader in other key markets around the world, as you can see on this chart.

*Nucala*'s leading position is built on its proven efficacy, derived from its precision targeting of IL-5 to reduce eosinophils to normal levels, differentiating it from other biologics, and we are using that benefit to rapidly expand into other eosinophil-related conditions. In the US, we now have approval in EGPA and HES, and have recently submitted our application for nasal polyps.

We have also had a first for GSK, when we submitted three indications in parallel to EMA earlier this month, and our studies in COPD are ongoing, and we continue to see a great growth outlook for *Nucala*.

#### Trelegy: growing the market with leading performance

Staying with respiratory and moving to *Trelegy*, we continue to not only lead the way in once daily single inhaler triple therapy for COPD, but grow the market as well. We are growing our share in the US, where we are the market leader, as well as in other major markets around the world. This is an increasingly competitive area, but we have maintained a leading share of voice in the US, Europe and Japan, and continue to see strong growth.

The opportunity in COPD is significant, with less than 25% of patients in the US who need triple or who needed triple being on it today, so there remains substantial scope for growth. Additionally, we received US approval for asthma: about 30% of adult patients in the US with asthma on an ICS/LABA remain uncontrolled, so they could benefit from triple therapy. It is early days but in the first three weeks to market, we have seen a doubling of NBRx prescribers showing that there is an unmet need that is recognised.

#### Benlysta: consistent growth in an expanding market

Switching to *Benlysta,* it continues to be a great product for us and for lupus patients around the world. In Q3 we again saw double digit growth after more than nine years on the market, supported by the uptake of the subcut formulation and the success of our IV launch in China. Lupus is a market with considerable upside potential and we are driving this through targeted life-cycle management, building data and working on new indications. This quarter, we are very pleased to say we have published positive data from the BLISS LN trial

in the *NEJM* and received priority review for our submission to the FDA. We expect to have approval by the end of the year and are on track to become the first and only drug indicated for both SLE and Lupus Nephritis.

We will also have our combo study with Rituxan in house by the end of the year and we are hopeful that this combination, if successful, could potentially lead to clinical remission. With our ongoing investment in generating important data, we are well-positioned versus potential competition with established efficacy in a broad base of lupus patients, longterm real-world outcomes data and a recognised long-term safety profile.

What is interesting is that more than 80% of eligible patients remain untreated with *Benlysta* in the US and, of course, even more around the world. The number treated will increase further with the Lupus Nephritis indication, so there is plenty of opportunity for growth remaining to help these patients.

# Zejula: strong label and commercial execution drive share in 1LM OC

Now to Oncology. Although the ovarian cancer market is being impacted by the pandemic with fewer patients undergoing first line treatment in the first half of the year, we have been able to execute commercially with *Zejula* and to drive our share of the market. Our best-in-class label, the only PARP inhibitor for all comers in the first line maintenance setting, has been key to driving market penetration not only in the BRCA mutant population but across all patient types. That is now supported by both the NCCN and ASCO guidelines for patients who respond to chemo.

As of August, almost half of all patients starting on a PARP inhibitor are now getting *Zejula* and by now one in three, whether new or repeat patients, are on *Zejula* in the front line. In Q3 we saw a 50% increase in the average weekly new writers in the US, and we have doubled our overall market share from 14% in April to over 30% in August.

We also know that there is significant opportunity to continue to penetrate the market with 'watch and wait' still, unfortunately, being used in more than 70% of women in the first line maintenance setting in the US.

Finally, we are focused on accelerating opportunities beyond ovarian where we can improve outcomes for a broader set of patients. In Q3 we initiated the ZEAL study in combination with pembro to investigate the impact of *Zejula* on both squamous and non-squamous non-small cell lung cancer patients in a maintenance setting. With its differentiated properties, superior tumour penetration and the ability to cross the blood brain barrier, we believe that *Zejula* has the opportunity to improve outcomes and be the best-inclass PARP in lung.

#### *Blenrep*: first-in-class treatment for multiple myeloma

We launched *Blenrep* for heavily pre-treated multiple myeloma patients at the end of August in the US and, though it's early days, we are seeing a positive response across the board from physicians, patients and advocacy groups. There is a high unmet need in multiple myeloma and over 500 HCPs and over 200 patients have already enrolled in a fully operationalised REMS programme. We have a highly experienced salesforce and our inperson access to HCPs is highest among the competitive set.

We are also focused on the continued development of this important medicine and have a robust programme in place to improve the safety profile by studying alternative doses and scheduling.

Importantly, we also have studies investigating *Blenrep* in novel combinations with other drugs like pembro, which could have potential synergistic effects, and a combination with SpringWorks' gamma secretase inhibitor which appropriately inhibits the cleaving of BCMA, potentially enabling a clearer target, driving superior efficacy and an improved side-effect profile. We anticipate sharing data on some of these combinations in 2021.

#### Shingrix: encouraging recovery of demand trends

Shifting to Vaccines, we saw continued impact from the pandemic in the quarter with lower adult wellness visits and vaccination rates in the US, although momentum improved substantially in September. For *Shingrix*, we saw a steady increase in US prescription volumes through the quarter and by quarter end they had reached a similar level to that last seen before the pandemic and comparable to the same time last year. We have been very successful in driving this recovery through our DTC campaign in conjunction with the flu season, and wholesaler inventory levels are now considered normal with about 1.2 million doses in the channel.

Outside of the US, we saw strong demand from Germany and great progress in our phased launch in China which is going well.

# Vir collaboration: potential best-in-class antibody for COVID-19

Before David takes you through the 2DR momentum in HIV, I just want to highlight the upcoming readout we are anticipating for our COVID antibody that we are developing in collaboration with Vir. Although there are many vaccines in development for COVID, including our own collaboration on adjuvanted approaches with Sanofi and others, we believe a therapeutic option will still be necessary. There is a lot of uncertainty about how the pandemic might develop but it seems likely that we will continue to see a high level of infections in 2021 and beyond. Even if a vaccine is successful, it will take time to distribute and is unlikely to be 100% effective for everyone. On that basis, it is fair to say that there will be a clear need for therapeutics.

The Vir antibody has been developed from an antibody taken from a patient infected with SARS-Cov-1. The S309 antibody was found to have extremely high affinity for the SARS-Cov-2 spike protein and it is highly potent at neutralising SARS-Cov-2 in live biosimilar assays. It has three features which lead us to believe that we have a potentially best-in-class asset.

The first is that it has a unique receptor binding site which is highly conserved and is required for viral entry into the host. In silico tests of over 80,000 sequences, show that this epitope is highly conserved across circulating viral strains and therefore we expect a high barrier to resistance. Furthermore, escape mutants identified for similar antibodies against other viruses have attenuated or no infectivity.

Secondly, the antibody has high potent effective function *in vitro*, allowing the recruitment of immune cells to kill off infected cells. This potency potentially allows us to have a lower single dose, which will be important as we scale up manufacturing, given the large number of potential patients, and the fact that global demand for therapeutics is likely to outweigh supply for some time.

Finally, the antibody has been engineered to extend half-life and will potentially enhance the bio-availability in the lung. The pivotal COMET-ICE study in the early treatment of patients at high risk of hospitalisation is ongoing and we anticipate having initial data available by the end of the year. On top of this, we are planning to expand studies to include hospitalised patients and for use in prophylaxis. This collaboration has significant potential and is very exciting to us.

Let me now hand over to David to take you through HIV.

# Strong momentum on 2DRs

**David Redfern:** Thank you, Luke, and hello, everyone. As in the rest of our business, HIV is also benefitting from strong competitive execution. We have the leading share of voice in both the US and Europe and the benefit is clear in the momentum we are delivering in the two-drug regimens and across our HIV business.

We are now seeing US dolutegravir NBRx share outstrip our TRx share – a key point of inflection which demonstrates the traction that we have achieved for two-drug regimens, which now has over a 9% share of NBRx in the US.

*Dovato* in particular is performing very strongly. We saw the inclusion of the TANGO switch data on the US label in August, and this has helped *Dovato* to accelerate its share of the US switch market. We now see about one-third of *Dovato* scripts coming from new patients; one-third from competitor regimens, and therefore only one-third from other dolutegravir containing regimens. As such, overall, we are seeing a positive net switch to dolutegravir regimens, helping to increase our overall market share in the US.

In Europe, we are growing ahead of competitors and dolutegravir is gaining market share as we continue to roll out *Dovato*. We have been able to launch early in all markets across Europe, despite the pandemic, and *Dovato* now has the leading share of voice in all measures in all countries.

We have also seen a positive start for *Rukobia*, which has US insurance coverage of over 70%, with 250 patients already on therapy. We are making good progress in our discussions with the FDA on Cab in the PrEP setting: we are on track to file for US approval for PrEP in the first half of next year and anticipate a 2022 approval.

We still expect HIV revenue growth overall to be broadly flat for 2020 but anticipate a return to growth in 2021, building on the momentum we have established for *Juluca* and *Dovato*, and with the expected US launch of *Cabenuva* in the first quarter of 2021.

I will now hand over to Brian, to talk about Consumer.

#### **Consumer Healthcare**

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

# Integration update

I would like to provide a quick update on our progress with integration, which is progressing well and is firmly on track.

Our positive momentum has continued, despite the challenges related to the pandemic. Importantly, we have delivered significant milestones to date. 96% of the Pfizer Consumer Healthcare revenues are now on our system, with 71 markets having made this transition since the start of the pandemic. 87% of co-locations are complete, and 39 of the 41 warehouses identified for closure are now closed. Furthermore, all future market cutovers, employee transfers and production site integrations remain on track.

At the time of the transaction, we provided synergy and financial guidance for 2022 and this remains unchanged. We continue to expect annual synergies of £500 million by 2022, with up to 25% reinvested back into the business to drive growth.

We have also delivered on our divestment commitment, with transactions meeting our target of £1 billion in proceeds already signed. Through this process, we have divested more than 50 growth-dilutive brands, strengthening our existing portfolio.

Our separation programme is also on track, with work around the future organisational structure and systems separation well underway.

It is important to remember that the end goal of all this integration work is to bring together the fantastic portfolio of category-leading brands with a strong geographic footprint, positioned in a sector which is now more relevant than ever. I continue to be excited about the potential of what we have created, a 100%-focused global leader in Consumer Healthcare, addressing consumer needs and driving better everyday health.

I look forward to sharing more with you on this great business over the coming years and in the run-up to separation.

# **Consumer Healthcare Ytd Performance**

Coming back to performance, I would like to share some detail on the growth drivers behind today's results.

I will focus on year-to-date results to take out the volatility behind the pantry loading and the systems' cutover.

Pro forma revenue excluding brands divested and under review grew 6% year-todate, supported by healthy brand growth and overall share growth.

Vitamins, minerals and supplements continued to benefit from increased consumer focus on health and wellness, and as a result, we saw strong performance by *Centrum, Emergen-C* and *Caltrate.* 

On a pro forma basis, category sales grew in the high teens across all three quarters this year, and with growth at one-and-a-half times the market.

E-commerce was strong across all categories, growing at about 80% year-to-date, and now representing about 6% of sales, up a few percentage points over last year.

Key markets such as US, China, UK and Germany are ahead of this level. Importantly, we grew significantly ahead of the market and are gaining share.

Turning to our priority brands, across our nine power brands we saw five of them deliver high single-digit or double-digit sales growth, with eight of the nine gaining or holding share.

On Innovation we have had a number of exciting launches so far this year. Let me share some details on just a couple to give you some colour on what we are doing.

We launched the *Voltaren* Rx-to-OTC switch in May, our fourth Rx-to-OTC switch over the last six years, and the first in the pain category in the US in over 20 years.

*Voltaren* is the number one topical pain reliever globally, despite having not been in the US, the largest pain market in the world. The brand is off to a great start, growing the overall US topical category, delivering 100% of category growth, and since launch is the number one HCP recommended topical pain brand.

In the quarter we also launched *Advil Dual Action*, which is the first ever combination of ibuprofen and acetaminophen and early results are encouraging.

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

#### Maintaining momentum; delivering long-term priorities

**Emma Walmsley:** In summary, we have delivered a resilient performance this quarter, with strong commercial execution of our growth drivers underpinned by disciplined control of costs.

This, together with an improvement in vaccine immunisation rates mean that we remain on track to deliver adjusted EPS for the year within our guided range.

We are also pleased to have maintained progress in delivery against our long-term priorities of Innovation, Performance and Trust.

In R&D we have had four new approvals in the quarter and generated data to support development of major pipeline assets, including our portfolio of RSV vaccines, and, very importantly, we have also been able to advance five possible COVID-19 solutions into clinical development - two very promising antibody therapies and three collaborations for adjuvanted vaccines.

Beyond R&D, integration in Consumer Health continues at pace and we have achieved some important milestones in our programme to prepare the group for separation into two new companies: a Biopharma company focused on the science of the immune system and genetics; and a new world-leading Consumer Health company dedicated to everyday health.

We believe the creation of these two new companies will deliver significant new options for sustainable growth and returns to shareholders.

We are now joined for Q&A by Hal and Roger with the rest of the team, so with that, operator, we are ready to take your questions.

# **Question and Answer Session**

**Keyur Parekh:** Thank you for taking my questions. Dame Emma, first of all, congratulations on your recognition of your achievements, so congratulations very much on that. Just linked with that, who amongst your Senior Management Team has the best curtsey technique so far?

**Emma Walmsley:** A lot of hands going up on that! It is a recognition for the company, I can assure you, Keyur. Nobody in my house picks their towels up off the floor anymore, but, anyway, going to your technical question?

**Keyur Parekh:** You haven't answered the question, but the two questions are: one, Hal, there is some amount of confusion on the update that your partners and Merck and you put out about bintrafusp, so I am just wondering if you could share your perspectives on what you made of the update? Clearly, the drive continues, but the proposed expansion of the enrolment isn't happening, so I was wondering if you could share some perspectives on that?

Then, secondly, as it relates to the reiteration of the guidance for the full year, how much of that relies on *Shingrix* coming back into the fourth quester, and what level of *Shingrix* revenues might be required to get there, or do you feel comfortable enough to get to the bottom end of the range, irrespective of what *Shingrix* does during the fourth quarter? Thank you.

**Emma Walmsley:** Thanks, Keyur, so let's come to Hal first and then over to lain for a bit more specifics on the guidance and *Shingrix* contributions.

Hal Barron: Okay, thank you very much for the question, Keyur. Maybe backing up I think it is important to note that when we initiated the collaboration with Merck KGaA we did it on a very large and robust Phase 1 dataset of over 400 patients really demonstrating activity and a very well-tolerated safety profile, and some encouraging response data. As we've said many times, we think it's important to do randomised control trials to see whether these observed effects are real when compared to the appropriate controls, and that is really what initiated the so-called 037 studies, to obtain this randomised data.

As you say, we updated you last week about the study not expanding and we'll be continuing with 300 patients at the sites. I can't really answer any of your questions more

specifically. I will say that we need to await the final data to ensure the integrity of the trial, and it's important to wait to discuss any results of the study until we have a full dataset, including data on PFS and OS. I realise this will leave you with some questions, but that's really the extent to which I can comment at this point.

**Iain Mackay:** Just to be absolutely clear, it's my opinion that I do the best curtsey by a long, long way in this group, being the only guy that wears a skirt in this place anyway!

Moving on from that to the more important point, on *Shingrix*: really encouraged by the progress that we've seen through September, and happily that has continued into October. That recovery in older adults immunisation rates has been extremely important in terms of how we've formed the guidance for the full year, and we don't necessarily need to grow immensely beyond where we are, but we do need to sustain the recovery that we've seen.

Now, September was a great month, I think it was probably the best single month that we'd had in *Shingrix*, overall growth year-to-date 6%, obviously below the number that we had guided to for *Shingrix*, but provided that we can sustain the recovery that we've seen through September - we're also very encouraged by the weekly prescription data and immunisation data that we see so far through the month of October - then that certainly should take us to the lower end of our guidance range.

**Emma Walmsley:** Just to complement that, I think fundamentally we are absolutely convinced that *Shingrix* will be a great growth driver for the company for years to come, and if ever we wanted to be reminded of the opportunities and growth prospects in the vaccines segment, this is definitely the year to reinforce that.

**Graham Parry (Bank of America):** Firstly, would it be possible to quantify the *Blenrep* inventory and pension restructuring benefits on adjusted operating income and margins in the quarter, so would you still have been coming in around the sort of consensus level without those in there?

Secondly, your guide now assumes that R&D mid to high single digit increase. I think at the start of the year you were flagging similar growth to 2019 for both 2020 and 2021, that would have been about a 13% increase in R&D, and it's obviously benefited from some of this *Blenrep* inventory write-back. Could you just help us understand, should we be expecting a sharp upward inflection in R&D in 2021, as the one-off benefits go away and you continue to invest in the pipeline? Thank you.

**Emma Walmsley:** I think both of those to lain, but just to reiterate, our number one priority is still to keep strengthening the pipeline, so we do expect to see a strong increase next year, but perhaps lain you could put some data around that?

**Iain Mackay:** Absolutely. Graham, thanks for your question. *Blenrep*, the capitalisation of a pre-approval inventory was just north of £50m, in that factor. When you turn more broadly to R&D expense, the main point to reiterate in here - and Hal can go into more detail - is that we've kept all our programmes very much on track, to the extent that we'd experienced any slight delays earlier in the year, on the back of the pandemic, those have been largely recovered, we still have a little bit to do on gepotidacin but those are very much back on track again. What Hal and the team have continued to do is realise fully the efficiencies and synergies we expected from the Tesaro acquisition, and continue to deliver benefits and savings through R&D, just in terms of how we prioritise and manage spend within that.

Reflecting on next year, our guidance would remain absolutely consistent. We would expect to see double-digit growth in R&D expenditure next year, as we continue to invest in those priority programmes across the R&D pipeline and make progress in that regard.

**Emma Walmsley:** Hal, I wonder whether you would like to add anything in terms of the overall governance and progress of the pipeline, because the other thing to note, Graham, would be that, you'll have seen, we're slightly down in both Vaccines and Consumer Healthcare R&D through integration and cost control. But Hal, perhaps you could add some more colour around the governance aspects of spend.

**Hal Barron:** Yes. Thanks, Graham. We're making a lot of good progress, as Emma highlighted in her last comment from the last slide, and in particular highlighting that *Blenrep* started three pivotal studies, making very nice progress on ICOS, starting a second Phase 2 head and neck study. The two COVID trials that we are doing in the Pharma side have been highlighted and they are going well, three vaccine trials, including moving the RSV to Phase 3.

We've added 10 new molecules of vaccines or Pharma assets into the pipeline but, importantly, we are also using a very high bar to advance things. We are using a high bar for interpreting data and based on that, we removed eight assets as well, we are tightening up our focus on research in areas that we think are most promising, making a lot of great progress on the human genetics/functional genomics side of research, but we have reduced a little bit of spend in the research area. However, overall, I am very encouraged by the progress we are making on the pipeline and we shall continue to move aggressively to strengthen it even further.

#### Emma Walmsley: Thanks, Hal. Next question please?

**Tim Anderson (Wolfe Research):** I want to go back to bintrafusp if I can for Hal. Would you agree that there are two very different but equal interpretations to the recent update? One is that you saw enough of a signal in the interim that you didn't feel the need to upsize the trial to hit survival? The other would be the opposite, that it is not worth upsizing the trial because the interim only showed a weak signal? Just to clarify, will there be a milestone pay to your partner?

Secondly, I have another pipeline question which is on the ICOS agonist data coming up in the first half of 2021. You have a second line lung trial randomised ICOS versus docetaxel, versus docetaxel alone. Can you give us your updated thinking on the odds of success of that trial?

**Emma Walmsley:** Just to confirm that there has been no milestone paid to date on the basis of the data to date, which doesn't mean that there couldn't be one in the future. Hal, do you want to make any further comments on bintrafusp and on ICOS?

**Dr Hal Barron:** Tim, thanks for your question. Our goal is to be the partner of choice and to be an outstanding partner when we work with another company. We have committed to Merck KGaA to have them be the lead on discussing how to interpret all of this. I sense the frustration and I would typically comment more, to be honest with you, but I believe it is best that we await the data from the trial before making any comments, so I am sorry for not being more transparent about that.

As far as your question about the ICOS lung study, from memory that is about a 105 patient study with the design as you described, and it is a Phase 2 where we shall be looking at all the classic sort of endpoints you might expect. It will be important because these will be the first randomised data that really give us a sense of the incremental activity that ICOS can engender there. I am cautiously optimistic that might show activity and it would certainly be a huge boost to the programme that drives subsequent study designs and probably in thinking about where the molecule fits into the medicine.

James Gordon (JP Morgan): I have two questions please. Coming back to the same point, one more on TGF-beta. I noted the comment about not giving specifics on what you saw at the interim and that there hasn't been a milestone paid, but can you say more generally about how is GSK thinking about investing in this mechanism in other frontline cancer trials? Could this be an area where we shall see much more investment

over the next few years and you are going broader? Or do you still see this as just as much as a bet when you first entered into this partnership? Any increased confidence to go broader would be the first question?

Secondly, specifically dostarlimab, the bit on the slide there dostarlimab, the non-COVID-19 NCEs we have Phase 3 data in 2021. I know you recently renegotiated the deal on dostarlimab so that it allows you to partner *Zejula* with other PDX agents, other than dosta. How much potential does dosta have: is this something that is a big focus, should we think of this as one of the key readouts for 2021, or are there other assets you are much more excited about than dosta now?

Hal Barron: We are excited about having dostarlimab, it is part of the PD1 class, which has transformed oncology and probably as a class will be the biggest medicine perhaps ever, so we are excited to have one. We believe that it is two-week dosing, it is dosed at a higher level than other PD1s which could be an attractive attribute. The greatest opportunity for us with dostarlimab is to be able to combine it particularly with our pipeline assets. We have the DREAMM 4 study with belantamab with a PD1 inhibitor and we have the opportunity to combine PD1 inhibition with niraparib, whether that be in lung or in ovarian with first trial. We certainly have opportunities to combine dostarlimab with other pipeline agents earlier on like CD96 and STING and ICOS and other agents, so it is a nice complement to our pipeline and we are very excited about its activity. Of course, it is also active in endometrial cancer, both in second line and we have a front-line study going.

We are hoping that we can have the tumour diagnostic approval at some point with the data beyond endometrial, with colon, etc., so we think it has a lot of potential and that's in part why we are renegotiating, as you described, to give us a lot of flexibility in niraparib as well.

I am sorry the other questions was – I didn't write it down.

Emma Walmsley: Bintrafusp in broader studies.

**Hal Barron:** Yes, so for bintrafusp we were very excited about the preclinical rationale for inhibiting TGF-beta, the bifunctional nature of the protein to hit PD-L1 and target the protein to the tumour is attractive. The Phase 1 data, as I commented on, was very large and robust and seemed to have signals of activity and a well-tolerated profile.

As we get more data we will make data-driven decisions about where to invest. I can't really say more than that, but as soon as we get the incremental data we will be sharing that and sharing where that leads us to invest in subsequently.

**Steve Scala (Cowen):** Thank you. First, do you think the inflection in the two-drug regimens that you speak to is already reflected in *Dovato* numbers or is that yet to come? That is the first question.

The second question is: I would like to ask about the recent thinking on the dividend. I know it is a Board decision, but 25% of the Board is on this call and another 25% are former CFOs of drug companies, so I would think that half the Board can't find appealing paying out the majority of free cash flow to cover the dividend. Emma, would you disagree that a good portion of the Board likely thinks that a change in dividend policy would be in the best interests of building the company, thank you?

**Emma Walmsley:** Thank you. We will come to David in a moment on 2DRs and the growth prospects for our HIV business, also including their upcoming pipeline.

On the dividends, Steve, I am afraid I am going to reconfirm there is absolutely no change to the Board's position on capital allocation or our dividends policy.

Obviously, we are working towards separation of the group. We have been clear on what the dividend is going to be for the Consumer Healthcare business in contract with Pfizer and as we get closer to the separation and the confirming on that we will update with the full Board's views in terms of distribution for that, but no comment on that at this stage.

David, over to you for HIV.

**David Redfern:** Yes, thanks, Steve. It is true, we are pleased with the performance of two-drug regimens across the world and particularly *Dovato*. It is very strong in Europe where it is now rolled everywhere and we are seeing rapid pick up, and, as I said in my remarks, in the US we have seen a very clear inflection in the NBRx, and particularly in switch since we got the TANGO data included in the label in the summer, so 2DR NBRx is running at about just over 9%. TRx is running around 5%, so some of it is in the numbers, but I think still quite a lot more to come in the US, in particular, and, of course, there is always obviously a reasonable gap, time gap in NBRx coming through into the TRx, but the trends are there. I think it is just symptomatic of all the data, whether it is the clinical data, the real-world data, the experience that physicians now have, we are seeing very good momentum and I think that will come through more and more strongly in TRx and the numbers.

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

Andrew Baum (Citi): Thank you. I have only got one question but it is a slightly longer one. Emma, you just recently restated that building the pipeline for the Pharma business is your number one priority.

# Emma Walmsley: Yes.

Andrew Baum: GSK doesn't have the strongest balance sheet compared to its peers, and the dividend policy doesn't help, but you still have firepower to do meaningful bolt-on acquisitions for late stage assets. When I look at the last 18 months, Merck has taken out ArQule, and Abbvie signed with Genmab, Astra Daiichi, before that, Lilly, Loxo. I am surprised that we haven't seen any activity from GSK, particularly in haematology given the investment that you are making in the space and the obvious synergies that could be with the late-stage products within that area.

The question is what am I missing? There still are late-stage haematology assets for BV, some of which could be accretive immediately. Is this the valuation doesn't make sense for you? Is it you are looking for internal gating in order to determine the strategy? Is it concerns about the future of US reimbursements? What am I missing here?

**Emma Walmsley:** It is an important topic and I am not sure that you are missing anything because we are absolutely clear in recognising your observations that our number one priority continues to be strengthening the pipeline and it is our number one priority for capital allocation including business development. Whether it's for internal assets or external ones, as Hal has alluded to, we keep the bar high, we want to make sure they are in line and fueling the strategy that we've laid out for Biopharma, and have the right kind of discipline around returns, but we certainly see it as a priority and that's exactly why last quarter we set up a deal with Vir, which clearly we see as having significant potential as we have announced this year, but if it's successful with data later this year could be in market next year, for something with really significant sale and global demand; but we also continue to look at technology platforms, as evidenced by the deal we struck with CureVac around multiple options in terms of vaccines development.

So continue to watch this space, and we continue to be prioritising this as an area for team focus and energy.

I think we now have time to move to one last question.

**Kerry Holford (Berenberg):** Two questions, please: firstly, on the COVID antibody, Luke, you spoke about the potential for an extended half-life. I wonder if you can provide us with any more detail – are we talking weeks, months, do you think one shot could

cover a whole winter season, for example? I know we haven't clinical data, but any feeling around your comments would be helpful.

Then on *Zejula*, you talked about the progress being made in the first line ovarian market, but did that indication contribute much to sales in the quarter? It still feels relatively slow, and I guess, when do you think we should expect to see more sales to come round in that setting? Thank you.

**Emma Walmsley:** Thanks Kerry. We'll come to Luke on *Zejula*, but I'd like to come back to Hal please, to finish up with the comments on the prospects on and possibilities for the Vir antibody. Luke, first to you on *Zejula*.

**Luke Miels:** Sure, thanks Emma and thanks Kerry. One thing I'd put in context that's really interesting when you look at de-bulking surgery, in the US – it's not interesting, I think it's sad. They dropped by about 35% in April and May, and they've steadily recovered through June and July, but they are still around 10% below the levels of February, so that's obviously having an effect on patients' lives.

If we look – and it's really in the US, because when we look in the quarter we didn't have the label on first line in Europe - but if you look at our spread of patients in the US for *Zejula*, about a third of them are into first line now. Split between treatment and maintenance, about a third of patients on treatment and about two thirds on maintenance, but yes, around a third of sales are now coming from first line.

If you look at our share growth, your point is accurate, our growth has come from taking it away from olaparib, within the class. Hopefully as we now move through and start to at some point see some stabilisation in the COVID environment, we can begin to see the overall class grow in first line and the number of people on watch and wait will be reduced.

**Emma Walmsley:** And that 70% on watch and wait is really the opportunity here, as well as, we hope, in due course expanding *Zejula* beyond ovarian. Hal, back to the Vir antibody.

**Hal Barron:** Yes. The Vir antibody is actually very special, very unique, for a number of reasons. As Luke mentioned in the presentation, I think it's important to highlight that this was found through exploration of antibodies from patients with SARS-CoV-1, and that the argument and the rationale for choosing such an approach was that if over this period of time the SARS virus that resulted in COVID-19 has a neutralising antibody to both, that the epitope the antibody is binding to was likely very important for its infectivity, and therefore significantly reduced chances of mutating around that.

The CDR readings we think are incredibly important and why we think there's going to be limited resistance to a single monoclonal. That's particularly important given some of our validity data where I think it was somewhere between six and eight per cent of the patients have resistant clones, and the many, many clones that are emerging through the genetic drift, and even the D614G mutation that's becoming more prevalent, probably due to a fitness advantage.

In addition to that, it being highly neutralising, it actually has a modified FC receptor that not only gives it an extended half-life – to your point – which we think, we're not exactly sure how long that will be, but it will be most likely potentially longer, somewhere probably between two, three, maybe even four months of duration, considerably more than what you would expect from a typical antibody because of this modification, which has been done on other antibodies that have been into clinic, so we are reasonably confident it will extend half-life.

In addition, there is modification of the effector function, so that in addition to being neutralising, the antibody, through this increased effector function, should be able to bind and destroy cells that are infected with the virus, and that's very unique, that's not something you would see with the other antibodies, we don't think, so this could give us greater efficacy, maybe allowing us to use lower doses, etc. We think the FC modification only extends half-life but the effective function may be very important. Combined with that, the lower dose is being explored compared to other monoclonal antibodies – the single monoclonal nature and the ability, most likely, to effectively neutralise the resistant strains, is unique.

Lastly, I would just mention that we see lung accumulation of the antibody and whether that is due to some of these modifications in the FC or other attributes is not clear, but the antibody also seems preferentially to go, bio-distribution-wise, into the lung, which we think will give it yet another advantage. We are very excited about this programme and think it could really offer a significant solution, and hopefully we will have the data soon to support that.

**Emma Walmsley:** So, a concluding reason for optimism, to which I would add that there is a resilient performance that we have delivered, and the fact that we are on track to be within our guidance range in particularly challenging circumstances. We are encouraged by the commercial execution across multiple growth drivers and optimistic for both the near-term recovery and long-term prospects for Vaccines. We are seeing strong progress on our strategic imperatives, whether that be in pipelines particularly including

COVID solutions, or indeed in some of the separation preparation which is very much firmly on track, and we think gives exciting options for returns to shareholders in the coming years.

With that, thank you all very much for joining us. We look forward to speaking and seeing you soon.

- Conference call concluded -