

**GLAXOSMITHKLINE  
FULL YEAR 2019 RESULTS  
PRESENTATION TO ANALYSTS  
Wednesday, 5 February 2020**

**Sarah Elton-Farr (Head of Investor Relations):** Good morning and good afternoon. Thank you for joining us for our full year 2019 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 not able to view the webcast, slides that accompany today's call are located on the Investor section of the GSK website.

**Cautionary statement regarding forward-looking statement**

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

Our speakers today are Chief Executive Officer, Emma Walmsley; Iain Mackay, Chief Financial Officer and Dr Hal Barron, Chief Scientific Officer and President of R&D. We have a broader team for Q&A. We request that you ask only a maximum of two questions so that everyone has a chance to participate. Our presentation will last for approximately 45 minutes, slightly long than usual, to give Hal time to update you on our R&D progress. With that, I shall hand the call over to Emma.

**Emma Walmsley (CEO):** Thank you, SEF. When I became CEO of GSK in 2017, I laid out my three long-term priorities for the company: Innovation, Performance and Trust, all to be powered by a necessary change in culture.

**Significant progress on our long-term priorities in 2019**

In 2019 we made significant progress across all three of these priorities as we begin to work towards setting ourselves up as two new companies, and I shall talk more about that in a moment.

Our strategy is continuing to deliver results. You will hear from Hal on Innovation and, under his leadership, we have strengthened our pipeline, focusing on increasing our investment in R&D with exciting new developments in Oncology and a significant number of positive results across the portfolio. We have also strengthened commercial and supply chain delivery, and we are showing progress in launch execution in Pharma and Vaccines.

In Performance, we have delivered growth across the company, with improvements in operational execution as we reshape the Group portfolio. In Pharma, we continue to invest in our Specialty capabilities with talented leaders ready to support the launches we

anticipate this year. In Consumer Healthcare, we completed the transaction we announced at the end of 2018, our joint venture with Pfizer to create a new leading Consumer Healthcare company.

On Trust, we are also making good progress. We have continued to pioneer innovations in Global Health, in TB, malaria and HIV, and we were delighted to see our performance on our Trust commitments reflected in the Dow Jones Sustainability Index where GSK was listed for the first time as a top ranked company in the sector.

I said that cultural change in GSK is very important. We are also making good progress on this to develop a more performance-focused culture with a strong emphasis on ethics and values, and we are seeing this reflected in 2019 achievements and our latest employee engagement surveys.

### **Group sales and earnings growth in year of progress**

In terms of financial results, I am happy that in the year of generic *Advair*, we saw Group sales growth of 8% in CER terms, or 4% on a pro forma basis, and we have delivered an adjusted earnings growth of 1%.

Sales benefited from a particularly strong performance in Vaccines. Our new products in Pharma continue to do well and pro forma Consumer sales were driven by a strong performance in Oral Health. Group operating margins decreased 2.1% on a CER basis to 26.6% as we invested behind our priority pipeline programmes with Pharma R&D spend up 16%. The Pharma margin also reflects both investing in new products and launch preparation, and absorbing the price impact of generic competition in the ICS/LABA class. We were pleased to see margin improvements in both Vaccines and Consumer.

On a total basis, earnings per share were up 23% to 93.9 pence and adjusted earnings per share were up 1%. Free cashflow for the year was strong at £5.1 billion, although down versus last year as anticipated. Today, we declared a dividend for the fourth quarter of 23 pence, resulting in a total dividend for 2019 of 80 pence and we expect to pay 80 pence in 2020.

### **New product momentum continues to build**

Turning to our new launches, I am pleased to see that sales have been driven by new data, further approvals and our improving commercial capabilities under new leadership.

In Respiratory, *Trelegy* continues to do well, driven primarily by an increase in US market share. Globally, launches are also doing well and we now have the only once-daily

triple therapy for COPD in 44 countries. We met the primary endpoint of the CAPTAIN study in asthma patients, and anticipate US approval in the second half of the year.

### **New product momentum continues to build**

In asthma/biologics, *Nucala* remains the market leader in total sales and continues to grow well, up 33%, benefitting from the introduction of self-administration. The opportunity in this market remains significant.

In Oncology, we were delighted to see positive data on all 3 of our pivotal readouts: *Zejula* in first line maintenance therapy of ovarian cancer, belantamab mafodotin in the fourth line treatment of multiple myeloma, and dostarlimab in the second line treatment of recurrent endometrial cancer.

Hal is going to take you through much more of the detail in a moment, and I am pleased that we have submitted these data to regulators and we look forward to potential approvals later this year.

2019 was also an important year for HIV with a strong flow of positive data that further supports the transition we're leading to two-drug regimens.

Our new regimens are now growing at a rate that is offsetting the decline in our three-drug regimens, and we were pleased to see *Dovato* included in both US and European Treatment Guidelines at the end of last year.

We continue to lead in HIV innovation, and are working to bring new therapies to market. Following the Complete Response Letter related to CMC matters for our long-acting two-drug regimen, cabotegravir plus rilpivirine, we are working with the FDA to determine next steps and bring this important treatment option to patients.

Later this year, we also anticipate US approval for fostemsavir, our first in class attachment inhibitor for heavily treatment-experienced patients.

Finally in Vaccines, *Shingrix* continues to be a major driver of our growth. We estimate that 14 million patients now have been vaccinated in the US with at least one dose since launch, and plenty of opportunity remains. Our capacity expansion plans for this transformative product in our portfolio are making good progress.

We continue to see high levels of demand in the US, and we were pleased to receive approval in China where we are planning a phased introduction later this year.

### **Driving our growth outlook to 2022 and beyond**

We are very focused on building the pipeline for our next wave of growth and have made significant progress.

We have reported positive data on a number of our programmes and this year we have the potential for at least six new approvals, including in Oncology, HIV and Respiratory.

Last year we closed transactions with Tesaro and with Merck KGaA, strengthening our position in Oncology further. To help improve our R&D productivity over the longer term, we also initiated alliances to build out our platform technologies, in genomics with the University of California and in cell therapy with Lyell.

The overall shape of our pipeline is changing and Hal will talk more to this, but given the positive data we are generating, we are confident in investing behind the opportunities we see to support longer term growth.

### **Integration progressing rapidly**

Also key to the reshaping of the Group is the delivery of a successful integration of the Pfizer Consumer Healthcare business, delivery of synergies from the joint venture, and investing in its future growth

We have a major opportunity to create a new leader in Consumer Health, and to deliver material value to consumers and shareholders. Since closing the JV at the end of July, we have made rapid initial progress, announcing 500 critical leadership roles, completing closes in all major markets and co-locating employees in 31 locations globally so far. Over the next two years the integration will continue at speed, with the majority of systems and process alignment work to be completed over the next 12-18 months.

We are building best in class capabilities – in innovation, digital and retail – benefitting from the complementary strengths of the businesses, and we are building an efficient and effective model to deliver synergy targets and operating margin improvement. We have a particular focus on overlapping commercial infrastructure and also on streamlining the supply chain. In addition, we see considerable opportunity in procurement, logistics, media spend and marketing costs.

Of the £500 million synergies we are targeting, we will reinvest up to 25% in our capabilities and portfolio, behind the brands and markets with the most promise, to generate long term sustainable top line growth.

### **Preparing for 2 new companies**

So, our first priority remains, as I have said many times, to invest in R&D and future growth drivers.

Today, we are also announcing the start of a new two-year programme, to prepare GSK for separation into two new leading companies: one in Biopharma, and one in Consumer Healthcare.

Our intention remains to separate the company in around three years from close of the transaction. This programme will use this unique catalyst to reset the capabilities and cost base for both companies, and help support delivery of the significant value creation opportunities we see in both New GSK and New Consumer Healthcare. Internally, we are calling the programme “Future Ready”.

For New GSK the programme will set up a leading biopharma company with an R&D approach focused on science relating to the immune system, use of genetics and new technologies by driving a common approach to R&D, which will help us be more effective in how we allocate our budget and share technical and scientific expertise, and deliver the pipeline, regardless of modality.

We will also improve our capabilities and efficiencies in global support functions, continuing to simplify processes and systems, and considering where our teams are based to deliver a cost base comparing favourably with industry benchmarks.

We will continue to simplify and refocus our manufacturing network, ensuring our supply chain is specialty ready, and continue to improve working capital management, productivity and procurement with a relentless focus on quality, safety and service.

We will further rationalise our portfolio through divestments, to align with our strategic priorities. A number of assets are under review, including our Prescription Derms business.

For the new Consumer Healthcare company, this programme will support the build of the key technology infrastructure, and, of course, in due course, the corporate functions necessary to operate as a standalone company, while simultaneously we will continue our work to fully integrate the Pfizer brand and business, deliver our planned synergies, and invest in driving future growth.

Using the catalyst of separation, we believe that our investment priorities, together with our new two-year programme will set each new company up with strong foundations for future performance.

Iain is now going to take you through some of the financial details behind this. Iain –

## **2019 results and 2020 guidance**

**Iain Mackay (Chief Finance Officer):** Thanks, Emma.

All the comments I make today will be on a constant currency basis, except for where I specify otherwise, and I will cover both Total and Adjusted results.

### **Headline results**

On slide 12 is a summary of the group's results for 2019, which overall were at the upper end of our guidance, and demonstrated continued execution on our strategic objectives.

Reported turnover growth was 8%, reflecting the closure of the Consumer joint venture with Pfizer, with group revenue growth of 4% on a pro-forma basis.

Total operating profit was up 23%, with total earnings per share up 23% also, primarily reflecting reduced remeasurement charges on the contingent consideration liabilities and put options compared with the previous year.

On an adjusted basis operating profit was flat on a reported basis, and declined 3% pro forma, while adjusted earnings per share was up 1%. I will go through the drivers behind these in more detail in a moment.

We made good progress in the year with free cash flow, generating £5.1 billion, reflecting a number of factors, most importantly, improved working capital management.

On currency, a weaker sterling, particularly against the US dollar and Japanese yen resulted in a tailwind of 2% on sales and 3% to adjusted earnings per share.

### **Results reconciliation**

#### **2019**

Slide 13 summarises the reconciliation of our Total to Adjusted results. The main adjusting items in the year were: intangible amortisation, with higher charges as a result of the Tesaro acquisition; major restructuring focused on improving the efficiency of the supply chain, with also some initial charges for the integration of the Consumer JV with Pfizer. Within transaction related, the main contribution was the unwind of the fair value uplift on inventory taken on as part of the Consumer Healthcare JV, and finally, the Disposals column includes the proceeds from the divestment of the travel vaccines, as well as a gain from the revaluation of the embedded derivative in respect of GSK's exposure to movements in Hindustan Unilever's share price.

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

## Pharmaceuticals

### 2019

Slide 14 summarises the Pharmaceuticals business where revenues were flat in 2019.

Emma has taken you through the performance of some of our key products, so I will just point out a couple of important considerations.

Starting with Respiratory, sales were up 15%, with continue growth from *Trelegy* and *Nucala* across all regions.

This was partly offset by *Relvar/Breo*, which declined 13% globally, driven by 37% decline in the US, reflecting the impact of generic *Advair* on pricing in the ICS/LABA class.

We continue to have good growth expectations outside the US, where sales grew 12% in Europe and 19% in international.

In HIV revenues were up 1%, with the dolutegravir franchise up 2% globally. The dynamics in this market reflect the impact of competition, as well as the shift within our portfolio towards our two-drug regimens, with growth in *Juluca* and *Dovato* offsetting a decline in *Triumeq*. At a regional level, dolutegravir grew in international and was flat in the US and Europe.

We continue to build momentum with the two-drug regimens as access and physician acceptance increases. As the transition in our portfolio continues this year, we expect 2020 revenues for HIV to be broadly flat, excluding any material contribution from cabotegravir plus rilpivirine.

Our Established Pharmaceuticals portfolio declined 8% overall, driven by US *Advair* sales, which were down 56%, as expected given generic competition. We expect pricing pressure in the ICS LABA class to continue. This was offset by continued upside in *Ventolin* from the Authorised Generic launch in the US early in the year, which you will remember is an in-year benefit ahead of the introduction of substitutable generics expected in 2020. We also saw favourable RAR true-ups in the US, primarily on *Flovent*.

Outside Respiratory, the remainder of the Established Pharma portfolio declined by 6% in 2019, in line with our expectation of a mid-to-high single digit decline for the longer term for this part of our established products portfolio, excluding Respiratory.

Overall, we expect to see Pharma sales decline slightly in 2020 excluding divestments, as the growth of our new products is offset by a decline in Established Pharma.

Turning to the operating margin, we saw a decline in the year, informed by an anticipated unfavourable product mix, and price impacts, including, notably, the impact of generic Advair, as well as non-restructuring related manufacturing facility impairments and a number of legal settlements; and, importantly, by strategic choices we made to invest in R&D behind priority assets, promotional activity for new launches, as well as building specialty capability.

## **Vaccines**

Slide 15 gives you an overview of Vaccines performance, with sales up 19% driven mainly by *Shingrix*, but also by our meningitis vaccines. *Shingrix* continues to benefit from our actions to increase our supply capacity, with revenues in Q4 of £532 million driven by continued strong uptake in the US, as well as in Germany and Canada.

We have been successful in expanding our supply capacity in 2019. Annualising the Q4 performance with some slight improvements is, we believe, a reasonable run rate outlook for 2020. With supply capacity acceleration achieved in 2019, at this time we see limited opportunity for further growth beyond 2020 until we bring our new facility on line, which we don't expect before 2024.

In our Meningitis portfolio, which had revenues of over £1 billion in 2019, *Bexsero* continued to perform well, growing 16% with share gains in the US and strong demand across all regions. The operating margin of 41.4% in 2019 is higher than our medium term expectation due to enhanced operating leverage from *Shingrix*, positive inventory adjustments and higher royalties. In the longer term we continue to anticipate a margin in the mid-30s, as we increase investment in SG&A as we expand *Shingrix* geographically, and in R&D as we invest behind priority assets.

Note that we completed the divestment of travel vaccines *Rabipur* and *Encepur* in December, which will have a slight drag on sales growth this year.

## **Consumer**

Turning to slide 16, revenues of the new Consumer Healthcare JV were up 2% on a pro-forma basis, despite a drag of around 1% from the combined impact of divestments and the phasing out of low margin contract manufacturing.

We saw good performance from our Power Brands, particularly in the US and International, although we saw some adverse impact in International during Q4, due to the alignment of in-market inventory levels of some Pfizer brands.



In Oral Health, *Sensodyne* grew double digits, while in Wellness *Panadol* performed strongly and *Advil* saw continued recovery from historical supply issues. Respiratory overall had a weaker performance, reflecting a milder cold and flu season earlier in the year.

We expect the divestment of the Indian nutrition business to Hindustan Unilever to close around the end of Q1, subject to legal and regulatory approvals.

We are moving forward with other divestments which will continue through this year, and as previously announced we are expecting to generate net proceeds of £1 billion from these tail-brand disposals, which will fund integration and restructuring activities within Consumer Healthcare. These disposals, along with the Indian nutrition business, represented 2019 revenues of approximately £1 billion.

We expect to have a revised external category reporting structure in place from Q1 2020 to appropriately reflect the key drivers of the combined businesses, and we will provide you with details of this ahead of the Q1 results.

We are pleased with the progress of the integration, with further milestones to be achieved over the next 24 months, and we are very optimistic about the combination of these two portfolios.

The operating margin for the year was 20.8%, reflecting the strong ongoing focus on cost control, and benefits from restructuring in manufacturing, while we continue to increase investment in key brands.

### **Sales and operating margins**

On slide 17 we summarise sales and adjusted operating margins. Note that on royalties, these were higher in 2019 driven by *Gardasil*. We expect royalties for 2020 to be around £300 million due to reductions in some of the other royalty streams. I have already covered the drivers behind the other cost lines in some detail and, to be clear, we shall continue to prioritise investments in R&D to develop our pipeline, in customer-facing SG&A, building specialty teams and launching new products.

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

Moving to the bottom half of the P&L, I would highlight the following. In interest expense, we continue to see the benefit of our refinancing activities with interest of £810 million, which also included a fair value gain on interest rate swaps. We expect an interest expense of between £850-900 million for 2020.

The effective tax rate of 16%, which was slightly better than expected, reflects our ongoing progress in settling historic tax matters in key jurisdictions. We continue to expect

to see an average effective tax rate of 19% over the medium term, although this will be slightly lower in the near term with our expectation for 2020 at around 17%.

On non-controlling interests, Q4 saw the first full quarter of Pfizer share of profits of the new Consumer Healthcare JV, and this will continue through 2020.

### **2019 free cashflow of £5.1 billion**

On free cashflow, we remain focused on driving greater cash discipline across the Group and generated £5.1 billion of free cashflow in the year, reflecting good progress, although, as expected, it was a step down versus 2018 given the impact of *Advair* genericisation.

Key drivers of free cashflow were improved operating cashflow and working capital management, as well as the benefit from FX and proceeds from the sale of the travel vaccines, offset by the launch of generic *Advair* and related phasing of rebates, and the upfront payment of €300 million to Merck KGaA.

We expect a step-down in 2020 as we pay out higher distributions to non-controlling interests, as we see the continued flow-through of rebates relating to *Advair* and as a result of the separation preparation programme we have announced today.

However, we have made great progress on cashflow and working capital management in 2019 and our focus here will continue into 2020. As in 2019, we expect cashflows to be weighted to the second half of the year.

### **Preparing for 2 new companies**

As Emma outlined earlier, we are today announcing a programme over the next two years which will help deliver the value creation opportunities we see within both New GSK and New Consumer Healthcare.

As we look towards New GSK, we shall drive a common approach in Pharma and Vaccines R&D, further improve our capabilities and efficiencies in support functions and continue the simplification of our manufacturing network.

In R&D, our focus is more about building capabilities and a common approach, improving capital allocation across R&D and less about realising cost savings. In the support functions we will drive a leaner organisation, leveraging recent and ongoing technology investments to improve efficiency, deploy consistent operating models globally and pursue a location strategy to ensure functions are best placed to support our footprint. In these areas, we shall compare favourably with industry benchmarks.

In the Pharma supply chain, we have made significant progress to simplify our manufacturing network. We have reduced our manufacturing footprint by 25% over the last three years. Under this programme, we shall maintain momentum, continuing to review our network to ensure that it is competitive and adapted to our portfolio.

Taken together, these actions will deliver £800 million of annual savings through a new major restructuring programme, which has estimated total costs of £2.4 billion, comprising cash costs of £1.6 billion and non-cash costs of £800 million. This programme will be substantially complete by 2022. We shall continue to prioritise allocation of capital within the portfolio through the divestment of non-core assets, and a number of assets including our prescription Derms portfolio are under review. We expect the proceeds of divestments broadly to cover the cash costs of delivering New GSK. This is an important aspect of capital allocation discipline to fund future growth and profitability, with a clear alignment to our strategic priorities.

To set the New Consumer Healthcare company up for success, we need to build the key technology infrastructure and corporate functions necessary to operate as a standalone company. We expect to complete the majority of this work in the next two years and our initial estimate of the one-time costs to establish these capabilities is in the range of £600-700 million which will be incurred by the JV.

These will be included in our total results and there is no change to our adjusted operating margin outlook of mid to high 20s in 2022 for the Consumer business, as we have outlined previously.

Delivering this two-year programme will set solid foundations for the future competitive growth and operating performance of New GSK and New Consumer Healthcare.

## **2020 guidance and considerations for the next two years**

Moving to 2020 guidance.

On revenues, *Shingrix* will continue to be a growth driver with some slight improvements on the Q4 run rate being a reasonable guide for our full year 2020 expectation. Pharma is expected to decline slightly, driven by the Established Pharma portfolio, while our new products continue to make good progress. And in Consumer, the divestments we are targeting will be a drag to top line growth.

Our investment priorities remain clear. Given our positive data readouts, we expect to continue to grow R&D investment at a rate similar to that delivered in 2019, and we shall continue to invest in our new launches and building our specialty capability.

Taking these factors into account, we expect adjusted earnings per share in 2020 to be between -1% and -4% at CER compared to 2019, excluding the impact of any further material divestments.

Our guidance today excludes any potential impact of the Coronavirus which is yet to be seen.

### **2021 and 2022 considerations**

While we are not providing guidance on 2021 and 2022 at this stage, there are several points I would highlight as you think about the next few years.

For *Shingrix*, at this time we see limited opportunity for further growth in supply capacity until we bring our new facility on line, which we don't expect before 2024.

In Pharma, we do expect an increasing revenue contribution from our new launches. We will continue to grow our R&D investment in 2021 at a similar rate to that in 2019, and will also continue to invest behind our new launches.

Therefore, overall we would expect the slight incremental pressure on Group adjusted operating margins in 2020 to stabilise in 2021 as we begin to see benefits from the programme we have announced today.

From 2022 onwards we expect to see most of the savings from the programme flow through, offsetting the increased investment and leading to meaningfully improved operating performance.

Our intent to separate the company in around three years from close of the transaction remains unchanged, and, as I said, we will be pursuing divestments, which we will keep you informed on as we progress.

In summary, I am pleased with our performance in 2019, and we will be building on this progress over the next two years.

I am confident that we are taking the right steps to prepare for a successful separation, optimising our operating model to ensure we have the right capabilities and cost bases in place to support investment in future growth and value creation within both companies, and with that, I will hand over to Hal.

## R&D Update

**Dr Hal Barron (Chief Scientific Officer):** Thank you Iain. It has been approximately two years since I took over as head of R&D and I am very pleased with the progress we have made so far.

Today I will be focusing on progress we have made over the last 12 months and two key medicines that we feel have great potential to transform how we treat patients, *Zejula* for ovarian cancer and belantamab mafodotin for multiple myeloma.

In addition, I will briefly discuss other assets that have made important progress in our pipeline and share key milestones for the year ahead.

Before I get into my presentation, I want to take a moment to say that I am very excited about the R&D changes Emma mentioned earlier. I believe that taking a common approach to how we conduct R&D at GSK will help us be more effective in how we discover and develop transformational therapies for patients.

With that, let me begin my presentation.

### **Science, Technology, Culture**

I'd like to start with a brief reminder of our approach to R&D at GSK which is to leverage Science, Technology and Culture

Specifically, we are strengthening our R&D pipeline through a focus on the science related to the immune system, the use of human genetics, and advanced technologies, including functional genomics and machine learning, while creating a culture that fosters an innovative mindset.

### **Preparing for 2 new companies**

We made significant progress on this strategy in 2019 and substantially strengthened our pipeline. In the last 12 months we had three major approvals, made eight submissions, had six positive read-outs from pivotal studies and progressed four new assets in to pivotal studies.

Towards the end of my presentation I will share a brief update on our use of human genetics, functional genomics and machine learning to discover new targets.

I am also pleased with the progress we are making in transforming our culture in R&D, but I will not be focusing on that in today's presentation.

## **Our R&D pipeline of 39 medicines and 15 vaccines**

This slide shows the 39 medicines and 15 vaccines being developed. It has been a busy year with 20 assets progressing or being added, 14 terminations and three medicines being approved.

We have also strengthened our late stage pipeline with four new assets progressing in to pivotal studies, including: *Otilimab* for patients with rheumatoid arthritis, *Bintrafusp alfa* for patients with biliary tract cancer, *Gepotidacin* for patients with uncomplicated urinary tract infections and gonorrhoea, and our ICOS agonist for patients with head and neck squamous cell cancer.

Notably three of these four potential medicines are biologics.

## **In the last 12 months we have achieved 23 positive pipeline milestones**

I have previously said we intend to be transparent about the decisions we are taking related to the pipeline.

This slide shows our 2019 milestones, and as you can see it was a very successful year for R&D with 23 pipeline milestones having positive readouts, including all six pivotal studies.

I now want to talk to you about *Zejula* and belantamab mafodotin which both had positive pivotal data in 2019 and are expected to bring significant benefit to patients.

## **At Q2 2018 we said: Functional genomics combined with machine learning will be powerful**

In July 2018 I shared how powerful I thought the combination of functional genomics and machine learning could be for R&D, particularly in identifying gene-gene interactions and exploring the concept of synthetic lethality to discover novel targets and improve R&D productivity, including identifying which patients are likely to benefit from a given drug.

It was in part, based on data generated from this approach, that we predicted that PARP inhibitors should work in a much broader population of women with ovarian cancer than just those who have the BRCA mutation.

## **Zejula - PRIMA showed clinically significant benefit in all biomarker subgroups**

In July 2019 the results of the PRIMA study validated our thinking. While we were confident *Zejula* would benefit patients with a BRCA mutation, as you can see in the middle panel, *Zejula* also had a dramatic benefit in BRCA wild type patients whose tumour had evidence of a homologous recombination defect. In fact the benefit in progression free

survival was similar to that seen in patients with a BRCA mutation – 11.4 months in wild type patients versus 11.2 months in the patients with a BRCA mutation.

In addition, we observed a clinically meaningful and statistically significant benefit in the homologous recombination proficient, so-called HRp, patients who represent approximately 50% of the overall population.

As you can see from the *New England Journal* publication of the PAOLA-1 study data, this was not observed with olaparib where the hazard ratio for this population of patients was 1.0.

The PAOLA-1 study hypothesized that combining Avastin with olaparib would result in a synergistic effect, essentially converting HRp patients to HRd patients. Not only was that not the case, there was no incremental benefit of olaparib, when given with *Avastin* to HRp patients, so why is *Zejula* demonstrating this differentiated benefit in homologous recombination proficient patients?

### ***Zejula***

One possibility is *Zejula*'s unique PK profile, which is highlighted in this paper by Sun et al. The article compares the plasma PK and the tumour PK of both *Zejula* and olaparib in preclinical models. What they found was that at steady state there is a 3.3 times greater exposure of *Zejula* in the tumour xenograft to plasma, whereas with olaparib the tumour exposure is less than plasma.

Where might this manifest? If you look preclinically in the BRCA mutant TNBC model, which you see on the top left here, the two drugs look very similar in terms of their efficacy and both are profound.

When you look at the BRCA wild type ovarian model on the right, you can see that while *Zejula* has a statistically significant benefit in terms of tumour growth, this is not observed with olaparib, and that may be related to the concentration of drug in the tumour.

In addition, we had a poster at ESMO, which provided clinical confirmation that there was higher exposure to *Zejula* in tumour tissue versus plasma in patients with breast cancer. In fact, the data showed that the concentration of *Zejula* was around 36-fold greater in tumour tissue compared with plasma.

### ***Zejula***

#### **Developing the most compelling PARP inhibitor in ovarian cancer**

To summarise, the PRIMA data demonstrates the value of monotherapy of *Zejula* for all women with ovarian cancer when given the front-line setting as maintenance therapy.

We have submitted these data in the US, having been chosen to participate in the FDA's Real-Time Oncology Review pilot programme.

In 2019 we also received approval for *Zejula* as treatment in late stage ovarian cancer based on the QUADRA data, and enrolment started for the pivotal MOONSTONE study investigating *Zejula* plus dostarlimab for platinum resistant ovarian cancer patients, which will actually read out in 2021.

Together we believe these data will help establish *Zejula* as the most compelling PARP inhibitor for women with ovarian cancer.

In addition, given *Zejula's* unique PK profile, including its ability to penetrate the blood brain barrier, we plan to initiate one or two pivotal studies in patients with lung and/or breast cancer by year end.

### **belantamab mafodotin**

#### **DREMM-2 showed a clinically meaningful benefit with both doses**

Now moving onto belantamab mafodotin, another molecule with a successful 2019.

Belamaf was one of the first assets I highlighted to you back in July 2018. This is our BCMA immunoconjugate for patients with multiple myeloma.

Based on data from a relatively small number of patients we decided to aggressively accelerate development. Eighteen months later we have treated over 550 patients, and completed and submitted the pivotal study data in patients with relapsed, refractory multiple myeloma who have failed a proteasome inhibitor, an iMiD and a CD-38 antibody - a group of patients who have limited treatment options.

In this patient population, belamaf demonstrated a clinically meaningful overall response rate of 31% with the 2.5 mg/kg dose and 34% in 3.4 mg/kg dose.

As you can see, the median duration of response has not been reached in either arm at the time of the primary endpoint.

### **belantamab mafodotin**

#### **DREMM-9 initiated and DREMM-7 on trace to start 1H 2020**

DREMM-2 is the first of our pivotal studies for belamaf and demonstrates the benefit this treatment could bring to patients with multiple myeloma.

As I said, we have successfully filed these data in the US and Europe, and as with *Zejula*, we are participating in the FDA's Real-Time Oncology Review pilot programme, and anticipate approval in the first half of 2020.



As you can see in this slide, a robust development programme is in place for belamaf that will enable us to quickly move into earlier lines of treatment.

We have recently started our front-line pivotal study, DREAMM-9, in combination with *Velcade*, *Revlimid* and dexamethasone. This study has an initial safety assessment phase to determine the appropriate dose.

DREAMM-7 and DREAMM-8 are our second-line, pivotal, combination studies, which we expect to start this year based on data from the on-going DREAMM-6 study, and the investigator sponsored 418 study. We hope to share data from these two studies at medical meetings later this year.

We are also exploring novel combinations of belamaf, including with pembrolizumab in DREAMM-4, and with our ICOS agonist and gamma secretase inhibitor in DREAMM-5.

### **belantamab mafodotin**

#### **Lower dose provides similar efficacy with a better safety profile**

I want to spend a couple of minutes discussing the corneal events that we have seen in the belamaf programme, specifically in the DREAMM-2 study.

We take patient safety very seriously, and helping clinicians understand and manage this unique adverse event will be important.

Here are some facts:

- 71% of patients were diagnosed with keratopathy, that is a change in the corneal epithelium as seen on an eye exam, of whom about a quarter were asymptomatic.
- 27% of patients experienced a Grade 3 keratopathy, and no patients had Grade 4 or Grade 5 keratopathy.
- 22% of patients experienced blurred vision and 14% experienced dry eyes.
- Among the 95 treated patients, 42 – or 44% - had no eye symptoms, nor clinically significant worsening in their vision.
- 41 – or 43% – experienced significant worsening of their visual acuity at some point during the trial, but most of these patients either fully recovered or had meaningful improvement in their visual acuity during the study or during the follow-up period.
- Importantly, only 1% of patients in discussions with their doctor, decided to discontinue the treatment.

Thus, keratopathy, although occurring in a little over two-thirds of patients, was well managed by the DREAMM-2 investigators in collaboration with their ophtho colleagues.

We have developed educational materials and programmes to help ensure that, upon launch, patients treated with belamaf are managed optimally.

### **Progressing our innovative new medicines**

#### **Building momentum with impactful programmes across the portfolio**

While I have spent the majority of this call discussing *Zejula* and belamaf, we also continue to make good progress across our broad pipeline of innovative medicines.

In November we presented promising data from a Phase 2a study with our novel anti-sense oligonucleotide for patients with chronic hepatitis B, and we are on track to move this asset into Phase 2b before the end of the year.

In October we announced the start of our Phase 3 programme for gepotidacin, a potential first-in-class antibiotic for patients with gonorrhoea and uncomplicated urinary tract infections. We expect these Phase 3 data to read-out in 2021.

At ESMO in September we presented data from the INDUCE-1 study showing promising anti-tumour activity with GSK '609, an ICOS receptor agonist, in combination with pembrolizumab in head and neck squamous cell carcinoma. These data supported initiation of a Phase 2/3 trial – called INDUCE-3 – to investigate the potential survival benefit of GSK '609 with pembrolizumab in front-line recurrent/metastatic head and neck squamous cell carcinoma. INDUCE-3 is designed to have a registrational component should it pass the phase 2 interim gate.

And finally, towards the end of the year the Phase 3 ASCEND program, investigating daprodustat for patients with renal anaemia, was endorsed for continuation by an independent data monitoring committee, increasing our confidence in this programme. Daprodustat was filed with the Japanese FDA earlier in the year, and we feel increasingly confident about the science behind this potential new medicine and the very robust trials we have designed.

### **Accelerating our innovative vaccine candidates**

In addition to strengthening the Pharma pipeline we continue to make good progress in Vaccines and we anticipate key data this year for two vaccines candidates, one for RSV and one for COPD.

In children, respiratory syncytial virus (RSV) causes acute bronchiolitis, which can lead to respiratory distress and hospitalisation. In older adults the infection can cause pneumonia, which can also lead to hospitalisation.

We have three candidate RSV vaccines: a maternal vaccine which aims to achieve protection during the first six months of life, covering half of the burden of RSV; a paediatric vaccine that will expand that protection for up to two years; and lastly, a vaccine for older adults. All three RSV vaccines have fast track designation from the FDA, and we anticipate having key data in-house later this year.

In addition to RSV we are also progressing a therapeutic vaccine for patients with COPD. We know that two bacteria - *haemophilus influenzae* and *moraxella catarrhalis* – are associated with COPD exacerbation, so we extracted the functional antigens from these bacteria and combined them with our AS01 adjuvant, the same adjuvant used for *Shingrix*. Initial studies show that the vaccine is safe, highly immunogenic and induces very high functional antibodies against these bacteria. GSK is the only company moving ahead with a vaccine for COPD patients, and we should see proof of concept data by the end of this year.

### **Improving our lifecycle management**

Turning to our approved medicines, Luke Miels, Chris Corsico our Head of Development, and I are all working together to strengthen the collaboration between our Commercial and Development organisations, to make sure we are maximising the full potential of our medicines for patients.

*Benlysta* is a great example of this: in late December we announced headline data from a Phase 3 study in patients with lupus nephritis. Lupus nephritis is an inflammation of the kidneys that occurs in up to 60% of patients with systemic lupus erythematosus and can lead to end stage kidney disease. This pivotal study met its primary endpoint and all secondary endpoints. We expect to file these data in the first half of the year and *Benlysta* could be the first therapy for lupus nephritis to be approved in the US.

*Nucala* has a growing number of additional indications beyond severe eosinophilic asthma. We received approval for eosinophilic granulomatosis with polyangiitis at the end of 2017 and now also have positive data in patients with hyper eosinophilic syndrome, which we expect to file in the first half of this year. We are also expecting to report data from a pivotal study in patients with nasal polyps in the first half of 2020, which we hope will add a fourth indication to *Nucala*; and importantly, at the end of December we dosed the first patient in our pivotal COPD study.

Lastly, results from the Phase 3 CAPTAIN study supported the use of *Trelegy* for the 30% of patients with asthma who are on an ICS/LABA but continue to experience symptoms. These data were filed with the FDA in October and we anticipate a decision this year.

### **Embedding our approach of using human genetics, functional genomics and AI/machine learning**

As I mentioned at the start of my presentation, I want to spend a few minutes updating you on the progress of our efforts to use human genetics, functional genomics and machine learning to find novel and compelling drug targets.

We announced our collaboration with 23andMe in July 2018 and have now identified eight new targets including programmes in oncology, immunology, neurology and cardiovascular disease, and anticipate one of these projects will enter the clinic later this year.

We have also seen the benefit this collaboration can bring to clinical trials recruitment by successfully identifying and enrolling patients with primary biliary cholangitis and cholestatic pruritus for a Phase 2 study of our iBAT inhibitor, linerixibat.

The Laboratory for Genomics Research was announced in June with the University of California, and is led by the CRISPR pioneers Jennifer Doudna and Jonathan Weissman. We expect to have the first of our collaborative projects underway in the next few months.

In addition, we continue to attract extremely talented individuals to work in GSK R&D including Erik Ingelsson, previously Professor of Medicine and Genetics at Stanford, who recently joined us as our head of Human Genetics. We also now have 50 outstanding scientists across the globe in our AI/ML group and expect this number to grow to about 80 by year end.

### **Upcoming GSK R&D pipeline milestones**

I'd like to conclude my presentation with a summary of key upcoming pipeline milestones for 2020. We have a number of potential approvals this year including *Zejula* in front line ovarian cancer; belamaf in fourth line multiple myeloma; dostarlimab in second line endometrial cancer; fostemsavir for patients with HIV; *Trelegy* for patients with asthma; daprodustat for patients with anaemia from chronic kidney disease; and cabotegravir plus rilpivirine, our long acting treatment for patients with HIV

Pivotal data is anticipated for *Nucala* in patients with nasal polyps and from the BLISS-BELIEVE study investigating the combination of *Benlysta* with rituxan in SLE.

In 2020 we also expect a substantial amount of proof of concept data throughout the year, demonstrating the progress of our earlier stage pipeline, including data on combination

studies with various I-O agents. As I mentioned earlier, we are also looking forward to data on our potential RSV and COPD vaccines.

In summary, I am pleased with the progress we are making to prioritise and strengthen our pipeline, fuelled by the increased investment in R&D that Iain mentioned earlier. I look forward to sharing my next update on R&D with you in July. With that, I shall now hand it over to Emma.

**Emma Walmsley:** Thanks, Hal.

### **Significant progress on our long-term priorities in 2019**

To summarise, in 2019 we delivered a good performance with growth in sales and earnings and strong cash generation. We also made significant progress on all our IPT priorities, strengthening the pipeline, improving operational execution and reshaping the company.

### **Focus on execution as we prepare for the future**

In 2020, our first priority remains Innovation and to progress our pipeline and support our new product launches. Recent data readouts underpin our decision to further increase investment in R&D and our long-term growth drivers.

At the same time, we are again focused on operational performance and execution, including delivering a successful integration in Consumer Health and, as we have outlined today, with the unique catalyst of the separation, we are starting a new programme to prepare GSK to become two new companies.

In Trust, we shall continue to pursue actions to deliver the public commitments we have set out: these support our business and ESG performance and mean that GSK continues to provide a broader contribution to society, in addition, of course, to financial returns.

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

Finally, and most importantly, I want to say a big thank you to all our employees and those who have worked with us in 2019 for their enormous contribution. Without them, we would not succeed and we count on them now as we prepare GSK for this exciting future. With that, operator, this team is ready to take your questions.

## Question & Answer Session

**James Gordon (JP Morgan):** I have two questions please. The first one is about Consumer and the separation we have seen today, and my question is about the top line outlook. Pro forma there wasn't any Consumer top line growth this quarter and, more generally, the market for Consumer Health is meant to be something like 2-3% and the big players have underperformed that a bit. More generally in Consumer, there has been debate from some investors asking whether the Consumer companies need to sacrifice some of the increasingly high profitability they have been achieving to invest more to get faster growth. Is that a valid question for the Consumer Health business: is it possible to have high 20s margins and an exciting top line growth rate?

My second question is on SG&A booked for the Group. I know there have been various cost-saving initiatives and there is a plan to shift some of the SG&A to R&D but that SG&A was still up about 3% local currency and pro forma. Is there anything exceptional in Q4 or do we extrapolate that forward for the next few years, that you are not just in investment mode for R&D but that SG&A will grow quite a lot as well and that is why no operating margin expansion until 2022?

**Emma Walmsley:** Thanks, James, and I shall ask Iain in a moment to comment on SG&A - I think he covered a few of those points previously, particularly on our investments in the future growth drivers, but it is worth coming back on the details on non-customer-facing.

On Consumer, Brian is also on the call, so I shall ask him to comment on the outlook. Just to reiterate, as far as Q4 top line, there were a couple of points, one point from divestments and one point from alignment of stock levels across the Pfizer portfolio. Fundamentally, we are still very confident both on extracting the synergies and on the value that will be created by the combination of these two businesses and our investment in growth there. Brian, would you like to give a little more commentary on Consumer, and then we shall come back to Iain on SG&A.

**Brian McNamara (CEO, GSK Consumer):** Thanks, Emma. When you look at full year growth for the business, we grew 2% and we had a 1% drag from divestments and phasing out a low margin contract manufacturer, as we previously communicated. In Q4 we were flat and, as Emma said, we had a point of drag from that and some alignment of inventory levels.

If you look across the portfolio, we still grew healthily on our power brands: we have a very clear strategic resource allocation and saw mid-single digit growth, and double digit growth on brands like *Sensodyne* and *Panadol* and our gum health brand *Parodontax*.

The integration continues to go well, we are on track and we are confident in delivering those £500 million of synergies. If you remember when we communicated that, we said that we would invest back 25% of those synergies into innovation and growth.

As I look at the make-up of the business, I am still incredibly excited and optimistic about the combination of the two portfolios, our ability to grow ex-divestments, as Iain laid out, and when we look at the mid to high 20s margin commitment by 2022, given where we are on integration and our confidence in the synergies, I believe we can also deliver that.

**Iain Mackay:** James, thanks for your question. Let me give a view on both the fourth quarter as well as the full year in SG&A. In terms of the fourth quarter, it was very much a consistent story around investing in customer-facing activities where it is continuing to build out around specialty care capabilities, but also ensuring the right support behind new product launches and commercial activities. That was true across both Pharma and the Consumer Healthcare businesses in the fourth quarter. That is a consistent theme across the whole year.

If you look at SG&A for the whole year, that was also influenced by a number of legal settlements that we had, which was reflected, most importantly, in the third quarter. However, when you look at customer-facing versus non-customer-facing SG&A, both in the fourth quarter and across the year, we have kept non-customer-facing SG&A very flat over the course of the year in the quarter, and we have put our eggs behind making sure we have taken the right decisions and made the right investments around supporting new product launches and capability in the markets.

**Emma Walmsley:** Thanks, Iain. Now we can go to the next question, please.

**Matthew Weston (Credit Suisse):** Thank you very much. Two questions if I can, please?

For 2019 I think exactly 50% of Pharma business revenue is now established products. It declined 8%. Can you give us some indication of what we should expect going forward in 2020 in the mid-term for that large product segment?

Then, secondly, Hal, there has been a great deal of investor focus on bintrafusp alfa. I noticed that on Slide 47, your catalysts that will inform progress, there is no mention of

anything in 2021 in terms of read-out. There has been some suggestion of the trial being upsized in front-line lung versus Keytruda. Could you just let us know what could drive any decision to upsize the study, and whether it really is planned?

**Emma Walmsley:** Thanks, so we will come back to Hal on that in a second, and then just ask Iain to comment on established products, but just as a reminder, this is the business, or part of the business, when we are considering the divestments review and wanting to focus on our core priorities that will be impacted, and obviously we will update you on that as we go through its execution. Iain –

**Iain Mackay:** Yes, Matthew, you are absolutely right, in 2019 we saw about a 8% reduction in the established Pharma portfolio over the prior year, and going forward, we would expect a mid-to-high single-digit decline for that portfolio.

That, I think, is very consistent with how we have guided, and, in actual fact, how this portfolio has performed, and just as an *aide memoire*, we obviously moved *Advair/Seretide* into the established Pharma portfolio at the beginning of the year as genericisation, loss of exclusivity, took place, but, broadly speaking, mid-to-high single-digit decline in the established Pharma portfolio.

**Emma Walmsley:** Thank you. Hal, on bintrafusp, please.

**Hal Barron:** Thank you, Matthew, for the question. We are pleased with the on-going collaboration with our partners at Merck KGaA on the development of bintrafusp, and have been deferring to them on much of the disclosure timelines related to the programme.

That said, the study is on track for the estimated primary completion at the end of 2021. We will hopefully be able to have the data read out after that, but, remember, that's an event-driven trial, and there could be an interim analysis in 2020, which could lead to expansion of the study, depending on what is evaluated.

No interim data, as we have mentioned before, will be shared externally to protect the integrity of the study. The data will only be provided once the study is completed and the endpoints are analysed.

**Emma Walmsley:** Thanks, Hal. Next question, please.

**Andrew Baum (Citi):** Thank you, just one question. What's the appetite, financial capacity and bandwidth for further BD on the pipeline, given the existing upward pressure required for expansion of the existing programmes that Iain alluded to in his



presentation, continued growth at the same levels as last year, and I assume the same is true for 2021? Does that allow for additional pipeline products to come in, or is there still the capacity to do such?

**Emma Walmsley:** Thanks, Andrew. The answer on this is that there is absolutely no change to what we have said previously in terms of the prioritisation of our capital allocation. Our No. 1 priority is to continue to strengthen the pipeline, be that organically or inorganically.

Obviously, we are particularly pleased with the positive data that's read out more recently, and also pleased with the quality of the execution of the business development that we have done to date, so we will continue to keep an eye out for that with due alignment to the R&D strategy that Hal has laid out and, obviously, the discipline in terms of allocation of capital.

Next question, please.

**Mark Purcell (Morgan Stanley):** Thank you very much for taking my questions. I have two. Firstly, on *Zejula*, Hal, breast and lung cancer starting a new set of trials towards the end of the year.

Could I just ask – and we discussed PARP is potentially the new platinum in the summer after the first-half results - just why is it taking 18 months before you move into pivotals in these new indications, given the exciting data you have presented today? Is this a case of waiting for internal and additional competitive external data points, or is this a case of just managing the overall R&D spend?

Then, secondly, on the COPD vaccine, clearly, multi-blockbuster potential, but I am hoping could you provide us a little bit of an idea in terms of the risk/reward here? When we dig into this clearly 35/45% of patients are persistently colonised by *H. influenzae* and *moraxella catarrhalis*, but if you look at acute infective exacerbations, you see the involvement of these two bacteria at roundabout 15%, so clearly a very exciting programme, but given the acute exacerbations you don't see much in terms of the over-colonisation of these bacteria could help us understand what kind of signal we could see as we gauge the potentially enormous potential in the latter part of this decade.

**Emma Walmsley:** Thanks very much. I am going to ask Roger Connor to talk about the COPD vaccine, because I think he is on the line with us as well, but I'll ask Hal, though, first of all to comment on the PARP programme.

**Hal Barron:** Thanks for the question on the PARP, and we agree with you, it is a very exciting class and we think *Zejula* is very unique, both in its PK and its ability to cross the blood-brain barrier, and our decision with regard to which indications and the design of the trials was actually not driven really in any meaningful way by competitor data or budgetary constraints.

One of the interesting observations that came out of the PRIMA study, which we think we have an explanation for and I went over, is regarding the 50% of patients who had no evidence of a homologous recombination defect, the HRp patients who benefited substantially. Not only was there improvement of PFS, and it is very early days and limited data, but there appeared to be suggestions of maybe even potential survival advantage, in an early analysis. That led us to rethink exactly how to design the trials, which populations to pursue, whether it's treatment, whether it's maintenance, and what indications, leading us to conclude in lung and breast, but the populations within them and how to apply a diagnostic was something that we were taking time to digest after PRIMA.

Having said that, we also are trying to take advantage of the potential unique feature of *Zejula* to cross the blood-brain barrier, so designing trials that might enable us to confirm the pre-clinical data that suggest it does cross and is active and is important. We're excited about getting those programmes off the ground and being able to demonstrate significant benefit for those types of patient.

**Emma Walmsley:** Thanks, Hal. Roger, do you want to comment on the COPD vaccine?

**Roger Connor (President, Global Vaccines):** Certainly. Thanks very much for the question. I would just echo the excitement that we have around the development of the COPD vaccine that we have, we are the only company really working in this space.

A couple of things just in terms of illustrating the opportunity: first of all I'd say, third largest cause of mortality globally is in COPD, so we think the opportunity is definitely there. In the US alone we estimate there are around 16 million people suffering from COPD. Obviously in GSK in the development we in Vaccines are working very closely with our respiratory colleagues in Pharmaceuticals, because obviously the huge experience that we have as well there will be key.

The readout is the proof of concept, as you mentioned, it's going to be in the second half of this year. We're looking at a reduction in acute exacerbation linked to the bacterial types. I think in terms of what we expect from the data, we will have to see. What I would point out is that this vaccine does include the same adjuvant technology, our AS01 technology, that we have within *Shingrix* as well. We are expecting to see efficacy data

linked to that reduction in moderate to severe exacerbation and we are studying in a population of 40 to 80-year olds, so let's see, but we're excited about the opportunity.

**Emma Walmsley:** Thanks Roger. Next question, please.

**Graham Parry (Bank of America):** Thanks for taking my questions. First one is just to clarify the scale and quantity of divestments, so I think you said the amount of revenue that you envisage divesting would be a billion related to, say, *Horlicks* and other Consumer divestments, so can you just confirm that the Derms and other Pharma divestments would be needed in order to cover the £2 billion cash restructuring costs, and quantify what you expect lost revenues there to be, and perhaps any EPS dilution on top of your guidance in 2020 that you might envisage from that.

Secondly, when you talk about building R&D capabilities going forward, do you envisage that's more weighted towards technologies, or products, and how do you intend to fund those acquisitions if external M&A?

**Emma Walmsley:** Thanks Graham. I'm going to ask Iain to pick up first of all on the shape of the divestments, but just to be clear, the billion was referring to the Consumer part of it, in terms of net sales, including *Horlicks*, and remember we previously announced a programme of Consumer divestments, but I'll let Iain take up on that and then we'll come back to Hal on what we mean in terms of building the R&D capabilities through the new programme we've announced today.

**Iain Mackay:** Cheers Graham. Divestments - two buckets here, broadly speaking. As Emma described, we announced earlier, at the time that we announced the formation of the JV with Pfizer, that we would generate about a billion dollars of net proceeds from disposals of tail brands within the Consumer Healthcare company. We had obviously announced separately that we would dispose of our *Horlicks* and certain other brands to Hindustan Unilever, which, as I mentioned earlier, we expect to close sometime around the end of this quarter. Now, taking those Consumer deals together, in 2019 that generated about £1 billion worth of revenue for the top line of Consumer Healthcare, and from the tail brands, excluding Hindustan, we'd expect to generate about a billion in net proceeds.

That's bucket one. Bucket two is divestments or assets that are under review across the broader Pharma portfolio. We announced today the fact that the prescription Derms business is under consideration, that's a business the portion of which we're considering has revenues between £200 and £300 million, it's a good business, it's not a priority business for us, but we certainly believe it's a good prospect in terms of interest for other people.

In terms of the proceeds we would expect to generate from that portfolio reprioritisation, we'd expect to cover the cash costs of the restructuring programme, the readiness for separation, of £1.6 billion, so just for clarity on that, the programme that we talk about is total costs of £2.4 billion, £1.6 billion cash, £0.8 of impairments coming through that, and we would expect to generate proceeds that would cover that cash cost.

Now, within that, although we've mentioned Derms as one of the businesses, one of the areas we're looking at are also a number of equity holdings that we have, which clearly there aren't revenues or operating margins *per se* attached to, and that again represents an interesting opportunity for us to reprioritise capital allocation towards the growth drivers within the organisation. Hopefully that helps clarify what we're doing, and obviously, as we proceed with these divestments, we will get information to market about what we're doing and the impacts that has on the ongoing financials of the group.

**Emma Walmsley:** Thanks, Iain. Hal?

**Hal Barron:** Yes – thanks Graham. R&D capabilities – I think I would think about that in three different buckets. First, the one you mentioned, which is technologies such as AI, ML, functional genomics, human genetics and our cell therapy programmes. I think we've made terrific progress there and advancing further we will probably be focused on identifying new synthetic lethal combinations, and some new targets that are already emerging from some of the preliminary functional screens. That combined with, we've already had eight targets from 23andMe, we're just going to have a lot of stuff coming out of the technology that we need to execute on, so that would be the second bucket, executing on all the emerging data from the technologies.

Lastly, capabilities to actually build up the ability to get the trials done and filed – the pipeline's very robust now, a lot of successes, and we need the people and tools to actually turn all these medicines into approved drugs. Capabilities in all three of those is where we shall focus.

**Emmanuel Papadakis (Barclays Capital):** I have a couple on the Pharma side in terms of potential moving parts for 2020. Congratulations on the PRIMA real time oncology review. Could you share your thoughts on what that might potentially imply as far as commercial inflection in the second half of the year, indeed what is embedded in your current guidance for the Pharma business in 2020?

The second one is just on the cabotegravir CRL. CMC I don't believe typically implies huge delays historically but you have been rather elusive about clarifying when you

expect to refile and the potential ranges around that, so any guidance you can provide would be helpful? Thank you.

**Emma Walmsley:** Thank you very much, Emmanuel. We shall come to Luke first on the commercial outlook for *Zejula*, and then we shall come to David - although I am not sure we shall have a definitive answer for you - on the progress around the filing for the cab.

**Luke Miels (President, Global Pharmaceuticals):** Emmanuel, thanks for the question. As we have communicated in the past, PRIMA really is the critical readout in the near term for this product. We would expect it in the first half and then linked to that, we would expect some changes in the NCCN guidelines, which would then ideally place pressure on this persistent election by some physicians to watch and wait. We are well advanced and prepared for that. We reconfigured the salesforce in October. It had historically been footprinted based on Varubi, which is the product that Tesaro had for chemo-induced nausea and vomiting, so we took the decision to bite the bullet at that point and to re-frame the salesforce. That is important because around 50% of scrips come from Tier 3 physicians, it is quite dispersed for Oncology, but we would expect to see that flowing through in the second half of next year, once we get the label and the guidelines. Of course, if it comes sooner, we would then update you.

**David Redfern (Chairman, ViiV):** Thanks, Emmanuel. On cab, the CRL, as we said was entirely related to CMC, not to efficacy, safety or the clinical data. We believe that it is definitely resolvable, but I shall not commit right now on the timeframe. We need to meet with the FDA and there is a process for that called a Type 2 meeting, you have to apply and so forth, and that meeting is likely to happen very soon, certainly during Q1. When we have had that meeting, we shall be in a much better position to be clearer on the way forward.

**Geoffrey Porges (Leerink):** My first question is on *Shingrix*: could you talk a little more about the slight supply increase, particularly in the context of the two sequentially flat quarters? Could you also discuss what pricing trend you would expect over the next couple of years, given the fact that you are moving out of the US-concentrated portfolio into markets such as China? Thanks.

**Emma Walmsley:** I shall ask Luke to comment on the pricing dynamic, although we are thoughtful about that with any geographic expansion, not least because demand is not showing signs of slowing down. As far as capacity increases, I am not sure

that I would agree we have had two flat quarters on *Shingrix*. With the guidance we gave today, we expect a roll forward of Q4 with a potential slight improvement through 2020.

I am incredibly pleased with the progress that Roger's team has made in terms of capacity expansion, particularly in terms of bulk yield, and we are constantly seeing what further opportunities could be possible. However, we don't expect much further improvement beyond that until we get into the step change of a new site in 2024 but we shall keep you updated as the year progresses.

**Luke Miels:** We are very focused as far as next markets to introduce. You know we are in Canada and Germany where we have seen quite striking uptakes, which are limited by volume as in the US. Our approach globally will be to introduce this into the private market, at least for a considerable time, as we think there is significant opportunity there in the out-of-pocket segment. This is certainly consistent with what we have seen in Germany and China is the next one off the pack. What we are trying to do is to align the price in these new markets with the US price.

**Laura Sutcliffe (UBS):** First, on the prescription Dermatology business, you mentioned just now that it is a £200 to £300 million business in terms of sales. Could you tell us whether you are looking at that as one block as part of the review, or whether we might see products sold off piecemeal? Secondly, on 916, do you anticipate any patient monitoring requirements for the combination being studied in the DREAMM-9 trial?

**Emma Walmsley:** Thank you. David, do you have anything to add?

**David Redfern:** It is early in the review, Laura, so I am not going to get too much into it. Obviously, we shall do whatever we believe is in the best interests of the company and the shareholders as that review goes on, all options are on the table.

**Emma Walmsley:** Hal - 916?

**Dr Hal Barron:** Laura, thanks for the question. First, as I said in the presentation, we take patient safety very seriously and helping clinicians to understand and manage this unique adverse event will be important. We are not disclosing any discussions we are having with regulators, but we believe it will be important that the keratopathy, that we think was well managed by the DREAMM-2 investigators in collaboration with their ophtho colleagues, is replicated in the real world. We are developing educational materials and programmes to help ensure that happens upon launch so that these patients are treated optimally. As we get more clarity with the regulatory authorities, we can update you further.

**Naresh Chouhan (Intron Health):** I have a question on dividend cover. I remember a while ago you set some targets around dividend cover and with free cashflow falling in 2019 and expected to be lower again in 2020. Can you just give us an update on how you are thinking about those targets?

Then, on the Consumer Health margin targets, can you help us to understand whether or not you need to have those divestments of potentially or likely lower margin products to help you get to the higher end of that range, or whether you can hit those targets organically? Thanks.

**Emma Walmsley:** I will ask Iain to comment on the Consumer margin re-divestments. I am sorry, I have forgotten what the first question was! [*The divi cover*] Yes, the divi cover, sorry.

The basic answer to that is we have absolutely no change to our policy around divi cover, which is a function of free cashflow from 1.25 to 1.5, and I am actually pleased with the cashflow delivery this year, and we are clear on the policy and clear on where it sits on the capital allocation priorities.

**Iain Mackay:** No change on that front.

I am sorry, Naresh, I am not entirely sure of all your question, Consumer Healthcare disposals. Could you just run it past me again? [*No response*]

**Emma Walmsley:** Okay, maybe we will go to the next question, please. [*No further questions*]

Alright, thank you, everybody. We will look forward to updating you again soon. Thanks very much.

[*Ends*]