

## **Pharmaceuticals Business Overview**

### **Abbas Hussain**

First, thank you, Moncef. For those of you who don't know me, my name is Abbas Hussain. I am Head of Global Pharmaceuticals at GSK.

#### **Three commercial business portfolios to drive revenue growth**

I will cover off three commercial portfolios that, combined, will drive revenue growth for GSK going forward.

First, I will start off with pure Pharmaceuticals, which you can divide into two groups. First, there is the Respiratory portfolio, which is worth roughly about £6 billion and, as many of you know, it is in transition from *Seretide/Advair* to a portfolio of new products.

Secondly, for the purpose of this presentation, there is a group of base products that are also about £6 billion. Within the base products, we actually promote about 60% of these, and they are growing in low single-digits. The other 40% we manage as cash cows: some of you may know the bulk of them as established products from the past.

I will also cover off today on our very fast-growing HIV ViiV business. Some of you may be aware that in 15 of the key markets around the world, ViiV has its own legal entity. Beyond that, the Pharmaceutical organisation actually does the sales and marketing for all the HIV products.

Then, finally, I partner with Moncef at a local operating company level, to make sure that we do all the sales and marketing and commercialisation of Vaccines, so I will cover these three areas.

#### **Successfully diversified our business to drive growth and manage risk**

Over the past seven or eight years since Andrew became CEO and started his diversification strategy, we have very successfully diversified our business. As of today, 70% of our global sales come from outside the US. In fact, you may have seen this morning that less than 10% of US *Advair* sales make up our total global revenue.

We have also built what is a natural hedge. In fact, to get to 80% of our business, you have to go to 25 markets around the world. These are scale markets, and all of them are about £100 million or above. From a product perspective, you need to access 30 brands around the world to access 80% of the business. What we have really created is a natural hedge, a diversified business, and an ability to get into lots of growth areas.

#### **Positioning us to succeed in a tough environment**

The market continues to evolve. Andrew touched on this and, in particular, we have challenges with pricing. Let me start with the US. The US pricing environment is challenging and we have seen significant consolidation of payors and, hence, visibility of rebates. Nine payors in the US now account for 80% of lives in the US.

Secondly, there is a trend now to brand exclusions. With CVS Caremark, we estimate that there are roughly 95 brands that have been excluded and, with ESI, there are roughly 65 brands excluded. Clearly, from a GSK perspective, we had *Advair* excluded from the ESI contract last year and that was a significant impact for GSK. We now have got *Advair* back onto the ESI contract but, clearly, at a price discount.

In emerging markets, we are tending to see pricing pressures as a consequence of fierce competition between brands and branded generics. Typically, in emerging markets, we are starting to see about 2% or 3% price erosion every year. As Andrew mentioned, in Europe, there is no pricing power. In a good year, in our business plans, we factor in about 2% to 3% erosion and, in an austerity year, it may be 6%, 7% or 8% price erosion.

Finally, the emerging markets are slowing down from a GDP perspective and that is having an impact on pharmaceutical growth. We clearly also have some challenges around foreign exchange.

Against that, however, there are significant opportunities, and Andrew touched on this. Demographics are in our favour, with 300 million more people over the age of 50. Moncef has just pointed out the opportunities that exist for *Shingrix*. Even with the slowdown in emerging markets, there will be 300 million coming into the middle classes and, clearly, with the significant footprint that GSK has in the emerging markets, we can leverage that.

Finally, there is a 130 million birth cohort across the world, which presents a significant opportunity for the Vaccines business.

We also now have excellent Respiratory access for pricing, reimbursement access, for all our new products. We are expanding our ViiV portfolio and we are also expanding our Vaccines portfolio. Finally, we have a sustainable R&D pipeline. The real uncertainty, and again, Andrew touched on this, is really about visibility around *Advair* generics in the US. Firstly, will there be *Advair* generics? Secondly, will they be AB rated? How many *Advair* generics do we really expect? What sort of volumes will these generics have, and what sort of devices will these generics have? All of that together makes it difficult to forecast the type of erosion that we might see with *Advair* in the US. However, we have made an assumption in our plans that there will be *Advair* generics in the US, and Andrew mentioned to you some of the sales data that we expect to see in 2020.

## **Pharmaceuticals: Respiratory – proactively managing the decline of *Seretide/Advair***

With that, let me move on to Respiratory, and start to tackle *Advair* first. I will just make a few comments as it relates to the Respiratory market.

The Respiratory market is worth £20 billion and it is forecast to grow at 2%. GSK is by far the leader in this market and we have 33% market share. To me, 2015 is actually the launch year for our new products because, for the first time in the 15 key markets around the world, we have competitive pricing, reimbursement and access. Specifically for *Advair*, as you can see by the chart here, as we lost the ESI contract, we had a significant drop-off from about 50% to 40% in terms of new-to-brand prescriptions. Our payor team in the US, led by Jack Bailey who is in the room today, has done a significant job to regain access: as of today, *Advair* has 90% commercial access and over 83% Part D access. What we have actually seen is a stabilisation of the *Advair* share in the US.

I will come on to *Breo* in a second but, if you look at the combination of *Advair* and *Breo* in the ICS/LABA segment, you start to see that now trending back up to the 50% new-to-brand prescription share that we had before we lost ESI.

In Europe, we also have generics to *Seretide*. There are generics in five of the 15 markets in Europe. We have competed extremely well in Europe with these generics. A great example of that is Germany. Germany have had generics – and multiple generics – to *Seretide* since the middle of 2012. As of today, the penetration of those generics in Germany has been less than 4% in volume terms and we expect to continue to compete with *Seretide* generics in Europe.

In the international market, branded generics to *Seretide* are a way of life. Typically, in an emerging market, you have multiple generics launched. You lose in price and volume, perhaps by 15% to 20% and, from that new base, you continue your promotion and, because of the brand equity and the quality of *Seretide*, you actually start to grow the product again. As you can see, in the emerging markets where we have had multiple generics, over the last two years we have had 10% value growth and 13% volume growth for *Seretide*. We therefore think we can manage the decline of *Seretide/Advair* globally and I still expect that *Seretide/Advair* in 2020 will be an important product for GSK.

It is important to manage the decline of *Advair* but it is also important to accelerate the growth of the new products, so let me start with the US.

## **Pharmaceuticals: Respiratory – Strong US access for *Breo* and *Anoro* is driving uptake**

Since taking over the US, we have made a number of changes, and I will just go through these. First, we have a new management team in place: Jack Bailey is the General

Manager, and we have a new leader for primary care. We have worked with an external provider to do a deep dive into our execution capability in the Respiratory primary care sales force. Where we have identified gaps, we are currently up-skilling the reps to fulfil those gaps.

We also now have dedicated selling teams. We have a team dedicated to *Breo*, who will do *Breo* for asthma and COPD. We have a team dedicated to *Anoro*, who will do just *Anoro* for COPD, and we now have a team that is dedicated to *Advair* to ensure, as a consequence of the good access, that we start to get the pull-through of the patients we expect to see. Also, importantly, with the label that we now have for *Breo* in asthma, we have a very competitive paediatric label for *Seretide/Advair* in the US. We will use this team to make sure that they also promote the paediatric indication for *Advair* in the US.

You can see here that we now have good coverage for both *Breo* and *Anoro*, both in commercial and in Part D. You can also see the impact and the inflexion points that we are starting to see in the new-to-brand prescriptions for both of those products since we have that good access. With *Breo* at the moment we are seeing an increase in 750 triallists a week and with *Anoro* we are seeing an increase of 550 triallists a week. We are very optimistic about the progress that we are making with *Breo* and *Anoro* and clearly we are extremely excited about the potential asthma launch that will happen in the next couple of weeks in the US.

#### **Pharmaceuticals: Respiratory – Ex-US markets have good access. *Relvar* launching well**

Let us move on to the international markets. It is a similar story in international and 2015 is really the first year where we have broad pricing, reimbursement and access for our new products in the international segment. We have only just launched with pricing, reimbursement and access in Italy, in Spain, in Mexico, in Brazil and in Australia. We have received pricing and access in France and Canada, and we will be launching this quarter. We plan to launch *Breo* and *Anoro* in the second half of the year in 16 emerging markets around the world. For the emerging markets, we plan to introduce these products at a premium price, at the top of the wealth pyramid: this allows us to push *Seretide* into the middle income groups and compete with the branded generics to *Seretide* and actually drive *Seretide* access and volume in the middle income group.

#### **Pharmaceuticals: Respiratory – EX-US markets have good access – *Relvar* launching well**

In Japan, the Ryotan prescription restriction was only lifted in the fourth quarter of last year. For those of you who are not familiar with the Ryotan restriction, for every new product in Japan, for the first year, the physician can only prescribe two weeks' worth of

therapy. This means that the patient needs to return back to the physician's office every two weeks to obtain a repeat prescription. As you can see from this chart on the left, post the lifting of the Ryotan restriction, we have had a significant uptake of *Relvar* in Japan.

Just to put that uptake into perspective, Competitor C on that chart had its Ryotan restriction lifted at the same time. That is a terrific performance in terms of *Relvar* in Japan.

Also in Europe, for those markets where we have had good pricing and access, you can see, from a launch analogue perspective that *Relvar* is beating most of the launch analogues that exist in Europe at the time. In addition to this, clearly we are very excited about two major read-outs. Later this year we have the SUMMIT read-out for COPD and next year we have the Salford Lung Study read-out. In addition, in the fourth quarter of this year we plan to launch mepolizumab – this is our first biologic in severe asthma. ~~We will also be launching the closed triple later next year~~ [Erratum: We expect to be able to file the closed triple in 2016/2017].

### **Pharmaceuticals: Respiratory – portfolio de-risked with balanced growth as new products gain scale**

What does this all mean? If you look at the Respiratory portfolio, our expectation is – and I think Andrew mentioned this – that by 2020 the sales for Respiratory will be equal to or in excess of the sales in 2015. However, in 2015, four products made 90% of the business and, by the time we get to 2020, nine products will account for 90% of the business in Respiratory. In fact, we have always maintained that we will never replace *Seretide/Advair*, like for like, but we will replace *Seretide/Advair* with a portfolio of respiratory medicines.

### **Pharmaceuticals: base brands – generating volume and cash to support innovative brands**

With that, let me move on to the base products. The base products are extremely important and they are worth £6 billion worth of business. They are extremely high margin products. In fact, we run this business rather like a generics business. It is run out of a centre of excellence based in Mumbai. The marketing, the medical and the regulatory are all based in Mumbai and we use low-cost promotion and we also leverage digital promotion to manage these products.

On the left of this slide you can see that some of these products are very significant, in excess of \$1 billion. As I mentioned earlier, 60% of this portfolio is promoted and they grow in low single digits, while 40% of the portfolio is actually managed for cash.

In emerging markets, we sell roughly 140 million doses a day. This is 40% more than the second largest competitor that we have in emerging markets. Andrew mentioned *Augmentin*, which has terrific brand equity. We in fact sell twice as many tonnes of

*Augmentin* today than we sold at the peak sales of *Augmentin*. We partner with our manufacturing organisation and our plan in Worthing right now is working 24/7 to produce *Augmentin*. We actually plan for 110% capacity and in fact as the year unfolds, we then allocate that capacity to the highest margin tenders.

On the managed-for-cash side, we are clearly trying to drive margin. We take as much cost out as we can without compromising any quality. However, we are also taking out complexity and, as you can see, we removed nearly 4,500 unprofitable slow-moving SKUs in this business. This has added 1% improvement in gross margin in the managed-for-cash business.

### **HIV – rapidly growing business, transforming the market**

Let me now move on to two fast-moving businesses, first starting with ViiV. I have been fortunate enough to be involved with ViiV from day one and I am a board member of ViiV. This is a fantastic business model, with a terrific management team: David Redfern is the Chairman of ViiV, and is in the room today. The HIV market is worth £14 billion and it is growing in double-digits: last year, ViiV actually exceeded the growth of the market.

*Tivicay*, dolutegravir, our integrase inhibitor, has rapidly established itself as the best third agent and, as a consequence of that – and, again, you can see it in the charts here – the launch of *Tivicay* has beaten every single analogue launch since the original single-tablet regimen launch of Atripla. We are also delighted with the launch of *Triumeq*: *Triumeq* has come in and launched and actually exceeded the launch of *Tivicay*. *Triumeq* is the first of our single-tablet regimens that also include dolutegravir. Importantly, as you can see at the end of the chart, the combination of *Tivicay* and *Triumeq*, both of which contain dolutegravir, actually accelerates the growth of the franchise.

In the US, in the dynamic market place – and about 10% of the HIV market place in the US is actually dynamic – *Tivicay* and *Triumeq* combined now have the leading share in the dynamic market place. The dynamic market place has naive patients and switched patients. Hence, ViiV was growing at 4% in the first quarter of 2014 and, as you may have heard today, ViiV was growing at 42% in the first quarter of 2015. Importantly, there is still plenty of growth with both *Tivicay* and *Triumeq* going forward: 90% of sales of *Tivicay* come from just five markets and 90% of sales of *Triumeq* come from just two markets. The ability for market expansion is significant. *Tivicay* is registered in 50 markets and *Triumeq* is registered in 30 markets.

I would just like to comment on the pipeline. I see dolutegravir as a pipeline within a product. As I said earlier, it has fast established itself as the best third agent and a best integrase inhibitor. Within R&D we are looking at dolutegravir and single-tablet regimens,

either in combinations of three compounds, or also in combinations of two compounds. Some of you may have read the press release today in terms of dolutegravir combined with rilpivirine.

Finally, we are also very excited about our long-acting 744 programme, going forward. The HIV business is a great business model and a fast-growing segment for GSK.

### **Vaccines – balanced sources expected to drive growth from 2016-2020**

Let me now move on to Vaccines, although I will try not to repeat a number of the things that Moncef has said. The Vaccines market is worth £17 billion and it is growing in mid- to high-single digits and we are clearly the global leader in Vaccines with 27% market share. This is a great business with significant perpetuity value and, as Moncef mentioned, it requires large capital investments.

In the emerging markets over the last seven years, we have had double-digit growth with Vaccines. In fact, in emerging markets, we have cumulatively added £8 billion worth of business as a consequence of Vaccines. We see three opportunities for growth within Vaccines, first with the legacy marketed products of both GSK and of Novartis. In the case of GSK, we see opportunities in high value markets and we expect a universal mass vaccination programme for *Rotarix* in Japan ~~this year~~[Erratum: ...at some stage]. In Japan, roughly 50% of patients are vaccinated with rotavirus and we actually have a 70% share and, when we have a universal mass vaccination programme, that will obviously increase and we expect to have a greater share. We have also just had approved our pneumococcal vaccine, *Synflorix*, in Japan. We will launch that later this year.

In China, we expect *Rotarix* to be approved some time in 2016 and *Cervarix* to be approved some time in 2017. Just to remind you, the birth cohort in China is 16 million, and rotavirus is a significant healthcare issue in China. That is a seriously important vaccine for China and something that is very important for public health.

With regard to Novartis, we believe that by pulling the Novartis products into the GSK commercial capability, we can accelerate sales synergies. In many of the markets around the world, Novartis had their products with distributors. In many cases, those distributors did not promote the products and so, accordingly, by taking the products from the distributors and putting them into our commercial capabilities, we have an opportunity to accelerate sales growth. These are markets, for example, like Australia, where we have a significant presence in Vaccines, or markets like Egypt, where we are the No. 1 player.

As Moncef mentioned, clearly there is also an opportunity to grow the meningitis portfolio. It is very, very important for the US organisation: the broader portfolio helps us win

contracting with private payors but also we can accelerate *Bexsero*. We are very pleased with the *Bexsero* result in the UK and we are currently in conversations with a number of governments as that relates to *Bexsero* around the world. We also see, in many markets around the world, that by putting *Bexsero* into our commercial capability, there is also a private market opportunity for *Bexsero*, moving forward.

Finally, we clearly have a very significant opportunity with *Shingrix*, with 90%-plus efficacy in all age groups, as Moncef mentioned, and a significantly untapped market. Only about 7% of patients who should receive a zoster vaccine are currently doing so and so this is clearly a 'create the market' archetype. However, with the efficacy of *Shingrix* and with the capabilities that we have around the world in the Vaccines organisation, we are very optimistic about the opportunity that *Shingrix* provides for the Vaccines organisation.

### **Pipeline and productivity – strong future asset flow while restructuring drives margin**

All of this is supported by a very strong pipeline. I will not talk too much about the pipeline and steal Patrick's thunder on his R&D day in Q4 later this year, but we are clearly excited. I have mentioned this already about *Bexsero* and about *Shingrix*. Importantly, for the Respiratory portfolio, mepolizumab is our first entry into the biologics space. It has a very targeted population of about 5% of asthmatics who will require this product. It has a 50% reduction of exacerbations in clinical trials.

The closed triple is also an important product: 20% to 30% of patients with COPD are actually on an open triple and clearly a closed triple would be an important product for them. Also, the importance of the closed triple is that it shines a light on our *Ellipta* platform. The device market in Respiratory will be very, very crowded and so to have an *Ellipta* device, which makes it easy for a physician to change from one type of compound to another in the same device, we believe would be a competitive advantage going forward.

Going further into the pipeline, we have a number of first-in-class and best-in-class products that I will allow Patrick to talk about when we move into the R&D day.

From a restructuring perspective, we are well on track. We have made great progress with regard to the £1 billion worth of restructuring in the US, in Japan, in emerging markets, and we are also making progress in Europe. We will deliver 50% of the £1 billion in 2016 and we will deliver 100% by 2017. All of this is actually driving sales force productivity - sales force productivity measured by sales per sales representative. Between 2007 and 2014, sales productivity increased by 12% and, as you go forward to 2017, we expect sales productivity to increase by 23%.

### **Portfolio approach at market level gives flexibility to deliver revenue growth**

To summarise, we have a large base portfolio, 60% of which are promoted products and 40% of which are managed for cash. This is a very profitable product portfolio. However, this portfolio will continue to decline. We have a Respiratory portfolio which, in 2020, will be equal in sales to 2015, regardless of whether we have a US generic of *Advair* or not. However, it may be lumpy in between, depending on when the generic arrives and what type of erosion we see with the generic. On top of that, there is a very fast-growing HIV business. Combined, all of that will lead to single-digit growth rates and, on top of that, as Moncef mentioned, we have a Vaccines portfolio that will start off with mid-single digit growth rates, going to high-single digit growth rates. All of this is supported by strong operational management, the delivery of the restructuring and the delivery of the restructuring on time, and a sustainable R&D portfolio.

With that, I am finished. Thank you very much for your time. I look forward to hearing your questions later. Let me call Emma to the stage.