GLAXOSMITHKLINE

Q3 2013 RESULTS
MEDIA BRIEFING

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Sir Andrew Witty (CEO): Welcome to this afternoon's third quarter call. I shall make a few introductory comments and then, as usual, open up to Q&A. GSK's third quarter performance has seen us continue to deliver broadly-based sales growth, bring significant new products from our R&D pipeline to market and grow returns for our shareholders.

Turning to the numbers first, total sales grew 1%, core operating profit was up 11% and core earnings per share were up 16% at 28.9 pence. The increase in core operating profit was driven by continued strong cost control, including a reduction in R&D expenditure and the delivery of a further benefit from the programme of initiatives we started last year to reshape and reduce certain long-term operating expenses.

As we saw last year, contributions from this programme are unevenly phased and we shall continue to look for more of these types of opportunities to help deliver sustained reductions in costs and our balance sheet liabilities in the future.

We continue to return cash to shareholders with the dividend again increasing by 6% to 19 pence per share, and £1 billion worth of shares were repurchased by the end of the quarter. I can also today reaffirm our full year guidance of core EPS growth of 3-4% on sales growth of around 1%, both at constant exchange rates.

Sales grew 1% despite the impact of a significant decline in China sales, and the timing of vaccine tender shipments. This was a resilient performance and is being driven by contributions from across the Group.

In the United States, sales grew 2% impacted by wholesaler and retailer destocking in the quarter. Excluding these effects, growth is estimated to have been 5%. This performance marks continued growth and is encouraging given the intensifying price competition we are seeing in the US marketplace. However, with our significant new product flow and the changes we have made to our commercial model, we remain very optimistic about future opportunities in the US.

I was also pleased to see pharmaceutical and vaccine sales growth in Europe of 5% and, while the environment here remains tough, I believe we are starting to see the results from our restructuring efforts we began last year to focus the business on core assets and key growth opportunities such as Respiratory, Oncology and Vaccines.

The performance in EMAP this quarter down 9% has been impacted by the timings of vaccine tender shipments, and the significant decline in China sales. If we exclude China, pharmaceutical sales growth in the region was +5%.

Operations in China were clearly disrupted in the third quarter with sales down 61% but we remain fully committed to supplying our products to patients in the country. At this stage, it is still too early for us to quantify the longer-term impact of the investigation to our performance in China. The investigation is ongoing and is complex and detailed. We continue to cooperate fully with the authorities and to respect the process of the investigation. As such, there is very little further I can say until it has reached its conclusion.

However, I do want to reiterate that the activities described by the authorities are very serious and totally unacceptable. They are contrary to our values and to everything I believe in. We very clearly recognise there is a profound need to earn the trust of the Chinese people again, and we shall take every action to do so.

To round off on business performance for the quarter, Consumer Healthcare sales grew 4%. We continue to focus this business around a portfolio of core brands and drive growth through geographic expansion and innovation.

Before closing, I want to highlight the great performance of our R&D organisation. 2013 was always going to be an important year for our R&D group and I am delighted with the progress to date with four of the six key assets highlighted at the start of the year now approved. Given how difficult drug development remains, this level of achievement in the last nine months is remarkable and unprecedented for GSK.

I want to thank everyone who has worked so hard to make this possible. The four approvals consist of *Breo* for COPD, *Tafinlar*, and *Mekinist* both for metastatic melanoma and *Tivicay* for HIV.

In addition, we have received approval for our quadrivalent influenza vaccine in the US and significant new indications for three other products. Taken together, these approvals represent substantial new growth opportunity in key areas of oncology, HIV and respiratory disease.

I would particularly like to highlight our Respiratory portfolio. Last week we started shipping *Breo Ellipta* to US wholesalers. This product is also now approved in Japan for asthma and has received a positive opinion in Europe for COPD and asthma.

We also received in the quarter a positive recommendation from an FDA Advisory Committee for potential approval of another product, *Anoro* for COPD. A regulatory decision here is expected before the end of the year.

These achievements mark the latest developments in our 40-year leadership of this therapy area. They are clear indicators of our ability to expand our current portfolio with new medicines and inhaler technology which can make a real difference to the lives of patients with respiratory disease.

I would also like to highlight the positive findings seen earlier this month for our malaria vaccine, candidate RTS,S. This is something myself and the whole company are delighted with. As many of you know, we have been working on this project for around 30 years and we are now preparing to file for approval with regulators in 2014. The vaccine has shown to reduce by approximately 50% cases of malaria in children aged five to 17 months and given the terrible nature of this disease has the potential to help transform public health in Africa.

Finally, as we deliver our pipeline we continue to reshape our business and divest non-core assets. We have agreed to sell *Lucozade* and *Ribena* to Suntory for £1.35 billion and have accepted an offer of £700 million from Aspen for our anticoagulant products *Arixtra* and *Fraxiparine* and their related manufacturing sites.

We believe these represent good value for shareholders.

With that, I am happy to open up for questions.

Question and Answer Session

Ben Hirschler (Thomson Reuters): Hi, Andrew. A couple of questions, first of all on China. Should we expect to see the impact continuing in the fourth quarter and into 2014 in terms of the hit to sales? Also can you give us some indication of what kind of scale of fine you might be prepared for and are you going to be taking provisions for that?

Secondly, I wonder if you could say a bit more about what is driving core earnings in terms of the cost reduction, particularly on the R&D front? There is a cost being taken out there and is that a one-time thing or is that on-going?

Sir Andrew Witty: Ben, thanks very much for the question. As far as China is concerned it is a bit early to take a view on what the on-going impact on the business is going to be. It obviously depends to some degree on what the ultimate outcome is of the investigations, of course. There has been some volatility month-to-month and again, we are just looking to see what the trend really is. I am obviously hopeful that we will see improvements as we go forward, but it is too early to really call that. Again, the investigation

is very much continuing, underway. It is very important for us to remain committed as we are to working with the authorities on this investigation and we really want to respect the process of the investigation. It is premature to speculate on what the outcomes or consequences might be.

As far as the core earnings numbers are concerned there are a number of different things going on in the cost line. I'll perhaps just focus on two in particular and they do address the specifics that you were asking. First of all we, last year, if you recall, announced and communicated to everybody that we were reviewing a whole raft of what we would describe as long term cost drivers of the company. For example, the cost of pensions, the cost of healthcare provision, all of those sorts of activities which very often historically haven't necessarily been the focus of day-to-day cost management. Last year in Q4 we made some decisions and took some actions around particularly the pension costs in our UK operations. That had a significant benefit last year for the company, much of which was reported in Q4, some a little bit earlier in the year. It also had a significant impact in reducing our long term balance sheet liabilities for pensions, which of course has the benefit to shareholders that over time we have to put less cash into the pension fund.

This year we have continued the same programme of challenging all of these sorts of activities. What we have done this year and this quarter has benefitted, a little bit like last year's Q2-Q4 benefit, from some changes we are making in our retiree health benefits for the US market. That is where we have delivered some extra benefit here this year. I fully anticipate we will continue to find further examples like this and so I anticipate you will see similar, not the same of course, but similar sorts of contributions to reductions in cost from different areas next year. I don't think you will see any more this year, but we are certainly working hard to bring these things forward in an orderly sequence as quickly as we can, because it delivers real value for shareholders in the short run. It sustains the reduction in our costs over the medium run and it also reduces our balance sheet liabilities, all of which are important long terms things for us to achieve.

The second area you touch on is absolutely R&D cost. We are in a fascinating phase at GSK in R&D where the output from R&D has never been more productive. Delighted with the new product approvals we have been able to achieve this year, continue to have more approvals than any other company in the industry during the year, yet our spend continue not only to be under control, but beginning to come down. The number of the more expensive late stage Phase 3 studies come to an end and that has allowed us to deliver all of this output for a lower cost of R&D. While it is premature for me to give you guidance for next year, it is unlikely that you will see a different trend next year to the one that is beginning to open up as we go through the end of this year. We do find ourselves in

a very good position with R&D, with very encouraging signs of sustained output delivery, significant numbers of approvals and a very well-managed and controlled cost-base. Thanks then, next question.

Jeanne Whalen (Wall Street Journal): Hi Andrew, I realise you can't comment on the investigation itself in China but can you clarify why the investigation made your sales fall so much in China: how did that hurt your ability to sell?

Sir Andrew Witty: Thanks, Jeanne. The bottom line is that, simply, the media in China, if you will, the commentary in China has created an anxiety which has led to some disruption in the business. Obviously, we have a number of products where we compete with other companies where there are choices in the marketplace, and I suspect it is as simple as that.

What we have also seen from the market data is that several other companies have been affected. I don't know to what degree but we are certainly seeing data showing that we are not the only company to have seen a slowdown of sales in China. As I said, this has been quite volatile month-to-month and it will be very interesting to see where we are in a quarter or two quarters to see what the real pattern actually is but, nonetheless, disappointing for this quarter. Next question.

Andrew Jack (Financial Times): On China, I wonder if you can give any more clarity on the impact product-by-product and vaccines on that 61%, and have you stopped marketing entirely? How, so far, have you responded organisationally and commercially to what is going on there? Secondly, more on the Respiratory franchise, any reflection: there is an intensifying generic competition to the older equivalent products so, at a time of cost control in Europe and elsewhere, what your sense is on the market share that you will be able to retain or grow with the new products at this time of intense competition?

Sir Andrew Witty: Thanks very much, Andrew. There is no really strong pattern in the China sales report other than one or two comments I have made. One I have just mentioned to Jeanne, which is that obviously where products have more competition and there are more products similar to ours, clearly that is an area where it is easier for the market to move.

Secondly, it is worth remembering that we were already anticipating a very rapid slowdown in our Vaccines business in China, which has nothing to do with this investigation, because of changes in the Chinese Pharmacopoeia. Every few years, the Pharmacopoeia

changes and there were some changes made, which meant that the products which we were registered to import and sell were no longer consistent with the new Pharmacopoeia. We knew that a year or 18 months ago, so we had anticipated that there would be a significant slowdown in our Vaccines sales in China, because it takes so long for us to reformulate these products to meet the new expectations. Therefore, there is more to the sales slowdown than simply the impact of the investigation, particularly with regard to the Vaccines business. It is probably just worth highlighting that. Those are the only two areas where I would say there is any pattern to point to.

As far as your broader question about Respiratory, first of all I remain very proud of the performance of the company with everything we currently have in the marketplace for Respiratory. Therefore, the performance not just of *Advair/Seretide* but also of *Flovent*, *Ventolin* and our legacy products remains extremely robust and, again, really supports our market leadership position that we have held now for so long. It is amazing to think that it is more than 40 years since we started in this business.

Great news this quarter that we have begun shipping *Breo* in the US, and we have made very good progress in getting coverage for *Breo* in the US for COPD, and we are moving close to the final decision for *Anoro* also for the US. Of course, we have *Breo* either approved or recommended in the rest of the world.

Today, we filed the next Respiratory product, this is a new steroid monotherapy. We have also filed umeclidinium, our new LAMA monotherapy, and it is no secret to anybody that we are working on triple combinations as well as other modes of action, including products for severe asthma. So we have a very broad portfolio, a very broad existing business which continues to perform well.

My goal, simply put, is that we are going to stay the market leader and we are going to work to grow our market share and, while we have a very strong position and we have clearly potential generics surfacing in parts of Europe as an example. We also have major new products coming along which take us into new parts of this marketplace that we haven't competed in before.

We believe that net/net gives us a tremendous opportunity to rely on the Respiratory business over the next several years, as a major part of the group's future. I am absolutely thrilled with the performance of the R&D organisation, who have been able, once again, to do some extremely difficult science and manufacturing development, which we know provides significant challenges for many other companies when they have tried to do similar things. I am very proud of the team at GSK who have been able to do this repeatedly well.

Thank you. Next question.

Andrew Clark (The Times): Hi Andrew. Two quick questions. First of all on China. I notice you say you remain committed to supplying drugs to Chinese patients. Does that mean that you can absolutely rule out the idea of pulling out of China? Can you say that is definitely not going to happen, or is that still a possibility, however remote?

Secondly, I noticed that more generally sales of *Lucozade* and *Ribena* did very well over the summer. Do you now regret selling them?

Sir Andrew Witty: Thanks for the questions. There is absolutely no question about our commitment to China. We are fully committed to it. It is worth just making a couple of comments in that regard, Andrew. First of all, even with this decline in sales this is still a multi-hundred millions of pounds business. At these levels of reduction these would still be a very significant European-sized country business. The numbers in China are significant. This slowdown is significant, but we shouldn't forget this remains a very significant business. That is why it is so important to reassure consumers of our products in China that we are absolutely committed to maintain supply to them as we go through this.

Secondly, it is worth noting we are the most integrated international pharma company in China. We are the only company that literally has activities in China. We start at molecule discovery in our integrated R&D unit in Shanghai and go through every single step of the value chain, all the way through to sales and distribution. We have 7,000 employees in China in all of those areas of discovery, development, regulatory and medical, manufacture and, of course, commercial. This is a very substantial business. It is a very important business for GSK. China is a critically important country of the future and we are absolutely committed to it. We are absolutely committed to working with the Chinese authorities to get through this investigation, find out what has happened, take the actions necessary and engage in rebuilding trust with the people of China.

As far as *Lucozade* is concerned, I was thrilled to see the performance of *Lucozade* during the summer. It comes from two things, one we can control and one we can't control. The thing we can control is we introduced a whole number of new flavours which really caught people's imagination. GSK's team in consumer over the last several years have done a terrific job of bringing real consumer innovation to the *Lucozade* business.

The thing I couldn't control was the amazing British summer; fantastic. Great that came along in the last year that we are the owners of *Lucozade* and I am delighted that we were the beneficiary of that summer. It does not change the strategic call on the disposal of *Lucozade* and *Ribena* because it is the right thing to do for the brands and for the

shareholders. These are great brands. They have been built brilliantly and this summer was such a great swansong, if you will, for the GSK team to prove what they can do. The reality is that a company like Suntory, with its existing platforms in the drinks business, with its focus on building up this business, they are going to make better investment decisions in the long run than we are, given that we have so many choices. With the group of our R&D pipeline and the delivery of the new products, we have to really make those decisions to ensure that we are focussed on the right thing. You should expect to see us continue to look for ways in which we will continue to streamline parts of the business to ensure that we deliver great focus on the pharma and vaccine business and the core consumer business, which we believe is where our energies should be dedicated. Next question.

Helen Thomas (Wall Street Journal): Hi, Andrew. Helen Thomas from the *Wall Street Journal.* I just wanted to follow up on a couple of things. Leaving the drop in China aside, have you seen any other slowing of growth in your Emerging Market businesses following volatility and economic slowdown in those markets?

Then following up on Andrew Jack's question on generics for *Advair*, is your understanding of the FDA revised guidance that that would also lower the bar for generics for potential triple combination therapies at some point in the future?

Finally, I was just keen to get a little bit more forward-looking on what is coming down the research and development pipeline and what you have in the hoppers to keep up the momentum you have seen this year. Thanks.

Sir Andrew Witty: Thanks so much, Helen. EMAP, yes I would say there is a kind of notch-down in growth across many of the emerging markets, I think directly correlated to some of the more macroeconomic trends.

We are still seeing, as you see in our numbers and when you adjust for China, the Pharma business is up 5%. That's actually not too far off the pace for the last two or three quarters but maybe a point or two, so we have seen over the last 15 months just a gradual slowing in the market.

I think it comes with the territory. The reality is that you do see slightly more rapid translation of macroeconomic trends into the pharma market in the emerging markets than we have seen necessarily in the West. We knew that when we made the decision to invest in this area; we understand that as a dynamic of these markets. It is complementary to dynamics in the West but it is a reality and it is a tad slower. It's still better than many other parts of the world, but a tad slower.

In terms of *Advair* generics, listen the reality is the FDA have published their draft guidance. Until it becomes final presumably it has the potential to change so we will see what the final draft, the final version of the guidance is going to be.

I think that there remain very significant challenges in being able to formulate these products. I would remind you actually that the hurdles in Europe are not as demanding as the hurdles in the US and yet in Europe there remains a real challenge for companies to be able to get generics registered. I think that has a lot to do with their ability to manufacture and formulate products which really do on a regular basis perform the way they should.

As far as its impact on the triple combination, again I would say that the hurdles to triple combination therapy are in other places in the regulatory process than necessarily in this specific area and therefore it's not completely obvious to me that this changes that dynamic very much and we ourselves spend a lot of time trying to work out how to answer the complex regulatory questions that exist there.

As far as R&D going forward is concerned, first of all let me reiterate I am just incredibly proud of what the team have delivered so far. To have this number of major NDAs approved and to then have one after another supplemental indications going in, three in the last week alone, just reflects the kind of scale of deliver that's coming from the organisation.

To give you an idea of what's coming, we are going to see the first darapladib data before the year-end, so while we have always characterised that appropriately I think as a wild card if you will, it remains potentially a very interesting opportunity so darapladib is really coming close now.

We will see the filing of the malaria vaccine come along; you will see more data on *MAGE-3* and while we didn't win on the first data, I think this programme remains absolutely alive with several more opportunities for the data to bring us to a positive place.

We will see data next year on mepolizumab in severe asthma; you will see us take that molecule into some other indications and some other diseases. You will see things like the anaemia programme roll forward; you will see our zoster vaccine move forward.

Overall we have eight Phase III programmes reporting out next year and really we have been incredibly busy to this point, it doesn't get any less busy. The good news about GSK R&D is that we have a whole raft of more stuff coming through behind these first six. Thanks, Helen, for the question. Next question.

Denise Roland (The Telegraph): Hi, Andrew. I have a follow-up question to Jack's earlier question, which is whether you have a sense of how much of the sales decline

in China can be put down to the expected decline in Vaccine sales, and how much would be attributed to disruption due to the investigation? Secondly, earlier you spoke about earning back the trust of Chinese consumers, and I wonder how you are going about that, or how will you go about that?

Sir Andrew Witty: We never split out the details but our Vaccine sales in China now are very, very low and that has been decline quarter on quarter over the last 12 months since the Pharmacopoeia came out, so a piece of that is absolutely what is driving it. Nonetheless, the broader disruption is clearly the majority of the impact of the reduction. I simply want to make the point that it is not the absolute total element of it.

The key for us, Denise, is that, first of all, we are totally committed to China. We are totally committed to working with the authorities on this investigation. We are totally committed to respecting the investigation. We want to work with them, let's get to the end of this, figure out what has happened, take whatever actions are necessary. That is then the basis on which to learn lessons and to engage in building trust with the people of China again, and that is really what we are going to do. Next question.

Makiko Kitamura (Bloomberg): Hi, Andrew, I just have a few questions. One on product launches. I imagine your sales force is very busy on the back of all the approvals. Given the uncertainty around the China market, how important will it be to get these new product launches right, especially *Breo/Relvar* and *Anoro*, assuming that it gets approved?

On a related note, you revised your incentive compensation programme in the US a few years ago. At this point, how would you rate the success of this reform and are you considering implementing similar changes in China as part of the strategy to regain the trust in that market?

Sir Andrew Witty: Thanks very much, Makiko, for the question. First of all, China is a significant business for us but we have to put it into the context of our overall business and, as you know, because we are such a diversified business, it represents a relatively small proportion of the total. At the same time as trying to deal with the issues we face in China in the way that I have described, and I am confident we are dealing with them appropriately, we are also absolutely focused on making sure that we complete the job that the R&D organisation have started for us with the successful launches of the new products.

In the last few months, we have launched two new medicines for melanoma. I can tell you that the two are more or less in balance and that they account for about half of the

market in which they compete, so we now have roughly-roughly through the two products 50% market share of the new prescriptions that are generated in the V600 melanoma marketplace, which is the marketplace where those products are positioned. This is a phenomenal performance and reflects great products but also an extremely accomplished Oncology operation in the US, which has also delivered fantastic performance from *Votrient* as well as *Promacta* and *Arzerra*. So we are very happy with the performance there

Tivicay has just been launched by the ViiV organisation, it has only been in the market now for five or six weeks but is tracking extremely promisingly compared to previous launches from some of our major competitors in that marketplace. It is early days but everything looks very encouraging for *Tivicay* and I was delighted that just yesterday we were able to submit the SNDA for the combination product based on dolutegravir.

We have also had an extraordinary year in the US for 'flu where we were able to bring to market not just one but two new quadrivalent vaccines. As you will have seen in the quarter, we had an extremely strong growth of our 'flu vaccine, up by nearly a third, and it is also important to recognise that whereas normally we ship all of our products in Q3, you will see continued shipments into Q4 and, as of yesterday, we sold 100% of all the doses that we manufactured to the US market of all of our flu vaccines. A very encouraging performance from that perspective.

Breo began shipping last week. We had a really positive progress in terms of building coverage, particularly in the critical Part D sector for COPD in the US and everything is looking pretty good for our expectations for *Breo* and, of course, we are working with the regulator for, hopefully, *Anoro* for the end of the year, subject to FDA review.

Very encouraging performance so far from the new product launches. We are not taking anything for granted. These are early days. We have to make sure that we are learning lessons as we go, day-to-day, to make sure that we fine-tune and refine our strategy and tactics, but so far so good in terms of the roll-out of the new products in the US.

Of course Japan and Europe are now coming close behind with the lead products, so we are exciting about other regions join the US over the next few months. One thing you will see for GSK in this wave of products is we have really tightened up the gap that historically existed between a US launch and other countries. For example, to have *Breo* approved in the same year in Japan and in America is unheard of for us and for most other companies. It really reflects the synchronisation of our R&D operation globally.

Incentive comp in the US, the changes to Patient First were really fundamental and important decisions for us as a company. I have reviewed this many times since we made these changes. Most recently I reviewed it just two weeks ago in Philadelphia. All of the

metrics, all of the measures that we look at, are telling us this was the right call. The most important measure, which tells me absolutely it was the right call, is our customers are telling us it was the right call. That is translated in terms of the type of relationship that we have, the type of trust we are able to build and the type of access that we are able to achieve. I am very pleased with the way it has been done. It was the right move and I have no doubt we will look to export some of the lessons learnt from that to other parts of the world.

Next question.

David Sell (Philadelphia Inquirer): Andrew, good morning. Thank you for taking the call. A question to go to the employee healthcare benefits and for retired workers, specifically in the US. Could you elaborate a little bit on what those changes are, both for current and former employees, especially in the light of other, big US based companies shifting retiree healthcare benefits essentially out of their company?

Sir Andrew Witty: It is important – first of all we are not shifting benefits out of the company, David. Also we are not changing anything for folks who have already retired. What we are doing is for people who are under 65 who haven't yet retired, we are giving them more choice. What we are saying to them is rather than having to take the package we offer you we are going to give you an amount of money for you to choose your package. We give you a defined contribution to go and invest in whatever programme or package suits your needs the best. The benefit to the employee is it gives them more choice and it gives them an ability to match their needs, healthcare expectations to the market. We recognise that the market now offers far more options than it did a few years ago. The benefit for the company is we have a definition around the contribution that we are giving. That is basically what we have done. We think it is the right, modern approach. We think it strikes the right balance, doesn't go too far, but strikes the right balance given the choices which exist in the US and the dynamic and variable nature of our workforce, where different people want access to different sorts of benefits. That is basically what we have done.

Jennifer Rankin (The Guardian): Hello. More on China. I would like to ask how you respond to the allegations in the Chinese state media that the corruption went right to the top of GSK in China and not just a few sales people? Secondly, I didn't hear the answer you give to whether you were putting aside any money for fines to resolve this.

Sir Andrew Witty: In response to the second question, what I said earlier was that the investigation is still underway; it's too early to make those sorts of judgments

and as a result we feel like our overall legal provisioning is where it should be given the information that we have at this point in time.

Obviously when the investigation comes to an end if that changes then we will have to change that judgment.

As far as the allegations are concerned, you have seen and I have seen through the media a variety of allegations. Obviously the investigation is focussed on different allegations. We are committed to working through those with the authorities. It is really essential for you to understand that we are going to respect that process. That means there is very little I can say about it until we reach a conclusion. I know that's a bit frustrating for everybody here but it's just absolutely the right thing for us to do and as a result I can't give you a lot more detail.

Obviously when the investigation is concluded, that will be the moment to give you a fuller update and summary of it.

With that, I think that was the last question we had. I very much appreciate everybody's attention on this call and of course if you have further follow-up the GSK Media Team are at your disposal.

Thank you very much.

[Ends]