Good morning, everyone. So it’s great to be back to kick off the largest day of our conference with Merck this morning. Please note that we need to refer you to our disclaimers at www.morganstanley.com/researchdisclosures. It is my pleasure to welcome Ken Frazier, Roy Baynes and also Adam Schechter this morning. Ken, as you know, serves as the President and CEO of Merck. He originally joined Merck in 1992 as Vice President and General Counsel of the Astra Merck group. Since then, he’s held a variety of roles and stepped up to the CEO position in 2011. Adam Schechter has been President of Global Human Health since 2010. Previously he held a number of executive positions within Merck and Roy has served as Senior Vice President of Clinical Research since December of 2013. Previously Roy led oncology, inflammation and respiratory therapeutics at Gilead Sciences. And before that, he held a leadership post at Amgen within oncology. So with that, why don’t I turn it over to Ken for some opening remarks and then we will go into Q&A.

Ken Frazier - Merck & Co., Inc. - Chairman & CEO

Thank you very much. First of all, good morning to everyone here. Thanks for coming out to the early session and also thank you for not being one of those people who is already standing in line up at the Apple store on Fifth Avenue. Based on Squawk Box, I thought no one would be here this morning. So we are very grateful for your presence. We are also grateful for your interest in supporting Merck.

So let me just say that we announced a new focused strategy last year. We said that we were going to focus on those areas where we thought we could lead and that is what we have been doing in terms of investing in our internal pipeline in programs like Keytruda, which we are pleased is already approved in the US. Also the work that we are doing in hep C to bring our combo, double combo to market and the work that we are doing to add a nuc to a triple combination that we hope will have great benefit to patients. We are focusing on our top markets. We’ve said we will take $2.5 billion out of our cost base and we are well on our way to delivering that $2.5 billion.

So we are seeing I think the fruits of a focused model. We’ve managed to sell off our MCC business for what we think is a fair amount of money that we can reinvest in our business in the right way. We’ve taken our Saphris franchise and our ophthalmology franchise and we’ve been able to sell those. So a lot of this is really fundamentally, first of all, about focus. Secondly, I would say what makes it exciting at Merck, as we are a science-based company, all these companies depend on their ability to invent medically important medicines and that is also happening right now at Merck.

So I mentioned before the excitement about Keytruda, but we are seeing as many products or more coming to market as any recent time inside Merck’s history. It’s not just Keytruda; it’s suvorexant, which Adam can talk about in a little while. It’s the work that we are doing again in hep C. It’s V503, the successor to Gardasil. We have Bridion coming. There are a lot of important things that are coming to the market right now and we are very excited to be bringing new products because that is the lifeblood of any new pharmaceutical company.

And the last thing I will say is we are mindful as we do all of those things, as we innovate both with respect to our business model and taking out costs, where we innovate where it matters, which is important new products, we are also mindful that we have shareholders and we are going to ensure that we can return cash to shareholders in a highly competitive way to make our investment worthwhile from the standpoint of share
repurchase and dividend. So I think we are making great progress against the promises that we made last October and with that, I will just open it up to questions.

David Risinger - Morgan Stanley - Analyst

Great. Well, congrats on the progress and congrats on the approval of pembro. I think we should probably start there. Obviously, you can take a little victory lap by leapfrogging your competitors and being with us today; we appreciate you taking the time. Maybe you could speak to, and this is really a question for any of you, but maybe you could speak to how investors should think about the launch of pembro. Obviously, there will be a lot of demand for it off label for which Merck won't promote or discuss, but it would seem like the super wealthy in the country with a variety of cancers would be interested in accessing pembro now that it's going to be commercially available this month. So maybe you could talk about the commercialization strategies, the launch plans and how you manage that.

Ken Frazier - Merck & Co., Inc. - Chairman & CEO

I am going to turn it over to Adam because this is what he is focusing on full time. But I will say that I think, again, the fact that we were able to get this product to market in record time, in effect 3.5 years after the first patient was dosed with the medicine, four months after the FDA accepted the file, I think it's actually a tribute to the importance of focus. We said we would create a unified oncology business unit where we would put the scientific people and the commercial people working side-by-side so they wouldn't be distracted by the normal rhythm and routine of Merck. So their only reason for coming to work in the morning was to find ways to accelerate this program. And I think what you've seen are the fruits of that. But I will turn it over to you, Adam.

Adam Schechter - Merck & Co., Inc. - EVP & President, Global Human Health

So obviously, we are very excited about the commercialization of Keytruda. We received our first orders yesterday and we are shipping today so the product should be available sometime this week. So that is a big moment for us to have the product available so quickly after the approval. We have our salesforce in place. We have a global oncology business unit, as Ken mentioned. In the US specifically, our salesforce is being trained and they will begin to call on physicians that treat melanoma patients in the very near future. There is about 6,000 physicians in the US that treat melanoma patients. About 1,000 of them represent the vast majority of prescriptions. We will get to that 1,000 of them within the first several weeks starting in the next couple days. We will get to all 6,000 of them over the first month, month and a half.

At the same time, we are going to focus on the indication that we have, which is for utilization after failure on other products for melanoma. If you look, there is about 10,000 patients with metastatic melanoma that are treated every year in the United States. About 5,000 of them are treated on Yervoy first. The other 5,000 usually get a BRAF inhibitor. If you then look at the number of patients available based on our indication for Keytruda, we figure there's about 300 to 350 patients that will be available per month based upon the flow of patients that will fail on either the two pathways for our indication. We think there is somewhere between 1,000 and 1,500 patients that are currently available in the marketplace based upon previous failures.

So although the indication is relatively restrictive and small and that is where we will focus our promotion and only where we will focus our promotion, we do realize, as you said, that there are physicians that will utilize the product off-label. We won't promote that, but we realize that that is the reality of what occurs. From a manufacturing perspective, we have a significant amount of supply. Whatever happens in the marketplace, we believe we'll be able to manufacture and supply immediately, but our focus will be on the indication that we have. But we have reimbursement support lines up and running already. We have everything ready to launch and we are in the middle of it as we speak.
David Risinger - Morgan Stanley - Analyst

And could you just maybe speak to how you will handle demand for off-label use and just how you think through that? Obviously, Merck won’t be promoting it or discussing off-label use, but the reality is that certain patients that can afford it out-of-pocket will ask for the PD-1 rather than going into a PD-1 clinical trial.

Adam Schechter - Merck & Co., Inc. - EVP & President, Global Human Health

Yes, so individual institutions and managed care organizations will develop their own protocols and rules for whether they will and if they will, how they will reimburse for off-label utilization. That is completely independent of anything that Merck would talk about or promote. We won’t go there, as you mentioned. Then based upon that, if there is a need for reimbursement support, we will provide reimbursement support for whoever needs help accessing the product based upon what their physician prescribes for them.

At the same time, we want to make sure there is enough supply in the marketplace. So our manufacturing division has done an outstanding job to ensure that whatever supply is necessary we believe that we’ll be able to have in the marketplace and that’s beginning immediately. We have supply that we are shipping, as I said, as we speak. So it is really important that we focus only on the indication that we have on our label. That will be our only focus, but we are prepared because we realize that there will be some off-label utilization to make sure we supply it.

David Risinger - Morgan Stanley - Analyst

And then just to stay on Keytruda for one more minute. There was some dreaming earlier this year that Merck was going to be announcing a filing and long before you had key data, which obviously didn’t happen. I think that negatively impacted the stock’s performance on your Analyst Day unfortunately because there was some speculation about an announcement of a plan to file in lung. I don’t know how that speculation got created, but it was there. Anyway, could you just update us in terms of where Merck is with respect to delivering lung data that is fileable in 2015?

Roy Baynes - Merck & Co., Inc. - SVP, Global Clinical Development

So we have a number of clinical trials ongoing in the lung cancer arena. We have single arm studies, we have control trials ongoing. We will have many opportunities to look at data over the next several months and I think you can rest assured that we would make every effort to get this drug approved as quickly as possible, that it will be a data-driven discussion. As I’d mentioned and I think people might have not heard, we have a single arm study, we have a control trial and we have actually moved into front-line treatment as well. So it is a broad program with many opportunities and we will obviously work with the agencies as soon as we have data that support moving forward.

David Risinger - Morgan Stanley - Analyst

And just remind us what is the data that is coming later this year?

Roy Baynes - Merck & Co., Inc. - SVP, Global Clinical Development

We haven’t actually commented on exactly when data will be forthcoming. We will be having some updates at ESMO in lung cancer. This is largely single arm data. We have ongoing control trials and we haven’t disclosed when we will have those data available yet.

David Risinger - Morgan Stanley - Analyst

Okay, thank you. And then stepping back to big picture, Ken, you touched on transforming Merck and your new focused business model. Could you just provide a little bit more detail on that and then also discuss your cost structure? So how far you are along in rebasing the cost structure and cost-cutting opportunities ahead?
So we said last October that we would aim for $2.5 billion in additional savings by the end of 2015. What you need to know is we are well on our way to achieving that outcome. At the same time, it's not just a question of spending less; it is also a question of reallocating to those areas where we could actually make a difference of -- for example, with respect to Keytruda, when Dr. Perlmutter came in to run the labs, there were a number of programs that were ongoing. He looked at Keytruda, pembrolizumab and said we really ought to prioritize our resources to get behind this in a concerted way. And I think that kind of focus, that kind of effort resource allocation made a big difference over the last few months. So we are continuing to do that. We are allocating our internal resources to those scientific programs like immuno-oncology, like hepatitis C where we think we have the greatest opportunities.

And also in Adam’s area, very much focused on those key products and on those key markets that make a big difference. And I must say I can see the impact of that focus, for example, on Januvia. A few months ago, people were saying well why would you put more resources behind Januvia? We are pleased to see Januvia responding in a better way over the last few weeks and if you look at the four-week rolling averages, that is a much more positive picture than it was a while back. So to me, this issue around taking cost out is important because we know that there is going to be continued pressure in this business. The margins continue to be pressured across the industry. But at the same time, I think it is just as important to make sure that you are focused with respect to where you do spend your money.

And I will just shift -- you didn’t ask me specifically on the business development side of things. The other thing we want to make sure that we do with our resources is that we find the best science outside Merck. And so a deal like Idenix was a deal that we were pleased to have an opportunity to do because it builds on our hepatitis C franchise where we already had a double combination that we thought would be formidable in its own right. So to be able to do that deal for Idenix to bring in that nuc was something that we thought would be potentially important in terms of a triple combination.

Thank you. Let me pause and see if there are questions from the audience. Just wait for the microphone.

Companies are looking for ways to bring their tax rates down.

I’m sorry?

Companies are looking for ways to bring their tax rates down below 20% to the mid-teens (technical difficulty). What is Merck’s strategy to bring its 26% tax rate down (technical difficulty)?

So without getting to the inversion thing first, we look at our activities and we try to order our activities, our manufacturing and our IP activities in a way that would be consistent with having a minimum tax rate consistent with the law. So we already do the things that are possible to do within
the current tax regime. Having said that, I think everybody recognizes that the US tax code puts a huge competitive disadvantage on US companies. There is no two ways about it. We obviously engage in Washington and public policy and legislative discussions aimed at hopefully moving us to a rational place with respect to the overall rate and also with respect to the territory nature of the tax system.

I continue to have some hope that the US will get its act together. I don't think it will happen before the mid-term elections or even the 2016 elections, but we are going to be in business for a long time and we expect that, through those kinds of productive discussions, eventually we will get some kind of rational change because I think my conversations with the leadership down there on both sides is everybody understands they are putting US companies at a huge competitive disadvantage.

Now with respect to Merck and tax inversions, I have been very clear that if you look at the size of the kinds of transactions that would make us eligible for an inversion, we don’t see that as consistent with our strategy as a company. And we want to do deals for strategic reasons. We want to do deals that give us access to quality commercial assets and quality scientific assets. We don’t see that the advantages that we would get from a tax inversion deal would either be durable long term because I think the US government will do something positive or negative in response to the flight of capital, if you will or flight of certainly headquarters from the United States.

And also, I think frankly that there is a lot of distraction that you create when you do a big merger and I’ve just been talking about the benefits of focus and the ability to take a product like Keytruda, which was originally going to be filed in 2019 if you look at clinicaltrials.gov at the beginning of this year and now we have a drug on the market in 2014, 3.5 years after first patient dose. Those kinds of things require that your scientists, your commercial people be able to work together and understand what the plan is for tomorrow, five years and 10 years from now.

So given the long leadtimes that we have in this industry, I just don’t see the benefit of doing a big merger. Now some big mergers make sense. I would argue that the Schering-Plough Merck merger was an exemplary one from the standpoint of value creation. Not only did we get the synergies, but now we are coming forward with important products in the pipeline like Bridion, like Keytruda. We have things that are future opportunities like[b]ase[\], so it was one of those few deals where we saw an opportunity to do both, if you will, the merger synergy consolidation efficiency play and at the same time, it held out the hope of some pipeline benefits and it’s actually interesting because many people said to me it was a failed merger because of the first vorapaxar study and indeed, we believe that is not true. I think with [basin], it was pembro, for example. This real hope of really important transformational innovation coming out of that merger and of course, Zontivity is now being launched albeit for a different indication.

David Risinger - Morgan Stanley - Analyst

Great. Yes, a question here.

Unidentified Audience Member

Can you shed some light on your future plans in terms of anything that’s in your oncology pipeline? And also given that there are a lot of smaller firms working on cancer research, in your opinion, what do you think -- what kind of characteristic would you consider to be a good fit for Merck?

Ken Frazier - Merck & Co., Inc. - Chairman & CEO

So part of our focused strategy as we have declared certain areas oncology being among them that we are going to focus going forward and where that really has salience is as you look across the constellation of business development opportunities, we want to find opportunities in those areas where we see an opportunity to be leaders. So we want to build on what we think is a very, very productive foundation that is being laid with respect to pembro in the cancer field. Obviously, there is a competition for those kinds of assets. We are looking at many assets right now. We are considering whether those are the right kinds of assets to have bolt-ons to the Company’s strategy. Then I will turn it over to Roy.
Roy Baynes - Merck & Co., Inc. - SVP, Global Clinical Development

Sure. So we have been obviously very impressed with the monotherapy activity and as Ken says, our strategy is to define the role of monotherapy and to move it proximal in lines of treatment. In parallel with this, clearly there is a huge amount of biology to be understood and so we are trying very hard to understand who the right patients are, who should be treated, how do patients fail when they do fail and thus far fortunately it’s a minority of patients that actually progress on treatment, but understanding that and those types of biologically informative measurements will help us decide logical combinations. We have a number of ongoing internal programs looking at potential combinations. Just to mention a few, we clearly have our interferon program, which has been a very active drug in melanoma. We clearly are exploring that combination. We have just recently moved our GITR program. This is a glucocorticoid-induced tumor necrosis factor receptor. This is a co-stimulatory pathway. We moved that into the clinic.

But as we think about combinations going forward, we’re really focused on really four major buckets and again, we are trying to do this in a biologically informed way. Firstly, is there any place for putting immunotherapy together with standard therapy? And by that, we mean chemo, radiation, potentially combinations of those two. And the theory here would be that you have an increased antigenic presentation, if you will, after such treatments. So the question there is it good to put these two together, is it good to do it in sequence. We are exploring that.

The next key area that we are looking at is in combination with, in fact, targeted therapies. And there has been, as you know, an explosion of targeted therapies. They are all interesting. Unfortunately, the majority of them have transient effects and usually resistance mechanisms kick in after that. But you can imagine we would be very interested in looking at these combinations and importantly, we are seeing the targetive therapies oftentimes have effects on the expression of PD-L1 and other ligands. So there might be some interactions between treatments and actually the immune system.

The third big bucket that we are thinking about is obviously putting immunologically active agents together and the two key questions there are if you put two checkpoint inhibitors together, do you get an additive or synergistic effect? And if you put a co-stimulatory molecule together with a checkpoint inhibitor, could you, in fact, get again synergy or additive activity. And again, we need to do this in a translationally savvy way to be sure that we understand the biology because otherwise it’s very hard to really learn anything from this.

The fourth big bucket relates to other methods of increasing tumor antigenicity and so we are very intrigued by the possibility of looking at checkpoint inhibition together with, for example, oncolytic viruses or indeed other tumor vaccine type approaches. And you’ve probably seen some collaborative deals that we’ve mentioned around this. So that is broad strokes how we are thinking about the combinations. As Ken mentioned, we have a very active business development group. We are looking at all assets all the time and anything that makes good biologic sense and particularly if it’s got good preclinical or clinical data, we are very interested in.

Unidentified Audience Member

You guys are very optimistic about your hep C strategy and when you come to market, what is going to be your strategy? You are going to be two years behind everyone else and there’s going to be very high emphasis on safety with combo. Is it just the market is going to be big or are you going to price lower or do you have a unique efficacy that you are going to bring to this (inaudible)?

Roy Baynes - Merck & Co., Inc. - SVP, Global Clinical Development

So as we think about hep C, I think we have a number of very exciting assets. So internally, we have a protease inhibitor, which is probably the most potent and probably one that addresses resistance factors better than any others. We also have a very nice NSSA, which is very active. This combination is 5172 -- 8742 and these two combinations together are looking extremely promising. You’ve seen data presented on that already.

Now the big question is can we get to a pan-genotypic, that is to say regardless of genotype, short course cure of this disease because ultimately that is really the goal, an all oral, non-interferon, non-ribavirin, pan-genotypic short course curative therapy. We are doing a proof-of-concept study right now where we’ve put sofosbuvir or Sovaldi together with our MK-squared combination, that is our PI and our NSSA, and in the genotype 1 situation in the non-cirrhotic patients, we are looking at four and six weeks of treatment. In the cirrhatics, we are looking at six and eight weeks.
and in genotype 3, we are looking at 8 and 12 weeks. So these would be marked shortenings of standard treatment courses if indeed this were to be successful.

If this is promising, we would be very eagerly moving forward with our own nuc to substitute out for Sovaldi. We basically use Sovaldi as the stalking horse, if you will, to really establish proof of concept so that we can then move our own nuc forward at that time. So I think it is a pretty solid strategy.

Adam Schechter  
*Merck & Co., Inc. - EVP & President, Global Human Health*

It's a solid strategy. In terms of the market, there is a very significant number of patients with hepatitis C in this country, but also around the world. There is only so many patients that can be treated in any given year based upon the number of specialists who actually are treating hepatitis C. So we think the number of patients that will still be available two years from now, even five years from now will be very significant and just like in every other class, having multiple competitors in a large class, there is room for success for multiple products.

Unidentified Audience Member

So last year, you announced a very large share repurchase program with products more than 50% funded with debt. Do you see the balance sheet as capable of supporting some more type initiatives or do you intend to fund share repurchases going forward with free cash flows?

Ken Frazier  
*Merck & Co., Inc. - Chairman & CEO*

Well, without saying what we will do going forward, I have to say that we have opportunities, particularly with the sale of MCC, to think about how to use those kind of proceeds in a way that is going to create the most shareholder value. You saw us go out and do the deal with Idenix. We thought that was a good use of capital given our focus in hepatitis C. I think what you could expect us to do going forward is to continue to return cash to shareholders in a way that we think is shareholder-friendly. We’ve returned $9 billion over the last 12 months ending in June and I think we see ourselves as continuing to do that, but we’ve always said that the first call is to fund important internal programs like our immuno-oncology program.

Our second call is to continue to build the Company for the future through business development because you are not going to be able to grow if you don’t get access to the best outside science and technology and then we want to have the ability to look at our shareholders and say we have done the right kinds of things to be shareholder-friendly. So without being more specific about our plans going forward, I don’t expect that Merck will behave significantly differently than it has in the past with respect to capital allocation with the exception of perhaps accelerating some of the bolt-on acquisitions.

Unidentified Audience Member

You announced moving into an allergy immune therapy as a kind of new exciting area for you guys. How do you see that with (inaudible), how do you see that evolving in the future?

Ken Frazier  
*Merck & Co., Inc. - Chairman & CEO*

We talk about all the new approvals and the fact that we have more this year than any time since 2006 and I should've said Grastek and Ragwitek because those are important too.
Adam Schechter - Merck & Co., Inc. - EVP & President, Global Human Health

So we've launched Grastek and Ragwitek in the United States, but we launched after the allergy season, so it was really a soft launch. It is all about educating physicians right now, focusing on the allergists as we speak. The key is going to be how can we get patients to come into the office prior to the allergy season so that they begin therapy before they have the allergies and then there will be long-term utilization. So we are continuing to promote the products. We are discussing those with the allergists right now and we will have a much better sense of the magnitude of the success as we go into the next grass and allergy seasons.

Unidentified Audience Member

How is your projection for the sales (inaudible)?

Adam Schechter - Merck & Co., Inc. - EVP & President, Global Human Health

I'm sorry?

Unidentified Audience Member

Your projections for sales in the (inaudible)?

Adam Schechter - Merck & Co., Inc. - EVP & President, Global Human Health

Yes, so we don't give specific projections of products that we are just launching, but I will say we are continuing to really focus on doing the best we can with this launch. We are also excited about the future where we've got dust mites and that immunotherapy, which I think can be another exciting opportunity for us.

David Risinger - Morgan Stanley - Analyst

So I think we've run out of time. Let me turn it over to Ken to wrap up.

Ken Frazier - Merck & Co., Inc. - Chairman & CEO

So as the clock has hit quadruple zeros, I will be very brief. The investment case in Merck has always been and will continue to be around innovation. I am very pleased to see that we have momentum. I am very pleased with the leadership that we have in our scientific organization and I'd say that if you watch the Merck space going forward, I think you are going to see really good things happening in the invention space. So thank you very much.

David Risinger - Morgan Stanley - Analyst

Thank you.
DISCLAIMER

Thomson Reuters reserves the right to make changes to documents, content, or other information on this web site without obligation to notify any person of such changes.

In the conference calls upon which Event Transcripts are based, companies may make projections or other forward-looking statements regarding a variety of items. Such forward-looking statements are based upon current expectations and involve risks and uncertainties. Actual results may differ materially from those stated in any forward-looking statement based on a number of important factors and risks, which are more specifically identified in the companies' most recent SEC filings. Although the companies may indicate and believe that the assumptions underlying the forward-looking statements are reasonable, any of the assumptions could prove inaccurate or incorrect and, therefore, there can be no assurance that the results contemplated in the forward-looking statements will be realized.

THE INFORMATION CONTAINED IN EVENT TRANSCRIPTS IS A TEXTUAL REPRESENTATION OF THE APPLICABLE COMPANY'S CONFERENCE CALL AND WHILE EFFORTS ARE MADE TO PROVIDE AN ACCURATE TRANSCRIPTION, THERE MAY BE MATERIAL ERRORS, OMISSIONS, OR INACCURACCIES IN THE REPORTING OF THE SUBSTANCE OF THE CONFERENCE CALLS. IN NO WAY DOES THOMSON REUTERS OR THE APPLICABLE COMPANY ASSUME ANY RESPONSIBILITY FOR ANY INVESTMENT OR OTHER DECISIONS MADE BASED UPON THE INFORMATION PROVIDED ON THIS WEB SITE OR IN ANY EVENT TRANSCRIPT. USERS ARE ADVISED TO REVIEW THE APPLICABLE COMPANY'S CONFERENCE CALL ITSELF AND THE APPLICABLE COMPANY'S SEC FILINGS BEFORE MAKING ANY INVESTMENT OR OTHER DECISIONS.

©2014, Thomson Reuters. All Rights Reserved.