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MRK - Merck & Co Inc at UBS Global Healthcare Conference

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PRESENTATION

Marc Goodman - *UBS - Analyst*

Good morning, everybody. Welcome back to our third day at the UBS Healthcare Conference. I am Marc Goodman; I do large cap pharmas and specialty pharmas, and we are going to kick it off this morning with Merck. And thank you very much, Adam Schechter, who is President of Global Human Health. You were here last year and thank you for joining us again.

And before we hopped on, you were telling me how you've been traveling around all over the world talking to all the different customers and employees and I guess maybe you can just begin by what are you hearing, what's going on, what's interesting, the feedback.

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

Absolutely. So good morning, everybody. It's a pleasure to be back. Marc, thanks for inviting me. I always appreciate having a chance to talk with you and give you a sense of what's happening in the industry, but also with Merck.

And right now, it's an exciting time to be at Merck. We have strength in our core areas in diabetes, hospital acute care, oncology and vaccines, and we also have some exciting launches with Keytruda and Zepatier, as well as others. And what I've been doing is going around the world to many countries. I've been in Italy, UK, parts of Asia, Latin America over the past several months, and when I typically go to the markets, I spend time with employees to find out how the business is doing in general, but then I spend time with government officials and I spend time with key opinion leaders and so forth, and I would say the general mindset that I see is that healthcare cost in almost every country around the world are either too high or growing too fast.

And every Minister of Health, Minister of Finance, Minister of Economy is worried about the growth in overall healthcare costs. And they are worried over time that they won't be able to invest in infrastructure, and roads, and bridges, and education if healthcare costs continue to grow. So part of our message to them is that we want to be part of the solution. We want to show how the 10% or 12% that they spend of their healthcare costs on pharmaceuticals or vaccines could actually, over time, reduce the other 80% of their spend in healthcare. And that's why a big focus for our industry has to be showing how the effective utilization of our products can actually reduce other parts of the healthcare budget.

Now it's easy to say. The issue is that most of these politicians are thinking in three or four-year terms, so they don't necessarily think, well, if I can reduce costs 10 years down the line, I should invest in that today. They are thinking what will happen in four years from now if I invest in healthcare today.

So what we have to do better is convince people to think a bit longer term, but also if there's a way to show them short-term ways to reduce overall healthcare costs by either effective utilization of our products, I think it will be even better for them to try to get their arms around. So I spend a lot of time with these ministers talking about why the use of vaccines for prevention or the use of products to prevent heart attacks in the future can actually help them with the biggest issue I think that they are facing, frankly.



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Marc Goodman - UBS - Analyst

Let's pivot to the -- how you think about allocating resources across the world and by franchise I suppose is probably how you run the business. But talk about where you've been increasing resources, where you are decreasing resources and how we should be thinking about the next year or two and how you are thinking about it.

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

Yes, so, obviously, resource allocation is one of the most important things that we do and the way that we are organized is we have -- commercially, we have four core areas -- vaccines, hospital specialty, oncology and diabetes. And first and foremost, we make sure that we fund those in order to win and to grow.

At the same time, we have 10 markets around the world that represent about 75% of our revenue. So in those 10 markets, you have to win. So you focus on the top 10 markets and allocating to your top four growth areas, and then the rest of the world you try to titrate to make sure that you have different types of models, new models, multi-channel marketing capabilities, in some of the smaller markets, distributorships. But it really is making sure that you invest to grow. And it has to be about putting your best investments behind where you think your best growth opportunities are.

Marc Goodman - UBS - Analyst

So let's talk through some of the franchises. Obviously, diabetes has always been a big one. Obviously, the Januvia franchise. Tell us what's going on there. I think most of us are surprised at the strength of that franchise, the resiliency of the franchise, the durability. Are you surprised and how do you keep it going?

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

Yes, so we are very excited that we continue to show strength in our Januvia franchise. If you saw first quarter ex-exchange we grew 4%. And if you look at underlying prescription volume in the United States, for example, you see about 5% new Rx volume growth year-over-year and the best way to look at our performance is to look at the underlying prescription volume growth, not to look at dollars in any one quarter because there's different things with buy-in, buyout price increases, timing and those things.

So if you look at our underlying volume growth, it's very strong and we are excited about the potential to continue to grow the franchise. I think there's three things that allow the Januvia franchise to continue to grow. Number one, it's a good product, and physicians have been using it with millions of patients for many years. They are very comfortable with the profile in both efficacy and safety and they are just used to prescribing it. It is now a staple of what they use for type II diabetes.

The second reason is we continue to put significant resources behind the diabetes franchise and I remember back even in 2013 people would say are you going to continue to invest in the franchise. And we said we actually are going to increase our investment, and diabetes if you look over the past few years has been an area that we continue to invest significantly in both promotion, but also salesforce, and I think that that has helped us to continue to grow.

And I think the third reason is that most companies with DPP-4s, which is the class where Januvia competes, have pulled away from that class and actually moved resources to the SGLT2s, and we see a lot of SGLT2 infighting within that class, but there's not a lot of companies that are still promoting the DPP-4 class and I think that's because of the strength of Januvia. So in the United States, we still have about a 75% marketshare within the DPP-4 class if you look at new Rx's.

So I think for those three reasons, we expect the franchise to continue to be strong. I've say that we expect Januvia to grow in 2016, and we continue to have very good managed care access, which has worked in our favor.



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Marc Goodman - UBS - Analyst

So are you spending more resources this year than you did last year on the diabetes franchise?

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

So we haven't given exact numbers for the exact resources by franchise, but if you look at it in general, we are spending about the same.

Marc Goodman - UBS - Analyst

About the same. And then talk about the SGLT2 versus the DPP-4 and what you are hearing out there.

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

Yes, so if you look at the SGLT2 class, what we had been seeing is that it's typically an agent that's used after DPP-4, not instead of DPP-4s. Obviously one of those products has had a positive cardiovascular outcomes trial result. What we are hearing about that is physicians want to wait to see if the next cardiovascular outcomes trial in that class is positive before they say we understand that this class may have overall cardiovascular outcomes. They don't understand exactly the mechanism that would have led to such a separation in the first cardiovascular outcomes trial.

The second thing we hear is that even with DPP-4, they always knew that they needed another oral possibility and that's why we began to work with Pfizer to develop an SGLT2 and an SGLT2 combo with Januvia. So we've always thought that the SGLT2 class would be a nice complement to the currently available oral anti-diabetic agents. And we believe that as it moves into the future that they'll still continue to be used third line unless there's other positive cardiovascular outcomes trials that show benefit along with label changes and along with guideline changes.

If those three things happen, then you may start to see some utilization as a second-line therapy versus mostly today as a third-line therapy. And that's why we are glad to have an SGLT2 and ultimately an SGLT2 in combination with the best DPP-4 inhibitor in terms of marketshare in the US. I think could be a strong target if those three things happen over time.

Marc Goodman - UBS - Analyst

And has that become your lifecycle extension strategy so to speak because I know that you pulled back from pushing the once weekly (multiple speakers)?

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

Yes, so we had a product in development for once-weekly DPP-4. We decided not to continue that in the United States, albeit it's doing very well in Japan, because it would have launched within six months or a year of our SGLT2 and our SGLT2 combo with Januvia. We think the better place to focus our resources is on an SGLT2 in combo with Januvia, and the primary reason why is because we had such a high marketshare of the DPP-4 class, it would probably just cannibalize our own Januvia sales as opposed to having a new class that we can go into with the combination with Januvia where, if the outcomes trials are positive, guidelines potentially change or labels change, we think could be a very important class for the future.



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Marc Goodman - UBS - Analyst

So let's switch gears to oncology, obviously very important, fast growing. Talk about I guess where we are right now. Bristol is out. You are out. Obviously, Roche -- change is coming. Before we even move to the change, talk about what we've seen so far, your share of the market, how you think that's going to change, commentary around testing. Let's start there.

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

Sure. So I'll back up just a moment and then I will answer the question specifically. But who would have ever thought we'd be sitting here today talking about immuno-oncology products that show promise in 20 cancer types. So if you look at ASCO and you look at our PD-L1, we are going to show activity in 20 different cancer types. I think it's just a remarkable time in the oncology world.

And if you go back -- I've been in this industry since 1986 -- and I remember when HIV was such a problem where, in a hospital, you'd gown up and put close on and you were afraid to be with a person with HIV. And today, people are living so long, we worry about people with diabetes and cholesterol that also have HIV.

Who knows where this will lead, but it feels like we could be on the beginning of something very important medically where someday our grandkids might think about the word cancer very differently than our grandparents. So I just think it's a very important, exciting time to be in the oncology field.

If you look at what's happening in the marketplace, it's exciting to be able to sit up here and talk about the two products in the marketplace because when we were together four or five years ago, we were saying -- you asked me, Adam, BMS is ahead of you by four years, how are you going to ever catch up. So I think our team has done a really nice job in our research labs to put a program together that was very sophisticated that allowed us to get to market quickly. So we were actually the first one to launch in melanoma in the United States.

If you look at where we are with melanoma right now, we are still the market leader in the United States if you look at TRx share, and if you look at most parts of Europe, we are the market leader in melanoma. Now melanoma is a smaller market versus lung. If you look at lung cancer, we are not the market leader; one of our competitors is the market leader. And I think there's a couple reasons why. The first reason is the drugs are only indicated right now for second-line therapy. And for second-line therapy, we recommend for our product and label that you do a PD-L1 test. If positive, then you can treat with KEYTRUDA. The competition says anybody that's failed in first line, all comers, you can be utilized for second line. So we are spending a lot of time educating the marketplace on the importance of PD-L1 testing.

I think over time that will work in our favor because if you look at first-line lung, I think everybody is going to be talking about testing for PD-L1. Right now, about 30% of lung cancer patients are being tested for PD-L1. The majority of those are actually for first-line treatment. So it's already moving in that direction. But in second line, when somebody tests positive for PD-L1, we are getting the vast majority of those patients on Keytruda. So we will see how this plays out.

What I've told people is I don't think you should look at this as one company versus the other. I would look at this as a very big market where we are showing potential in so many different tumor types, in so many different combinations that there will be lots of room for many different products in this class to grow. And I look at like the anti-TNFs where you have Remicade, and Simponi, and Humira and Enbrel. They are all big, fast-growing products. One might be doing better in one indication than the other, but overall they all do pretty well. I think you'll find the immunotherapy class like that as well.

The issue really becomes there are so many new products in development so you've got -- we have four products in clinics in addition to Keytruda today. So we've got a GITR, an IL-10, a cCAM and when you look at those products, you don't know exactly which combinations are going to be the best and which cancer types are going to work the best, so this is going to play out over 10 years. It's not going to play out in any one quarter, and I'm glad that we are significantly invested here.



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So we have over 120 combination trials underway. We've got over 200 trials underway overall. So there's going to be so much data and so much information over the coming years that it's just going to be a remarkable area to be involved in.

Marc Goodman - UBS - Analyst

So with the big cancer meeting coming up this weekend, I should say a week from this weekend, talk about two or three things that we should be focused on.

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

Well, I would look at how many different cancer types the IO agents are beginning to work in. I think that will give you a sense of the magnitude of how important the products can be, and you'll see there's data in over 20 different cancers where we see activity. I think that's remarkable.

The second thing is you are going to see starts of combination data. It's still very early. People don't know if it's IO plus chemotherapy, if it's IO plus IO. You will see data from us from IO with chemotherapy that looks very interesting, albeit very early. But we are doing studies in IO plus IO, IO plus chemotherapy and all different combinations.

So I would just start to look at those combinations. Nobody can tell you -- if anybody tells you for certainty which ones they think are going to work the best, they don't know because we have to wait for the data. We have to see how this plays out over time. And then you'll start to see things like our melanoma data, which shows long-term survival data over two years, which who would have ever thought you'd be talking about advanced melanoma patients three years of survival data.

So it's exciting to see the durability that we are starting to see. It's just the beginning. It's still very early. It's exciting to see the combination therapies, and it's exciting to see the number of cancer types with these drugs may be impactful.

Marc Goodman - UBS - Analyst

So just back to first-line lung. We are going to get the data very soon right? And so we will get this approved pretty quickly and then what you are saying is that because of the testing this is going to work to your advantage basically when this kicks in next year?

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

Well, what I would say is, so let's see the data. Let's see the response rates and so forth. I think that in first-line lung let's see the timing. Being first-to-market or second-to-market does matter in a class. Anybody that tells you it doesn't matter is probably not going to be first to market, so it does matter.

Let's see the timing and when products are approved, and then I do believe over time all lung cancer patients will be tested. I think for first-line in particular, they will want to do BRAF testing and they will want to do other testing in addition to PD-L1 prior to initiation of any lung cancer treatment for first-line. And because we've been the ones bringing the PD-L1 testing to physicians, I think they will be much more appreciative for us doing that once they realize for all first-line patients, it probably makes sense to do that. And I think that the labels for all of the products will probably recommend that. We will see.

Marc Goodman - UBS - Analyst

So let's pivot to hepatitis C, Zepatier, which is still in its infancy, I guess, on the market. Talk about where your share is coming from, what your strategy is and how your strategy evolves in a year or a year plus when you have another generation version out that's completely different from a competitive perspective.



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

Yes. So if you look at the hepatitis C market, this is a market that Merck has been involved in for a very long time, so it's a market that we know well, but it's also a market that has seen such fundamental change over the past 10 years. I can't think of any market that has seen so much change.

When we launched Victrelis not that long ago, we said, boy, a 30% cure rate, who would ever think you'd be able to get to these types of numbers. And then very shortly after, we are now seeing cure rates in the 90%. So it's an exciting time to think about the possibility to eliminate hepatitis C if we really find a way to do that in countries around the world.

But at the same time, the marketplace has changed pretty significantly and we came in with Zepatier. We think we have a competitive product profile to the market leader. So that's the first thing is we believe we have a competitive product profile. When you have a competitive product profile, what you want to do, our strategy, is to get equal access on managed care formularies to the other two. We are not looking for exclusivity. We are looking to have equal access. This way we can fight for marketshare in the marketplace.

We missed the cycle to some degree for this year's formularies. We may have some wins in the upcoming future for this year, but a lot of the cycle will be for formularies as you go into 2017. But with that said, we are already starting to see prescriptions. It's too early to give you an exact understanding of where they are coming from. We think a lot of them early on will come from renally-impaired patients where we have an advantage versus the competition. And then over time as we have equal access on formularies, including the Veterans Administration -- albeit the VA does not necessarily get tracked by IMS in prescription volume -- but we will see prescriptions starting to come in -- we will see dollars starting to come in from the VA, and then we will see prescriptions starting to come across genotype 1 and genotype 4 in addition to the renally-impaired patients. So over time, we think that we have a competitive product that we can compete in the marketplace pretty successfully.

Marc Goodman - UBS - Analyst

So the way you are fighting for access right now is really for 2017, as you mentioned. So does that mean whatever you do for the product this year, we should be thinking, yes, it should do better next year with better access? Is that -- everything else stays equal?

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

Yes, I think we will get some access this year, but it won't be as much as we would like. In 2017, hopefully -- we are going through a lot of those discussions as we speak.

Marc Goodman - UBS - Analyst

Right, now, yes.

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

Hopefully, we will be able to get even broader access and therefore, you would expect to do better in 2017 and 2016, but we are not giving any specific guidance right now particularly on 2017. We have to see where we end up with the formulary, where we end up with the access. But I think that we are certainly making some progress.

Marc Goodman - UBS - Analyst

Does anything change from your strategy when you have the next-gen version?



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

So right now, I think you have to focus on each product in the marketplace based on what you have. Let's see what the data of the next generation products look like. We have a competitive product today in the marketplace. If you look at our cure rates, they are between 94% and 97%, and if you do [RAF] testing, we saw in that patient population you are able to get almost 100% cure rates based upon the data on our label.

So we have a pretty competitive product for type I and for patients today, which is the vast majority of the patients. So we are going to maximize the opportunity before us. Let's wait to see the data for the next-generation products. I think there will always be a place for Zepatier, particularly in renal patients because we have that advantage. And then the question will be, over time, where do the next products that come into the marketplace fit in. For example, can you get more pangenotypic product with simple dosing?

Marc Goodman - UBS - Analyst

You started out discussing how you've been traveling around a lot. I'm curious what's going on in some of the emerging markets. It seems when you read the papers, a lot of these economies have slowed a lot. These are places where there's a lot of out-of-pocket spending on drugs, so curious how that's going and maybe you can talk about obviously China is one of the larger ones, if not the largest.

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

Yes, so I spend a lot of time in emerging markets as you can imagine, and the first thing I'd say is lumping them together is a problem because if you look at the problems that Brazil is having today, it's a very different than things that are happening in Peru or Argentina.

If you look at what's happening in China today, it's very different than what's happening in say Russia. So the first thing I would do is I'd separate them a bit and I look at what are their economies, how are their economies doing, what percent of their sales are coming from the public versus private market. How much is out-of-pocket for patients. So if you see an economy that is struggling and you know a lot of the marketplaces out-of-pocket where people have to pay out of their own pocket, you can have a pretty good sense it's going to be a tough market for a while. So I try to separate them a bit.

In general, I've always said that the emerging markets are going to have ups and downs. They are very, very volatile to some degree, but over time there will be much more ups than downs. So I still believe that the emerging markets are important for us to invest in. I believe that there are growth opportunities. We grew 11% in the first quarter in China. If you exclude Venezuela, we grew over 4% -- it was 5% in the emerging markets overall ex-exchange.

So we are still seeing growth there albeit it's slower than what we've seen in the past, but you have to really go market by market and figure out where your best growth opportunities are. In some markets, you might pull back a little bit, but we are not planning to exit necessarily any of those markets. And then when the economies come back and middle classes will continue to grow, then you continue to increase your [support].

Marc Goodman - UBS - Analyst

What's driving the growth in China? What are the key products over there?

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

Yes, so interestingly in China, a lot of our brands that we would think of as older brands in Europe and United States continue to do well like Primaxin and Zocor and Singulair. At the same time, we do have approval for products like Januvia and Noxafil, and those products are starting to do well. The issue in China is the NRDL, which is the reimbursement authority, hasn't listed new products for I think it's over seven years now. So it's been



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a long time since new products have been reimbursed. A lot of those new products are being paid for out of pocket, but they don't represent a significant opportunity until NRDL provides pricing for those.

So I think over time our new products, like Januvia in China, will represent a bigger portion of our total revenue in a market like that. But today it's based upon products that are like Zocor, Primaxin and those products.

Marc Goodman - UBS - Analyst

So obviously pricing in the United States is a hot topic, whether it's election season or whatever it is, but I'm curious when you just step back from all the noise and forget about election season, there's obviously change going on behind the scenes. There is a new type of pricing models that are being discussed and I'm just curious as you are out talking to the different payors, what are they saying to you? Like, hey, Adam, we would really like Merck to be doing this type of thing next year. What are you hearing and where are we evolving to?

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

Yes. So if you look at pricing in the US market, there is no doubt that this year is harder and there's more pressure than last year and next year will be harder and more pressure than this year. The question is do you see a step change that's going to happen over time. I don't know if that's going to happen necessarily, but you do see a lot more discussion about these different types of models and are there different ways for us to work constructively together.

I'd say there's three issues that are preventing that today. One is the ability to monitor patients and electronic medical records that could be used across different parts of the healthcare system are not sophisticated. So if I wanted to go into a pay for quality, number of patients to get their HbA1c down to certain levels or do you get cholesterol levels to the right level for people, it's very hard to implement that in the United States because you have a hard time following and tracking patients within a system and hospitals and so forth.

The second issue is that there are so many different products out there and different companies that if every company tries to do something different, you can imagine the managed care plan trying to figure out how to implement that. So there's no consistency yet that a managed care plan says here is what we are looking to do, let's try to see if we can do this with a lot of different companies in a similar way. If you have a very disparate system and you have everybody trying something a little bit different, you can do pilots, but it's hard to execute that on a broader level.

And then the third thing that is that pharmaceuticals still represents a very small part of the overall healthcare budget, so how much time the payors are willing to spend on that to track things versus other quality type of metrics is something that we have to work on.

With all that said, we are excited to try new things and I am always willing to pilot and to try new things with our customers. And Merck has always been at the forefront of saying let's see if there's a way to develop a new type of model. I believe in the future we will need different pricing models than what exists today and we will have to find more constructive ways to work with payors to ensure that the drugs and vaccines are used in an appropriate manner, but have broad access where necessary. So I think we have to find new ways to work together, Marc.

Marc Goodman - UBS - Analyst

It's interesting to think that you actually used to own a PBM years ago. It wasn't that long ago, I guess.

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

It wasn't that long ago. I was there for that. And I think we have to find new types of ways to work with customers. And frankly, it's sometimes easier in other parts of the world where they have national records and national electronic medical records. In smaller countries, you can actually be a little bit more creative today.



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I think with the IDSs and the certain systems that are becoming more closed and incorporating hospitals along with primary care and specialists, I think that in the future we will be able to do some new different pricing models and I actually look forward to that because the best thing we can do is ensure that we do everything we can within our industry to show who's most likely to respond to our product and that we work with our customers to ensure that the people that are most likely to respond are the ones that get it. And that's why I embrace PD-L1 testing. I embrace personalized medicine. I embrace trying to find out who is most apt to respond because I think we have to help payors figure out how to best utilize their healthcare dollars.

Marc Goodman - UBS - Analyst

Everyone must be watching what Novartis is going through right now with their new cardio drug, right, and what they are needing to do, and I guess the question is let's just say your CTEP works. Do you think this is the new normal, that you will have to do this as well? Maybe we should explain what we are talking about, but (multiple speakers)?

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

I think that our strategy is not only to be successful in specialty areas like HCV and oncology, we want to continue to be in primary care and to find medicines that will impact millions and millions of people around the world. I think in primary care the models may be different than in hospital specialty. I still think the Novartis compound is to some degree a hospital specialty product and I do think you need models there that are a bit different.

CTEP, if that makes it, which we hope it does, I think that will be more of a primary care product. And in primary care, as long as you get the right cost benefit if you can show on top of standard of care that you can reduce cardiovascular events and you can reduce morbidity and mortality, I think there will be a very broad market for that, particularly in primary care.

Marc Goodman - UBS - Analyst

Well, we are out of time, unfortunately. Thank you very much for joining us. We will go downstairs for a breakout. We can talk more and answer everyone's questions. Thank you.

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

It's a pleasure to be here. Thank you.

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