THOMSON REUTERS STREETEVENTS

EDITED TRANSCRIPT

MRK - Q1 2016 Merck & Co Inc Earnings Call

EVENT DATE/TIME: MAY 05, 2016 / 12:00PM GMT

THOMSON REUTERS

CORPORATE PARTICIPANTS

Teri Loxam *Merck & Co., Inc. - IR*

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

Rob Davis *Merck & Co., Inc. - EVP, CFO*

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

Roger Perlmutter *Merck & Co., Inc. - EVP, President Merck Research Laboratories*

CONFERENCE CALL PARTICIPANTS

Geoff Meacham *Barclays Capital - Analyst*

Steve Scala *Cowen and Company - Analyst*

Tim Anderson *Bernstein - Analyst*

Colin Bristow *BofA Merrill Lynch - Analyst*

Alex Arfaei *BMO Capital Markets - Analyst*

Jami Rubin *Goldman Sachs - Analyst*

Amlin Selveraja *Citigroup - Analyst*

Tony Butler *Guggenheim Partners - Analyst*

Chris Schott *JPMorgan - Analyst*

Seamus Fernandez *Leerink Partners - Analyst*

Jeff Holford *Jefferies LLC - Analyst*

David Risinger *Morgan Stanley - Analyst*

Vamil Divan *Credit Suisse - Analyst*

Marc Goodman *UBS - Analyst*

PRESENTATION

Operator

Good morning. My name is Darla and I will be your conference operator today. At this time I would like to welcome everyone to Merck's Q1 2016 sales and earnings conference call. (Operator Instructions) Thank you.

I would now like to turn the call over to Teri Loxam. Please go ahead.

Teri Loxam - *Merck & Co., Inc. - IR*

Thank you, Darla. Good morning, everyone. Welcome to Merck's first-quarter 2016 conference call.

Today I'm joined by Ken Frazier, our Chairman and Chief Executive Officer; Rob Davis, our Chief Financial Officer; Adam Schechter, President of Global Human Health; and Dr. Roger Perlmutter, President of Merck Research Labs. Before I turn the call over to Ken I want to point out a couple of items.

First, you will see that we have items in our GAAP results, such as acquisition-related charges, restructuring costs, and certain other items. You should note that we've excluded these from our non-GAAP results and provided a reconciliation of these items in table 2 of our press release. We've also provided a table to help you understand the sales results in the quarter for the business units and products, which can be found in table 3 of our press release.

Second, I would like to remind you that some of the statements we make during today's call may be considered forward-looking statements within the meaning of the Safe Harbor provision of the US Private Securities Litigation Reform Act of 1995. Such statements are made based on the current belief of Merck's management and are subject to significant risks and uncertainties. If our underlying assumptions prove inaccurate or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Our SEC filings, including Item 1A in the 2015 10-K, identify certain risk factors and cautionary statements that could cause the Company's actual results to differ materially from those projected in any of our forward-looking statements made this morning. Merck undertakes no obligation to publicly update any forward-looking statements, as you can see our SEC filings as well as today's earnings release on Merck.com.

With that I'd like to turn the call over to Ken.

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

Thank you, Teri. Good morning. Thank you all for joining the call today. We're off to a good start this year with our first-quarter performance.

Our Keytruda program expanded as we continued to launch this important cancer medicine around the world. Also in the first quarter, we launched our new hepatitis C medicine, Zepatier.

In addition to these ongoing product launches, our key in-line brands performed well, particularly Januvia, which continues to command predominant share within the DPP-4 class. Adam will provide context on this shortly.

We remain committed to delivering long-term growth and shareholder value. To do so, we will stay true to our goal of becoming the premier research-intensive global biopharmaceutical company, bringing forward medically important products that address many of the world's greatest health needs. And above all, it is critical that we do this in a sustainable manner that enables us to continuously reinvest in R&D.

Business development remains one of our most important priorities, and we are very actively engaged in finding the best external innovation that will help grow our portfolio and pipeline. We are confident that our scientific discernment coupled with financial discipline will allow us to identify and acquire the right assets at the right valuation to create long-term value for shareholders, consistent with our innovation strategy.

Before I conclude, let me also emphasize that we are fully engaged in the challenging policy environment that our industry experiences now. We are actively addressing the key policy issues that can have an impact on our ability to fund the discovery and development of the next generation of innovative and differentiated medicines and vaccines, most notably, pricing and tax reform in the United States.

We are engaging key stakeholders in the healthcare environment to seek constructive solutions and to ensure that they understand the therapeutic and economic value Merck's products and business operations provide.

In closing, we remain committed to our innovation strategy and are focused on advancing and augmenting our broad pipeline, both through internal and external means, as well as driving marketplace success with our launches and key in-line brands. And now I'd like to turn the call over to Rob.

Rob Davis - *Merck & Co., Inc. - EVP, CFO*

Thanks, Ken, and good morning, everyone. Our performance in the first quarter reflects our focus on execution and continued productivity improvements. We again delivered P&L leverage with growth, excluding exchange, on both the top and bottom lines.

Total Company revenues were $9.3 billion, a decrease of 1% year-over-year. Excluding the impact of exchange, first-quarter revenues grew 3% driven by both our Human Health and Animal Health businesses.

Venezuela negatively impacted Q1 revenues by approximately $240 million, reflecting the reduction of our operations in the country. As a reminder, we recorded $625 million of sales in Venezuela in 2015, which were more weighted to the first half of the year, so the year-over-year impact will be greatest in the first two quarters of this year.

Looking to the other parts of the P&L, non-GAAP gross margin was 77% in the quarter, an increase of 50 basis points versus the first quarter of 2015. Lower discards was the biggest driver of the year-over-year improvement.

Non-GAAP operating expenses of $3.9 billion was 3% lower year-over-year, or roughly flat excluding foreign exchange favorability. Higher promotional spend behind our new products drove a slight increase in marketing and administrative, while lower licensing expenses contributed to a decline in research and development. Taken together, we earned $0.89 per share on a non-GAAP basis in the first quarter, delivering 10% growth excluding exchange, which reflects our continued commitment to delivering a leveraged P&L.

Turning now to our outlook for the rest of the year, we are narrowing and raising our revenue and EPS guidance for 2016. While we are experiencing more favorable exchange rates versus our original guidance, we are facing a few headwinds, in particular the entry of generic Nasonex in the United States earlier than originally assumed, which we expect will partially offset the exchange rate favorability this year.

We now expect full-year 2016 revenues to be between $39 billion and $40.2 billion. This reflects an approximately 2% negative impact from foreign currency at mid-April rates. We continue to expect our non-GAAP 2016 product gross margin and operating expenses to be roughly in line with 2015, and we still anticipate the non-GAAP tax rate for the full year to be between 21.5% and 22.5%.

In terms of our 2016 EPS outlook, we are raising our non-GAAP EPS guidance range from $3.65 to $3.77. This reflects an approximately 2 percentage negative point impact from foreign currency at mid-April rates.

To summarize, we demonstrated strong performance, leveraging top-line growth to deliver 10% growth in non-GAAP EPS, excluding the impact of foreign exchange. We benefited from the contribution of new product launches while continuing to sustain growth in our key franchises and driving operational improvement across the Company.

With that I'll turn the call over to Roger -- I'm sorry, to Adam.

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

Thanks, Rob, and good morning, everyone. This morning I'll provide highlights on the Global Human Health performance for the first quarter and my comments will be on a constant-currency basis.

We're off to a solid start for the year. Total Human Health sales reached $8.1 billion, growing 2%, and we drove growth across our core areas of diabetes, vaccines, hospital and specialty care, and oncology. What I will do now is highlight a few of our key franchises and product launches, and I'll start with primary care.

The Januvia franchise had a strong quarter, growing 4% globally. In the United States sales grew 9%, driven primarily by volume increases and some benefit from customer buying patterns.

Outside of the US we saw strong growth in Europe and Japan, offset by emerging markets, which was impacted by Venezuela. Excluding Venezuela, Januvia franchise sales grew 5% outside of the US.

First-quarter results for Januvia demonstrate that we can continue to grow volume and retain strong market share of about 75% in the United States and 65% globally. We continue to expect global Januvia franchise growth, ex-exchange, in 2016.

Now I'll move on to our vaccine business. Sales of our vaccine portfolio grew 1% and reached about $1.3 billion on steady growth from Gardasil and pediatric vaccines, partially offset by declines in our adult shingles vaccine, Zostavax.

Zostavax sales declined in the first quarter, resulting from a weaker flu season in the US, which means that less people go to get vaccinated in general, but also the recent changes to ACIP recommendations for pneumococcal vaccines. We are actively working with customers to help them navigate the reimbursement for Zostavax and expect this to be less of a hurdle over time.

Global Gardasil franchise sales grew this quarter on continued strength from Gardasil 9 launch in the US. We are encouraged by the recent CDC publication that reported a significant decrease in vaccine-type HPV prevalence since the introduction of HPV vaccinations in the United States. The reduction was 64% in females age 14 to 19, and 34% in females age 20 to 24. If you consider that this reports its impact only through 2012 and does not yet include males, it becomes apparent that we really can make a difference to help prevent certain HPV-related cancers in the United States.

Next in hospital and specialty care, our acute-care portfolio performed well in the quarter on steady growth from antibiotics, antifungals, and Bridion. We are also pleased to be adding to our specialty care business with the launch of Zepatier.

Sales in the first quarter were $50 million. While we're still early in the launch, we are seeing positive signs that Zepatier will play an important role in the treatment of chronic hepatitis C.

Our team is working to secure access for Zepatier, with conversations currently ongoing with many different public and private payers. The addition of Zepatier to the formulary at the Veterans Administration and with other customers reinforces our belief that our payer and our pricing strategy will maximize revenue and market share, and it will also broaden and accelerate patient access. Customers value Zepatier's profile, which offers high cure rates across a diverse group of patients, and we continue to be enthusiastic about the opportunity for Zepatier.

Finally, in oncology we see significant potential for Keytruda, which positions us as a global leader in immuno-oncology. In the first quarter sales reached approximately $250 million, and they continue to be driven by our melanoma indications as well as early traction in the US in lung cancer.

We are working to integrate PD-L1 testing as part of the routine treatment of lung cancer, by continuing to demonstrate the value testing brings to physicians, to payers, and to patients. Testing rates in the United States continue to increase, which is important not only for our second-line indication, but we believe also for when we have a first-line indication.

We also see very strong performance outside of the US, which represented nearly half of first-quarter Keytruda sales. We're launching in melanoma in approximately 50 markets globally, and in some markets we are the market leader despite being second to launch. Given the strong survival results we've demonstrated in melanoma and second-line lung cancer, the early data we've seen in more than 20 cancer types, as well as the breadth and the depth of the Keytruda development program, we remain confident that Keytruda will become foundational to the treatment of cancer over time.

In closing, we're off to a good start in 2016. This year we'll have to offset generic penetration of products including Nasonex and Cubicin. However, our investments in Januvia and Keytruda and in Zepatier and other core areas are delivering results and positioning us for future growth.

Now I'll turn the call over to Roger.

Roger Perlmutter - *Merck & Co., Inc. - EVP, President Merck Research Laboratories*

Thanks, Adam. The momentum that our clinical development and regulatory groups established last year continues in 2016. I'll briefly review the highlights of the first quarter.

As has already been mentioned, beginning in January we obtained regulatory approval for Zepatier in Canada, the United States, and Switzerland. and speaking with hepatologists and infectious disease specialists, there is general enthusiasm for the high cure rates observed with Zepatier and the ability to use Zepatier in patients with compromised renal function, including patients undergoing hemodialysis.

Public health organizations are increasingly embracing the goal of large-scale elimination of hepatitis C infection, and we've been developing data -- some of which we presented at the liver meetings in Barcelona last month -- documenting the ability of Zepatier to assist in this process, including in very difficult-to-treat patients who suffer from opioid addiction.

As Adam indicated, we've successfully launched Zepatier in the United States and are seeking approval in many markets around the world. In the course of our European review for Zepatier, the European Medicines Agency cited Merck's third-party manufacturer for issues largely related to inadequate record-keeping and the need for improvement in their quality management systems. We're working assiduously with regulators to resolve these issues.

I should note that we do not believe that the problems identified at our third-party manufacturer affect the safety, efficacy, or quality specifications of the product, and we do not believe that these problems will affect the supply to the US market. Nevertheless, we take all matters related to good manufacturing practices very seriously, and we are working with regulatory agencies and the manufacturer to resolve these issues as expeditiously as possible.

We continue to believe that EU approval can be achieved according to the midyear timeline that we previously disclosed. However, our European launch will be delayed until the fourth quarter, or perhaps until the end of the first quarter of 2017, depending on how quickly these matters can be resolved.

While the registration process with Zepatier continues, we are also completing Phase 2b studies of MK-3682, our uridinyl nucleoside polymerase inhibitor when used in combination with Zepatier or in combination with another advanced NS5A inhibitor, MK-8408. Data from these studies which will emerge over the next few months will permit definitive selection of the appropriate registration-enabling regimens that will provide additional options for the estimated 150 million people around the world who are infected with hepatitis C virus.

During the first quarter our studies of Keytruda also advanced significantly. In April we announced that FDA has accepted our filing on a priority review basis for the use of Keytruda in patients with recurrent or metastatic head and neck cancer following platinum-based chemotherapy, with a PDUFA date in early August. This filing makes use of unit dosing at 200 milligrams every three weeks. We have shown that this dose yields exposures comparable to those observed using weight-based dosing; and unit dosing obviously relieves providers of the responsibility of calculating patient-specific dose volumes.

Our head and neck cancer filing is reinforced by an exceptionally broad array of ongoing studies in this disease, including a controlled second-line study, the KEYNOTE-040 study; our first-line study, KEYNOTE-048, which will provide data in 2017. We're also testing the use of Keytruda in combination with irradiation, with radiation plus chemotherapy, with the T-VEC oncolytic virus in collaboration with our colleagues at Amgen, and with an IDO1 inhibitor in collaboration with our colleagues at Incyte. A substantial amount of important new data from our Keytruda program will be presented at the American Society for Clinical Oncology meeting next month, including results in head and neck cancer patients who have failed both platinum and cetuximab therapy, and long-term survival data in melanoma patients from our original KEYNOTE-001 study.

Also in April we announced that the FDA granted a fourth Breakthrough Designation for Keytruda in the treatment of classical Hodgkin's lymphoma. As Margaret Shipp and colleagues from the Dana-Farber Cancer Research Center showed in a paper published last month in the Journal of Clinical Oncology, amplification of the chromosomal locus encoding both PD-L1 and PD-L2 ligands is very common in Hodgkin's lymphoma and may represent a critical factor in the malignant transformation of Reed-Sternberg cells, the characteristic cell type in this cancer. This observation may help to explain why the very high response rates following Keytruda treatment in Hodgkin's lymphoma patients are observed.

Meanwhile we continue to pursue registration for Keytruda in second-line lung cancer in Europe, and our KEYNOTE-010 study, which will improve understanding of how best to use Keytruda in this disease, is under review in the United States. You will recall that in the KEYNOTE-010 trial, Keytruda treatment meaningfully improved overall survival in patients with non-small cell lung cancer of any histology, where tumors expressed the PD-L1 biomarker in 1% or more of the tumor cells, as compared to what could be achieved using conventional docetaxel chemotherapy.

Our first-line study of Keytruda, KEYNOTE-024, comparing Keytruda treatment with platinum-based chemotherapy in patients with PD-L1 strongly positive tumors, remains on track to deliver data at midyear.

Finally, progress continues across a broad range of other programs. Bezlotoxumab, our therapy designed to reduce recurrences of C. difficile-associated enterocolitis, received Priority Review designation from the FDA with a PDUFA date in July. The FDA will hold an Advisory Committee meeting to review the bezlotoxumab filing on June 9, and our file is also under review in the European Union.

Clinical data are beginning to emerge for ertugliflozin which will support our comprehensive filing for this new molecular entity as both a single agent and in combination with Januvia or metformin by the end of the year. Separately the long-awaited adjudication of our Phase 3 odanacatib data is now almost complete. With these data in hand, we will at last be in a position to assemble regulatory dossiers supporting the registration of this important once-weekly treatment for osteoporosis.

And among the many programs for which considerable interest is expressed when I meet with external clinicians and scientists is our Phase 3 trial studying letermovir as prophylaxis for cytomegalovirus activation in patients receiving bone marrow transplants. We expect that data in-house from this study by the end of the third quarter.

Now I'll turn the call over to Teri.

Teri Loxam - *Merck & Co., Inc. - IR*

Thanks, Roger. Darla, I think we're ready to go to Q&A.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Geoff Meacham, Barclays.

Geoff Meacham - *Barclays Capital - Analyst*

Morning, guys. Thanks for the question. Just on Zepatier, wonder if you can go into a little bit more detail about where you are with the commercial formularies and what opportunities you have to expand that prior to the cycle next year.

Then also on hep C, on next-gen regimens, how much value do you guys place on a shorter four-week regimen in terms of a differentiation in the market? Thank you.

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

Hi, Geoff; this is Adam, and I'll start off with the update on Zepatier regarding how we're doing in the marketplace. I'll start by saying we really are pleased with the progress that we're making since the launch. We're still early in the launch, but we have been working really hard to secure access, and we have conversations ongoing across all segments, many different customers.

Many of them are for access in 2017, but some of those, such as the VA, we're hoping to have access some time in 2016. So it's still a little bit too early to give you exact accounts and names of accounts, but I can tell you that we feel good about potential access for 2017; and then we'll see where we end up for 2016, but I do think that there is opportunity there.

Then if you look at how we're approaching the marketplace, we really are focusing on having access. It's important that we have parity with the competitors, so we're spending a lot of time trying to get -- access that parity across the different segments in the United States so that there is physician and patient choice.

Teri Loxam - *Merck & Co., Inc. - IR*

Roger, do you want to answer the (multiple speakers)?

Roger Perlmutter - *Merck & Co., Inc. - EVP, President Merck Research Laboratories*

Well, I think with respect to shorter regimens, we'd love to be in a position to provide treatment that would massively shorten the regimen, because adherence is a problem in this patient population. Many patients who are infected with hepatitis C lead somewhat chaotic lives.

Unfortunately, I think there is really very little data to support the use of an oral direct-acting antiviral regimen in four weeks, and there are reasons to be concerned that that might not be possible. Over time, additional advances and other approaches which could, for example, involved long-duration implantable therapies and that sort of thing, could improve that. And there are, of course, other kinds of intervention, for example at the transcription level, that could help that.

But right now, four weeks seems like a reach.

Operator

Steve Scala, Cowen.

Steve Scala - *Cowen and Company - Analyst*

Thank you so much. A question for Dr. Perlmutter. All companies are analyzing I-O data with the FDA-required Cox stratified proportional hazard statistical test. However, Bristol implies that it analyzes I-O data in a unique way which emphasizes the non-proportional aspect of the I-O curve; and I guess in support of their view they have stopped more studies early than any other company.

It is also true that Bristol studies generally are longer than competitor studies. Does Merck understand what Bristol is doing? Does Merck believe it is doing the same thing? And if not, how is what Merck is doing different? Thank you.

Roger Perlmutter - *Merck & Co., Inc. - EVP, President Merck Research Laboratories*

Hey, Steve. There is no mystery here really. The mechanisms for statistical analysis of these kinds of studies have been refined over a period of many decades, and while the statistical literature continues to advance in ways that are quite intriguing, the reality is that we have a lot of data -- based on all of the prior studies that we've done with Keytruda, and with Opdivo, the studies that are been done and published with Opdivo as well -- that provide a substantial amount of positive predictive value. So in a Bayesian sense, one can predict outcomes fairly comfortably and we know, therefore, we can put that information into our power calculations.

We have pretty good understanding of where we're going and when we have to look. Of course, you can get surprises in different tumor types. But I guess one thing to stress is the general consistency of the responses that we've seen across a very large number of tumor types, both with respect to response rates and durability.

So we don't find it mysterious. I think the explanation for the early stopping of the Bristol-Myers studies is largely related to the size of the studies more than anything else, and there's nothing special about non-proportional analyses.

Operator

Tim Anderson, Bernstein.

Tim Anderson - *Bernstein - Analyst*

Thank you. On Keytruda, obviously you and Bristol will both have first-line data this year in lung, and that is in patients that need to be tested for the biomarker. Bristol, of course, points out that their testing encompasses a much greater proportion of patients than your testing.

I'm wondering how you see that playing out commercially. Won't it be an advantage in their favor, the fact that it will be applicable to more patients? Do you think that's going to make a difference?

Then, what were sales of Keytruda in the quarter in lung? So what proportion of sales were in lung?

And then, were there any wholesaler shifts or timing impact of purchasing that could have impacted what the results were? If I look at US sales they were flat versus Q4; internationally they continue to ramp. Is that reflective of demand in both geographies, or it was some timing issues?

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

Yes. Hi, Tim; this is Adam. If you look at Keytruda, as you said, we reported about $250 million of sales for the quarter, so we are now trending -- if you just look -- at about a billion-dollar product, just based on where we are today.

About half the sales were outside the US, half the sales in the US, and we continued to see growth in the US. There's really not inventory issues at any large degree for this product, frankly.

If you look at where sales are coming from, the vast majority of the sales are still coming from melanoma indications. And if you look at that, a lot of it is still coming in second-line, although we see first-line continuing to grow.

Internationally, the sales are coming primarily, obviously, from our melanoma indication.

As you start to think about lung, we are seeing increases in the number of physicians that are testing patients now. A lot of those increases are actually coming from patients with first-line lung being tested. So the fact that we continue to encourage testing, I believe, is only going to help us ultimately when we launch in first-line lung.

Then the first thing that you want to do is you want to see who gets to market first, and I think that that always matters. So let's see who gets to market first in first-line lung, and that will be an important milestone.

Secondarily, as you said, we have to see what the cutoff points are. But in addition to that, even with cutoff points, we also have to see what the guidelines say and how the reimbursement works.

So I feel pretty good about where we are today. I feel optimistic about first-line lung. I can tell you I'm thrilled that we're only one of two PD-1s in the marketplace today, and I think that sets us up for very good growth in the future.

Operator

Colin Bristow, Bank of America.

Colin Bristow - *BofA Merrill Lynch - Analyst*

Morning and thanks for taking the questions. Maybe just switching to anacetrapib, can you update us on your level of optimism for the CV outcomes study in light of the data we saw for Lilly's evacetrapib?

And can you perhaps comment on the baseline HDL of the enrolled population, at least relative to Lilly's ACCELERATE study, since this is potentially an important consideration for the realization of a treatment effect? Thanks.

Roger Perlmutter - *Merck & Co., Inc. - EVP, President Merck Research Laboratories*

Hey, Colin; it's Roger. My feeling about the anacetrapib study really isn't much changed. We knew, of course, about Lilly's evacetrapib study; it's nice to have the data now in much more detail.

The differences between the two studies have been discussed in terms of the patient populations that were enrolled and in terms of the duration of the studies, which -- the follow-up duration is important since you do expect that as you manipulate lipid profiles the effects should accrue over time. That's probably the biggest impact.

I think that when we look at this, because of the dramatic lowering in LDL cholesterol, the dramatic increase in HDL cholesterol, the changes in Lp(a), the expectation is that patients who are receiving anacetrapib should do better in terms of major cardiovascular events. That's what we're testing.

It's a 30,000 patients study, and we're going to have the data next year and we'll have a chance to look and see. We're approaching the end of the treatment period. And at some point the clouds will part and the sun will shine and we'll have a chance to see what the landscape looks like.

At the moment, there is no point in speculating. The study is nearly complete.

Operator

Alex Arfaei, BMO Capital.

Alex Arfaei - *BMO Capital Markets - Analyst*

Good morning, folks. Thanks for taking the questions. Apologies if I missed this, but did the extra calendar days in 1Q benefit the quarter in any way?

And Adam, do you think that PD-L1 testing will be restricted to a specific test by treatment? Or do you anticipate that it will basically be at the discretion of the labs and that we will eventually see that the labs basically concentrate towards one that's a preferred one -- arguably the more sensitive test? Thank you.

Rob Davis - *Merck & Co., Inc. - EVP, CFO*

Good morning, Alex; this is Rob. To your question on the impact of the days of sales, we did see some benefit from that impact in the US, but it was largely offset by channel. So it did not materially change our results.

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

And with respect to PD-L1 testing, first of all, what we're seeing is that PD-L1 testing is not specified in the label of the products for any certain test. It just says if you have a PD-L1 positive patient in the label. So therefore it doesn't matter what test the lab uses in order to designate whether the test is PD-L1 positive or not.

I don't think that is going to change. I think it will be up to the labs to decide which testing that they use and then how they determine it to be positive or not.

I think they're two other points that are important. First of all, we're already seeing about 30% of patients with lung being tested, and about 70% of those are in first-line.

The other thing that's important is that when patients are being tested, if it's positive right now the vast majority of those patients are going to Keytruda. So therefore I do think that the testing, irrespective of what test they use, is occurring more often and actually over time could be helpful.

Operator

Jami Rubin, Goldman Sachs.

Jami Rubin - *Goldman Sachs - Analyst*

Thank you. A few questions. Ken, first to you, I was intrigued that in your press release you highlighted business development as a high priority. If you'll recall, at our CEO conference back in January you highlighted your high priority to complete deals being more aggressive this year, moving up the risk curve.

Can you provide a little bit more granularity as to specifically what you're looking for? Clearly we've seen a major derating of valuations of biotech stocks; yet we haven't really seen any motion or rumors or anything out of Merck.

What are you looking for specifically? Are they late-stage assets? Are they early-stage assets? What compelled you to highlight that early on in your press release? That's my first question.

Second questions are for you, Roger; and Adam, if you want to comment. There's been a lot of focus on this call today on monotherapy. Obviously we -- first-line lung monotherapy. But our expectation is that monotherapy is rapidly going to move to combination therapy. As you know, oncologists believe that the best way to treat cancer is with cocktail or combination therapy.

Clearly your competitors have all pursued combinations either with I-O/I-O or chemo combo. So just, you have pursued a monotherapy strategy and are behind the curve on combination. What is your strategy to catch up?

Then just as a corollary to that question, the market wisdom is that you have to own a combination to speed them to market. What is your strategy to do that? Thanks very much.

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

Jami, thanks for the question. Let me start by saying what I was trying to say earlier this year and what I'm saying today are exactly the same thing. We feel it's very important for us to access the best external innovation, and we're very actively engaged with companies that we think have good science. You haven't seen the deals come through quite yet, but that doesn't mean that we're not very, very much engaged in active discussions with those companies.

You mentioned the issue around valuation. I think that a lot of those companies are looking at the current stock prices and trying to decide whether those are indicative of where they're going to be in the future. So I think those boards and those management teams are going through the process of letting the new reality, if you will, settle in with them.

But from our perspective I guess what I was trying to highlight is, first of all, we have a strong balance sheet and we can go after deals across the whole spectrum: early, middle, and late-stage compounds. And we will look for those deals consistent with good science and financial discipline.

So we want to be aggressive in going after deals, but we want to do deals that create value for our shareholders.

Roger Perlmutter - *Merck & Co., Inc. - EVP, President Merck Research Laboratories*

Right. And Jami, on the general approach to how one treats cancer, I actually don't agree with your assessment of our strategy, so let me try and reinterpret it a little bit for you.

First of all, what I've always said was in order to understand the benefits of combination therapy you have to understand how monotherapy behaves. We launched a very broad program in monotherapy with more than 30 different tumor types in many lines of therapy. But we've not shorted the combination studies. If you look on clinicaltrials.gov right now, about something over 270 studies on clinicaltrials.gov with Keytruda is -- I haven't checked today -- but more than 100 of those are combination studies.

They include studies that are potentially registration enabling. If you look at the KEYNOTE-189 study, for example, which will be delivering data next year in combination with chemotherapy, in addition to, of course, combination with chemotherapy data that we've already presented, there is quite a lot going on in combinations.

We have combinations with radiation therapy, combinations with immunotherapies, combinations with traditional chemotherapies, and combinations with targeted chemotherapies. In addition we have in the clinic GITR, LAG-3, IL-10, and cCAM, which are our own Phase 1 programs that provide immuno-oncology molecules that could potentially be used in combination.

So in totality we had a very, very broad of combination program which includes both things that we own and things that either shouldn't be owned -- because they're in essence generic -- or that we're doing in collaborations with others. For example, in the IDO program we're both collaborating with Incyte and we have our own programs that we own as well. So a lot of work going on in combination.

Our goal absolutely is to identify the very best possible regimens from the many thousands that you and I have discussed previously, the many thousands of regimens that potentially would employ in treating cancer patients.

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

Jami, the thing I would add -- so Roger and myself and our teams work very closely identifying potential combinations and uses. With regard to having to own them all, I don't think you have to -- particularly if they can't be combined into a similar dosage form or have the same type of dosing regimen.

I get asked that all the time in diabetes for many years, where people said: Don't you have to have an insulin and a GLP-1 for Januvia to be successful? We've shown that Januvia can be successful even if we don't have some of those combinations.

It doesn't mean that we don't want a GLP-1 potentially or other types of diabetes medicines, but we look at those as their own opportunities.

At the same time, the reason that we think the combination of our SGLT2 with Januvia can be successful is because you can put them into one tablet with the same dosing regimen. So that's the way we look at the combinations, and I think that our strategy is a good one.

Operator

Andrew Baum, Citi.

Amlin Selveraja - *Citigroup - Analyst*

Hi, this is [Amlin Selveraja] on behalf of Andrew at Citi. Thanks for taking the question. I have just one left. How does the pricing and rebate dynamic on your biosimilars work between you and your partners?

More specifically, does Merck have the ultimate decision? Or can some(inaudible) drive the list price? Thanks.

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

Yes, this is Adam. If you look at Europe for the pricing and rebates on biosimilars, it's determined by the Merck team and our European team. What we've done is we've been very successful competing for patients that are on existing therapy; but we have lost many new patient starts, hence you see a decline year-over-year for Remicade, and we expect that that decline will continue over time.

But what we see right now is that existing patients are able to maintain on therapy in many of the European markets.

Operator

Tony Butler, Guggenheim Securities.

Tony Butler - *Guggenheim Partners - Analyst*

Yes, thanks very much. Roger, back to an earlier comment you made on IDO, I wanted to explore IOmet and the acquisition and the rationale for that, relative to what you had with your partner and where you're going in melanoma. I assume only with IOmet you're thinking about a broader set of tumors. Was that the rationale?

Second, Rob, to generic mometasone, for Nasonex, how much pressure does that put on your gross margin? And more importantly, because that's a reasonably large product, would your tax rate not actually see a benefit because of the change earlier than you would have expected, or is it just marginal? Thank you.

Roger Perlmutter - *Merck & Co., Inc. - EVP, President Merck Research Laboratories*

Tony, thanks for the question. On IOmet, we have data that we have presented in the IDO1 inhibitor from Incyte in combination with Keytruda that is very suggestive with regard to a treatment effect in melanoma. And one of the good things about it is that the adverse experience profile for the combination of the IDO1 inhibitor along with Keytruda really looks very favorable.

With that in mind, we wanted to explore more fully the landscape of IDO1 and TDO1 inhibitors. We had an opportunity with IOmet to gain access to actually quite a large set of starting materials and new chemistry, which enables us to think about how we would design an optimal molecule that could be used in a whole variety of different tumor types.

We have a very good collaborative relationship with Incyte, and we're eager to see those programs advance just as quickly as possible for the benefit of patients. But we think there is some running room as well and an opportunity for us to use our chemical insights potentially to improve treatment regimens in that regard, and that was the driving force behind it.

Rob Davis - *Merck & Co., Inc. - EVP, CFO*

With regards to your question about generic Nasonex, if you look at Nasonex, it is a high gross margin product for us, but it does have a fair bit of discounting. So it will be a slight drag in the back part of the year to our gross margin, but it was fully reflected in the guidance we gave on gross margin.

As you look at the tax rate, this really has no meaningful impact to our tax rate, to speak of.

Operator

Chris Schott, JPMorgan.

Chris Schott - *JPMorgan - Analyst*

Great. Thanks very much; I just had two quick ones here. One, just coming back to business development, I think you used the term bolt-on acquisitions in your release. Can you just help us understand a little bit how large a deal could be and still considered to be a bolt-on for Merck?

I guess, for example, would Cubist or something a bit larger have been considered a bolt-on? Or should we think about Merck targeting some smaller transactions here?

My second question was on Zepatier and just the HCV marketplace in general. I think one of your competitors cited some pricing pressures in the space emerging again this year. How do you see the pricing environment evolving over time with three main players in the space?

I guess specifically, should we think about price continuing to erode here over time, where you'll get more access but we should think about a downward trend on price overall? Thanks very much.

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

Starting on the business development question -- thanks, Chris. When I talk about bolt-on acquisitions I think I'm not signaling anything specific with respect to size of the deal any more than I was earlier with the stage of development. We want to find the best assets at the best valuation to help us grow our pipeline going forward.

So I guess what I'm signaling is I'm not focused on a large consolidation-type merger such as we have seen in the industry in the past. But I also think that bolt-on acquisitions can be larger than, for example, a Cubist.

It depends on what the company brings, what their pipeline brings, what level of scientific innovation they have internally, and how we believe it can complement our portfolio and pipeline going forward.

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

Chris, this is Adam. As we look at the hepatitis C market we continue to be optimistic about our potential within the market. I think that price will continue to be under pressure over time in this market.

But despite that, I think the lower prices have expanded access to some degree. I think a good example of that is the VA and their removal of the fibrosis score restrictions.

So there will continue to be price pressure in the marketplace. We will continue, as I said before, to try to get parity access, but we have to see where our competition and where the payers go. The more they try to push for restricted access or exclusive formularies, we have to watch that closely.

Operator

Seamus Fernandez, Leerink.

Seamus Fernandez - *Leerink Partners - Analyst*

Thanks for the questions. A couple of quick questions. Just Roger, can you clarify the update on Zepatier in the EU with regard to the manufacturing issues that you mentioned? Just I think I missed a little bit of the facts there.

The second question, again, Roger, you mentioned a number of internally developed assets and collaborations. Can you talk a little bit about GITR? We're hearing and seeing a lot of additional companies pursue this target; enthusiasm amongst thought leaders is building. But there are questions about this target, as to whether or not, A, it's an agonist at all, and also how efficiently one can actually develop antibodies to this target.

My last question is for the team overall. In terms of the areas of greatest interest for business development, should we anticipate that your focus is mostly on oncology specifically? Or how broadly and what areas are of greatest interest to you on the BD side? Thanks.

Teri Loxam - *Merck & Co., Inc. - IR*

Why don't we start with Roger?

Roger Perlmutter - *Merck & Co., Inc. - EVP, President Merck Research Laboratories*

Yes. Seamus, just to reiterate that in the course of our European review, the European Medicines Agency cited Merck's third-party manufacturer for issues that were largely related to inadequate record-keeping and the need for improvement in their quality management systems.

The problems do not affect -- we do not believe -- the safety, efficacy, or quality specifications of the product; and hence we don't believe the problems will affect the supply to the US market. But we take these good manufacturing practice issues very seriously, and we're working with both regulatory agencies and the contract manufacturer to resolve the issues as expeditiously as possible.

Secondly, with respect to GITR, as you know, our program has been in the clinic for quite some time, but we have been advancing it very slowly because of concerns on our part, on the part of regulators, too. We share these concerns that an antagonist antibody could stimulate a fairly profound immune activation response, and those responses can be difficult to manage.

So we're just getting to the point in advancing that program where we believe we're in the therapeutic range. We certainly do have data that our anti-GITR antibody behaves as an agonist. I think one of the issues has to do with cross-linking and which Fc receptors are engaged by the therapy.

As you know, we have two GITR antibodies that are in the clinic. There is a lot of enthusiasm in the community; but it will be some time I think before we understand whether, to what extent, GITR antibodies will be useful.

Rob Davis - *Merck & Co., Inc. - EVP, CFO*

Seamus, maybe I can just add on the comment around Zepatier. I think it's also important to understand that was fully reflected in our guidance. In fact, just to give you a little bit more color, as you look at Zepatier in particular, thinking about roughly where consensus is now -- which ranges, but let's say it's around $650 million -- we're very comfortable with that and, as I said, was reflected in our guidance. I just wanted to make sure we get that out there.

Teri Loxam - *Merck & Co., Inc. - IR*

Do you want to comment on the BD, Ken?

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

Sure, sure. Thanks. I think as we look at BD, we look at it in two different ways. First of all, obviously, we're very eager to build on areas of leadership like immuno-oncology. You saw us do deals, for example with cCAM Biotherapeutics. You saw us do the deal earlier with IOmet that we talked about.

So we'd like to build on those areas where we already have leadership. But it's also important for us not to be too blinded to the fact that there is important science going on in other areas.

So what we want to look for are significant opportunities to have leading positions in growing areas of therapeutic significance going forward. Obviously immuno-oncology would be one leading area, but we are also willing to do business development if we think we can get an asset that we can leverage inside our portfolio for a leadership position.

Operator

Jeff Holford, Jefferies.

Jeff Holford - *Jefferies LLC - Analyst*

Hi, thanks very much taking my question. I wonder if you can just give us an update on your insulin glargine program. We were maybe expecting to see your pivotal data coming up at that program, perhaps a filing later this year; so an update there would be useful.

And then we get a lot of commentary from your competitor on how entrenched the use of nivolumab is amongst particular lung cancer oncologists. That would seem to be the case from the commercial data you're giving us in Q1 versus their data.

Could you just go through in a bit more detail why you think that isn't going to be a barrier for you in first-line lung cancer, given the relatively close potential timing of the launches? And if it is more of a barrier than you think, what could you possibly do to change to that? Thank you very much.

Teri Loxam - *Merck & Co., Inc. - IR*

Roger, you want to start with this one?

Roger Perlmutter - *Merck & Co., Inc. - EVP, President Merck Research Laboratories*

With respect to glargine insulin you'll be seeing data later in the year. We're filed in Europe and going through the process of gaining approval for that MK-1293 molecule. Probably not much more to add, I think, to that.

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

if you look at Keytruda, the first thing I'd say is right now we're the ones that have to talk about PD-L1 testing for second-line therapy and we're the ones that are training physicians and getting physicians to understand the utilization of PD-L1 testing. When you think about first-line lung, all competitors will be talking about PD-L1 testing, so I believe that barrier will go away because all of us together will be talking about it.

The other thing that I think is important is, if the playing field is equal in lung and all else is close, every three week dosing is an advantage versus competition. Therefore I think that the dosing for first-line lung patients could end up being an advantage for us if PD-L1 testing is communicated by all companies.

But the other thing I want to emphasize, as I've said all along, this is a long-term view of this market. There will be multiple competitors that can do really well in this market. I don't think we should look at any one quarter or short period of time.

This market over the next several years, with the number of tumor types that we're studying, with the amount of -- how well that we're continuing to develop combination products, we can continue to do really well.

The last thing I'll say is that if you look at Europe, in countries in Europe we actually came to market after competition. And in many markets, including big markets like Germany in melanoma, despite that we now are the market leader.

So I believe it shows our strength outside of the US, where I believe PD-L1 testing will be even more relevant and accepted by payers than potentially in the US for second-line.

Operator

David Risinger, Morgan Stanley.

David Risinger - *Morgan Stanley - Analyst*

Thanks very much. I have a couple questions. First, with respect to the timing of the upcoming first-line lung readout, Roger, I think you mentioned at the middle of the year. But could you just talk a little bit more about more specifically the timing that you expect, and the factors that you are assessing to be able to convey that timing?

Then with respect to ASCO, could you just talk a little bit about the chemo combo data that you'll be conveying? Obviously, it will be longer-duration data that supports your move into Phase 3 for the chemo combo; if you could shed some light on that.

Then finally with respect to Remicade biosimilar adoption, obviously Remicade is an infused drug used by hospitals and clinics. Do you believe that that route of administration and those customers have been more inclined to adopt biosimilars than the marketplace would be for a self-injectable therapy? Thank you.

Teri Loxam - *Merck & Co., Inc. - IR*

Roger, you want to (multiple speakers)?

Roger Perlmutter - *Merck & Co., Inc. - EVP, President Merck Research Laboratories*

Right, let me start with respect to the KEYNOTE-024 study, the first line-study in PD-L1 high patients in lung cancer. Again it's important to recognize that this is an event-driven trial.

They have about 300 patients that are enrolled in the study. There is -- we powered the study based on a certain number of progression events. Progression-free survival is the primary endpoint.

So it's actually just a question of when we hit the event number. From the time we hit the event number to the time we get to database lock involves holding the sites and there a variety of questions that have to be answered. And then once the database is locked, the statistical analysis takes relatively little time.

So we're not -- there are no other factors that go into this. We're not in any way manipulating it. We're just waiting until we hit this prespecified event trigger which defines the power for the study; and once that's available, then we'll be able to do that.

Just with respect to ASCO, since you mentioned it -- I didn't have a chance to go into it -- but there's going to be a lot of new material presented at ASCO. We have 84 currently abstracts, including 13 oral presentations, that will be presented at ASCO. We're going to be discussing from 20 different tumor types.

We'll have additional data that we'd be presenting with respect to chemo combinations. In particular, the data that comes from the KEYNOTE-021 study which is combinations with traditional chemotherapy, carbo, pemetrexed, where overall response rates are really very high, nearly 60%. So there's a lot of information that will be communicated at ASCO.

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

Dave, with regard to Remicade biosimilar adoption, I think it has more to do with price differences for new patients in tenders than it does with the way in which the drugs are administered. So I wouldn't expect a very significant difference.

Operator

Vamil Divan, Credit Suisse.

Vamil Divan - *Credit Suisse - Analyst*

Hi. Good morning; thanks so much for taking my questions. I just have one on the guidance, just to clarify on the sales side. I believe you said you went from a 3% negative headwind on sales from FX to a 2% negative headwind. I think that was about a $400 million benefit; but you only raised the midpoint of your guidance by about $100 million.

So wonder if you could just confirm that I have the facts straight. And if so, what is that's bringing down sales guidance by about $300 million, if you take out the impact of the currency moves?

Then the second question I have is on Alzheimer's. I would love to just get Merck's perspective on this. There's obviously been a lot of discussion around endpoints with the changes Lilly made recently to the solanezumab study.

I know for yours, for your BACE inhibitor in prodromal you have CDR, sum of the boxes as your primary, I believe, in the prodromal study, in the mild to moderate, you have ADAS-cog and ADCS-ADL as co-primary. So if you could just talk through those endpoints and how you think about the pros and cons of each in the different patient populations, I think that would be helpful, just given all the investor interest in that area. Thanks.

Rob Davis - *Merck & Co., Inc. - EVP, CFO*

Yes, Vamil, this is Rob. Good morning. To your question, you are correct that, as we said, original guidance at the beginning of the year, we expected a 3 percentage point negative impact from foreign currency. Using the mid-April rates, we now expect for the full year an approximately negative 2 percentage points of impact from foreign currency.

As you look at the guidance we provided, we flowed part of that benefit through in the guidance, but not all of it. The single largest reason we did not flow all of it is the fact that we face earlier than expected generic entry on Nasonex, which is the largest driver of the number you quoted.

Roger Perlmutter - *Merck & Co., Inc. - EVP, President Merck Research Laboratories*

Yes, and Vamil, it's Roger. With respect to Alzheimer's endpoints, of course there's been a lot of discussion over a long period of time about how best to measure the deterioration that occurs as a result of Alzheimer's-related neurodegeneration. They're at least two different things to be concerned about.

One, of course, is direct measurement of cognitive function by whatever tools one has, typically things like mental status examination. The other is the functional capability of individuals who are unfortunately suffering from Alzheimer's.

Typically the Agency has asked to see both of those things assessed directly, and often in a primary endpoint as a composite endpoint in clinical trials. It is possible, of course, to do that seriatum and take a single endpoint.

Our view with respect to mild to moderate is that the best strategy is to look at both of those aspects of Alzheimer's-related performance, and that's the way we've handled it. We understand Lilly's thinking with respect to their earlier study, and we continue to look at these questions. But at the moment I think we feel comfortable with where we are with our endpoints.

Teri Loxam - *Merck & Co., Inc. - IR*

Thanks, Roger. Darla, I know we're hitting up against the top of the hour. We're going to try and squeeze in one more question.

Operator

Marc Goodman, UBS.

Marc Goodman - *UBS - Analyst*

Morning. Emerging markets, we see the numbers in the press release. Can you give us a little more flavor on what's going on in the different areas, China, Latin America? How is it doing ex-Venezuela?

Eastern Europe looked tough. How much of this is currency and how much of this is just underlying stuff?

And then can you just comment on the omarigliptin? I thought I had read that you're not going to be pursuing this in the US and Europe; if you could just comment on that.

On the Januvia, were there any inventory changes? It wasn't clear from your comments. Thanks.

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

Yes. I'll get those quickly. If you exclude Venezuela, sales in emerging markets ex-foreign exchange were up about 5%, and we're seeing good growth in countries like China, where we had about 11% growth outside of foreign exchange. We're seeing good success in the areas of vaccines, our diabetes franchise, and so forth.

Where the pressure was primarily was Venezuela. But obviously there is some turmoil that is happening in some markets, particularly in the Middle East, that have some impact.

If you look at emerging markets over time, there's been a slight decline in growth, but we still expect there to be growth as we report into the future.

With regard to Januvia, I said in the US we had 9% growth versus prior year. But the best way to understand that is to look at underlying volume growth, which was about 5% versus prior year. Therefore we did see some inventory movement of Januvia.

It's important to note that, just like last year, the quarters will fluctuate to some degree from one quarter to the next quarter. But overall across the year we expect growth for the Januvia franchise.

Then the last thing I'll say is with regard to omarigliptin, for business reasons we decided not to move forward submitting the applications in the United States or Europe. It did not result from concerns on efficacy or safety. It was really for business reasons, for two primary reasons.

Number one, we have a very high share of Januvia in those markets, so a lot of the product would've been cannibalizing our own DPP-4 share. We have a 75% share in the US and a 65% share globally.

The second reason is we're excited about launching not just the monotherapy SGLT2 but also the combination of an SGLT2 with Januvia, which we would have anticipated would be launched not too far after omarigliptin. And in order to focus more on growing Januvia, but then also the SGLT2 mono and more specifically the combo with Januvia we thought was a better place for us to focus.

Roger Perlmutter - *Merck & Co., Inc. - EVP, President Merck Research Laboratories*

If I could, I'd just say that this was a very hard decision for Adam and me. Omarigliptin has very desirable properties as a once-weekly DPP-4, nearly superimposable over daily Januvia. But as Adam indicated, these decisions have to be made by putting our resources against those things that matter most.

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

Okay. I just want to thank you all for hanging in there with us this morning. We're off to a promising start this year with our growth of 3% ex-FX. I think we also continued to deliver our leveraged P&L with 10% FX on the bottom line, and we are looking forward to data readouts in areas like Keytruda and other areas of our pipeline. So we're very excited and we look forward to speaking to you soon.

Operator

Ladies and gentlemen, this concludes Merck's Q1 2016 sales and earnings conference call. You may now disconnect your lines.
