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MRK - Q1 2017 Merck & Co Inc Earnings Call

EVENT DATE/TIME: MAY 02, 2017 / 12:00PM GMT

OVERVIEW:

Co. reported 1Q17 total revenues of $9.4b and non-GAAP EPS of $0.88. Expects 2017 revenues to be $39.1-40.3b and non-GAAP EPS to be $3.76-3.88.

CORPORATE PARTICIPANTS

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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 2017 Sales and Earnings Conference Call. (Operator Instructions)

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

Teri Loxam

Thank you, Darla, and good morning. Welcome to Merck's First Quarter 2017 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, Merck Research Laboratories.

Before I turn the call over to Ken, I'd like to point out a few items. You will see that we have items in our GAAP results such as acquisition-related charges and restructuring costs and certain other items. You should note that we have excluded these from our non-GAAP results and provide a

reconciliation of these in our press release. We have also provided a table in our press release to help you understand the sales in the quarter for the business units and products.

I would like to remind you that some of the statements that we make during today's call may be considered forward-looking statements within the meaning of the Safe Harbor provision of the U.S. Private Securities Litigation Reform Act of 1995. Such statements are made based on the current beliefs 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 1-A in the 2016 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 statement. 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.

Kenneth C. Frazier - *Merck & Co., Inc. - Chairman, CEO and President*

Thank you, Teri, and good morning, everyone. Merck performed well in the first quarter with revenue gains in oncology, vaccines and Animal Health, which helped to drive growth in the quarter that more than offset the substantial impact of LOEs. These results reflect our continued performance across the company's broad range of products. We are executing our strategy with focus and discipline, investing in a pipeline of new drugs while driving for results from key launches in our in-line products, medicines and vaccines.

Having started the year with a firm foundation in the first quarter, today, we are raising the company's outlook for full year revenue and EPS. Rob will share the details in a few minutes.

We are excited about the opportunities ahead as we continue launching products around the world. In particular, Merck's strong position in immuno-oncology is reflected by the continued momentum for KEYTRUDA, which unquestionably is changing the paradigm for treating malignant disease. Merck's performance underscores the advantages of our balanced portfolio, including the contributions of our vaccines and Animal Health businesses.

To augment the work of Merck's own research labs, we continue seeking the right business development opportunities that will add value to our portfolio, with an emphasis on early- to mid-stage pipeline assets. As a leader in biopharmaceutical research, we will pursue the best internal and external scientific opportunities.

In closing, we're seeing strong performance across all elements of Merck's business. Guided by our long-term strategy, we will continue bringing forward important new medicines and vaccines while driving the performance of our core businesses and launching new products. Merck remains focused on delivering better outcomes for patients and health care systems and growth in value for shareholders.

With that, I thank you for your attention this morning. I will now turn the call over to my colleague, Rob Davis.

Robert M. Davis - *Merck & Co., Inc. - CFO and EVP of Global Services*

Thanks, Ken, and good morning, everyone. Our results in the first quarter reflect strength in our ongoing launches as well as continued solid performance in our in-line businesses, allowing us to overcome significant headwinds in the first quarter from generic competition for ZETIA, CUBICIN and NASONEX in the United States and REMICADE in Europe. As a result, we were able to grow sales, continued to meaningfully invest in R&D and still achieve EPS close to flat despite the impact of LOEs.

Total company revenues were $9.4 billion, an increase of 1% year-over-year. Excluding the impact of exchange, first quarter revenues grew 3%, driven by our Human Health and Animal Health businesses.

Our Human Health business grew 2% excluding exchange while our Animal Health business grew 14% excluding exchange.

The Animal Health business saw strong growth across all regions in nearly all species, including continued good performance from BRAVECTO. We did see some favorability due to timing of orders. As a result, we expect Animal Health growth in subsequent quarters to be more measured but still above market.

Looking at the other parts of the P&L. Non-GAAP gross margin was 77.8% in the quarter, an increase of 80 basis points versus the first quarter of 2016. Foreign exchange and lower discards were the biggest drivers of the year-over-year improvement.

Non-GAAP operating expenses of $4.2 billion were 8% higher year-over-year, driven by both an increase in R&D and marketing and administrative expenses. As we had anticipated on the fourth quarter call, operating expenses were higher in the first quarter due to increased clinical development and promotional spend behind our launch products.

Taken together, we earned $0.88 per share on a non-GAAP basis, down 1% excluding exchange.

Turning to our outlook for the year. We are now narrowing and raising both our revenue and EPS guidance ranges for 2017. We continue to believe that our launches of KEYTRUDA and ZEPATIER and our base business, including vaccines and Animal Health, will largely mitigate the headwinds we are experiencing from LOEs. We are also experiencing a slightly more favorable exchange environment.

For the full year, we now expect revenues of $39.1 billion to $40.3 billion and non-GAAP EPS of $3.76 to $3.88. Both of these ranges reflect approximately 1.5% negative impact from foreign currency at mid-April rates. All other elements of our non-GAAP guidance provided during our fourth quarter earnings call remain unchanged.

In summary, our first quarter results demonstrate our ability to deliver value through the prioritization of resources behind our innovative products and the execution of launches that will contribute to long-term growth. We are confident the investments we are making today will translate into continued shareholder value in the future.

With that, I'll turn the call over to Adam.

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

Thanks, Rob. Good morning, everyone. This morning, I'll provide highlights on Global Human Health performance for the first quarter of 2017, and my comments will be on a constant-currency basis.

We are off to a solid start for the year. Global Human Health sales of $8.2 billion increased 2%, with growth from launch products including KEYTRUDA, BRIDION and ZEPATIER as well as our broad portfolio of vaccines, which more than offset the impact of LOEs in the U.S. We had a strong quarter outside the U.S., with growth of 7%.

I'll now highlight a few of our key franchises and product launches, and I'll start with oncology. We continue to execute on the significant opportunity we see with KEYTRUDA and our global leadership position in immuno-oncology. Global sales in the first quarter were $584 million, which represents significant growth versus the first quarter of last year, including U.S. growth of approximately 170%. In the United States, KEYTRUDA growth was driven by the launch in first-line lung as well as the rapid penetration of head and neck cancer and continued strength in melanoma.

After seeing a significant increase in PD-L1 testing following our first-line lung approval in the fourth quarter, we are starting to see that translate into demand. In fact, the vast majority of patients as defined by our label are already being prescribed KEYTRUDA. Based on IMS brand impact new patient data, KEYTRUDA is now the most prescribed product in the first-line lung setting. In addition, our second-line lung share has been relatively stable, and we're working to grow that share with our expanded indication into all PD-L1-positive patients.

Outside of the United States, melanoma continues to drive the majority of KEYTRUDA sales, with approvals in almost 60 countries. We're now working through the reimbursement process for both first-line and second-line lung, so we anticipate lung will become a much larger contributor outside of the U.S. as we progress through the year.

Now I'll move to primary care. Global sales for JANUVIA franchise reached $1.3 billion and experienced a decline of 5% in the quarter, driven by the U.S. We continue to see good TRx growth of approximately 3% in the U.S. However, as we mentioned previously, the timing of customer buying makes a difficult comparison versus last year.

JANUVIA continues to maintain DPP-4 leadership, with more than a 70% market share in the U.S. and 65% market share globally. We remain confident in the diabetes franchise and look forward to expanding the franchise with our SGLT2 and SGLT2 combination with JANUVIA, which we filed in the first quarter of this year.

Moving to vaccines. Sales reached $1.5 billion and grew 21%, primarily driven by increases in GARDASIL and PNEUMOVAX. The addition of approximately $65 million of sales from the terminated vaccine joint venture with Sanofi, most of which was GARDASIL, also contributed to growth.

Global GARDASIL sales grew 41% this quarter, also on strength in the U.S. and emerging markets. In the U.S., GARDASIL sales growth was 25%, reflecting increased demand as well as timing of CDC purchases of approximately $45 million. We continue to monitor the negative impact of the transition to a 2-dose regimen in the U.S.

PNEUMOVAX sales increased 52% in the quarter. Growth was driven by another strong quarter in the U.S., where we continue to benefit from adoption of the ACIP recommendation for patients 65 and older.

Moving now to Hospital and Specialty Care. We continue to execute well on the launches of both ZEPATIER and BRIDION. ZEPATIER generated $378 million in sales for the quarter. We have seen rapid uptake in Europe and Japan since ZEPATIER's launch in late 2016, and we remain encouraged by initial feedback from physicians, payers and scientific leaders. In the U.S., we continue to drive share gains for ZEPATIER across public and private payer segments. Sales in the quarter also reflect an approximately $40 million favorable adjustment to rebate accruals.

BRIDION delivered another strong quarter, with growth of more than 60%. We continue to see strong uptake from the launch of the U.S. as well as growth in underlying demand in Europe and the emerging markets. As of this quarter, the U.S. represents the largest market for BRIDION sales.

In conclusion, this quarter, we had to contend with a nearly $700 million decline in sales due to LOEs. We anticipate further erosion from these products in 2017. But as we did in the first quarter, we will continue to look for opportunities to offset these losses with strength from across our broad portfolio of products and from our multiple new product launches, which are each off to a very strong start.

Now I'll turn the call over to Roger.

Roger M. Perlmutter - *Merck Research Laboratories - President*

Thanks, Adam. As Rob has outlined, during the first quarter, we continued to invest in late-stage development programs, generating new data to support the value of our products.

On the regulatory front, during the first quarter, we received U.S. approval for KEYTRUDA in the treatment of relapsed or refractory classical Hodgkin lymphoma, based both on the high overall response rate observed in our studies, including 22% complete responses, and the durability of these responses in this difficult-to-treat population.

Similarly, during the first quarter, the CHMP of the EU recommended approval of KEYTRUDA in the European Union for patients with classical Hodgkin lymphoma who have failed all other treatments, including stem cell transplant.

Also during the first quarter, we've worked closely with the FDA in the evaluation of 3 important KEYTRUDA filings: the combination of KEYTRUDA therapy with carboplatin and pemetrexed in the first-line treatment of non-squamous non-small cell lung cancer based on our KEYNOTE-021G study, the treatment of advanced urothelial cancer based on the KEYNOTE-045 and KEYNOTE-052 trials, and the treatment of patients with advanced malignancies whose tumors harbor DNA repair defects that were detected using tests for microsatellite instability. Each of these programs is under review with a PDUFA date in early May or June, and in each case, we have had productive discussions with FDA reviewers that have helped to capture the results observed following treatment with KEYTRUDA in appropriate labeling language. For example, in March, we supplied additional data to the FDA in support of our filing for the treatment of solid tumors with high microsatellite instability. The amended file is under review, with a PDUFA date of June 9.

New data are accumulating every day that demonstrates the activity of KEYTRUDA in a large set of malignancies and with many different supportive therapies. These include our collaboration with Incyte, which now involves 7 pivotal studies in melanoma, non-small cell lung cancer, bladder cancer, renal cell carcinoma and squamous cell carcinoma of the head and neck.

Regarding the latter, interim data will be presented at a clinical sciences symposium at this year's American Society for Clinical Oncology or ASCO meeting in Chicago. Additional presentations at ASCO from a field of more than a dozen oral presentations and more than 50 abstracts overall include early studies of KEYTRUDA when used as neoadjuvant therapy in breast cancer patients, safety and efficacy data in gastric cancer patients based on the results of our KEYNOTE-059 trial, and further analyses of data obtained in urothelial cancer patients and in patients with non-small cell lung cancer, the latter, of course, relevant to KEYNOTE-021G.

In the infectious diseases area, during the first quarter, the FDA granted orphan designation and fast track status to letermovir, the potent antiviral compound which we licensed from AiCuris, for prophylaxis against reactivation of cytomegalovirus in patients undergoing hematopoietic stem cell transplantation. Data from our first Phase III study were presented during a recent meeting of bone marrow transplant specialists, as were data on the Phase III study of V212, our inactivated varicella zoster vaccine. We were well represented at CROI, the Conference on Retroviruses and Opportunistic Infections, where we presented the first Phase III study for doravirine, our non-nucleoside reverse transcriptase inhibitor and early data for MK-8591, a novel nucleoside polymerase inhibitor with a very impressive clinical activity against the human immunodeficiency virus.

In the area of cardiometabolic disease, the FDA accepted for review all 3 of our filings for ertugliflozin, including fixed-dose combinations with metformin and JANUVIA, with reviews to be completed before the end of the year. Our cardiovascular outcome study for ertugliflozin is now fully enrolled, with data expected in 2019. Along the same lines, we do expect that by mid-year, we will have the opportunity to review the initial results from the REVEAL study, a 30,000-patient outcome study, testing whether anacetrapib, a potent once-daily oral CETP inhibitor, can, by both lowering serum LDL cholesterol and simultaneously raising HDL cholesterol, have a salutary effect on the incidence of major cardiovascular events in a population at risk for such events.

Finally, as we announced earlier in the quarter, on the advice of our data monitoring committee, we terminated our study of verubecestat, our BACE inhibitor, in patients with mild to moderate dementia. Data from this study are not yet available internally, but we do expect that these will become available later in the year. As we noted in our press release, the same data monitoring committee has been following our study of verubecestat treatment of patients with less advanced cognitive impairment, a study that they recommend that we continue without modification. And the detailed analysis of the complete dataset from the now terminated 017 study should identify areas for further investigation. I look forward to discussing these data as well as additional results for our many other programs with you later this year.

Now I'll turn the call back to Teri.

Teri Loxam

Thanks, Roger. Darla, we'll be going into our Q&A next. (Operator Instructions) And Darla, if we can get Q&A started, please.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Your first question is from Geoff Meacham with Barclays.

Geoffrey Christopher Meacham - *Barclays PLC, Research Division - MD and Senior Research Analyst*

One for Adam, one for Roger. So for Adam, can you talk a little bit about what you anticipate with respect to pent-up demand or expected use going forward for chemo combos with KEYTRUDA just ahead of the PDUFA date? And then for Roger, I realize that we'll see data at ASCO, but what was the tipping point in moving forward with the 6 additional trials of epacadostat? Was it more data-driven? Or was it reflecting the competition?

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

Geoff, this is Adam. So let me start by saying that we're pleased with the progress that we have with KEYTRUDA across indications, including lung. And if you look at what we've done with our approved indication, the vast majority of patients within our indication are already being prescribed KEYTRUDA for first-line lung. And KEYTRUDA is now the most prescribed drug for first-line lung in the marketplace. As we start to think about KEYNOTE-021G, first of all, it obviously expands the market opportunity in non-squamous patients, and it also includes patients with low or no PD-L1 expression. So basically, it opens up the rest of the market. But with that said, there's a couple of other things to consider. First of all, we believe that physicians will look at individual patients and decide whether or not combination therapy is right to start those patients. So if you have a younger patient that's relatively healthy, you might think about treating that patient with combo differently than if you have an older patient that is more complicated. In addition to that, we believe that since we studied the drug with ALIMTA, that early adoption will probably use -- where physicians would use ALIMTA. Over time, that will expand, we believe, to other chemotherapies as the physicians start to see the results with the combination that we studied. So in summary, we believe it's a very significant opportunity. It's not a pent-up demand. I would look at it as a build as new patients come into the market, and I think that it really is exciting opportunity for lung cancer patients but also to establish KEYTRUDA further as a real preferred treatment therapy.

Roger M. Perlmutter - *Merck Research Laboratories - President*

Geoff, it's Roger. With regard to epacadostat, the Incyte IDO1 inhibitor, it's really a data-driven decision process. We've been looking at a lot of different combinations, and as you know, there's a lot of interesting data, some of which was presented at AACR, showing activity of KEYTRUDA in combination with a variety of inter-tumoral injections, including IL-12 and electroporation, toll-like receptor agonists of different kinds. We've previously reported data with TVEC oncolytic virus. There's other virologic data. One of the nice things about IDO1 is the systemic therapy is extremely well tolerated, and from the studies that we've been doing, some data that was reported at AACR and more data that will be at ASCO, there's evidence for improvement in response. The ability to provide an additional systemic therapy with improved response and really very little penalty that we can see in terms of toxicity is extremely attractive.

Operator

It's from Seamus Fernandez with Leerink.

Seamus Christopher Fernandez - *Leerink Partners LLC, Research Division - MD, Major Pharmaceuticals and Biotechnology*

Just 2 questions. Roger, can you help us understand a little bit of the dynamics? You guys just brought a STING -- or are bringing a STING agonist into the clinic. Can you talk a little bit about your enthusiasm for that mechanism and where you really see a mechanism like that potentially playing an important role in the treatment paradigm? And then the second question is, as we look at the competitive landscape and all of the different treatments in I-O and the various combinations, one that continues to come up and where we will see some data at an investor presentation is the

combination of KEYTRUDA with niraparib, the PARP inhibitor. Can you just help us understand your enthusiasm for PARP combinations with PD-1 agents? And also, just the PARP mechanism in general would be really helpful.

Roger M. Perlmutter - *Merck Research Laboratories - President*

Yes. Seamus, first of all, with respect to the STING agonist, you're right, we brought a STING agonist forward. And we are -- we're interested in it in the same way that we're interested in a variety of other agents, some of which I mentioned a moment ago, that when given intra-tumorally create both a more inflamed environment that should stimulate the -- further stimulate immune cells that have had the brakes released, if you will, by KEYTRUDA administration and also provide an opportunity for an abscopal effect. We see that sort of thing in our preclinical studies very well, but of course, it's not clear that those preclinical results will translate to real patients. Time will tell. We're interested in it. We're enthusiastic about it. I'm not sure that there will be a winner among the various different choices, the oncolytic viruses, the toll-like receptors, other cytokines or things like a STING agonist, which regulates cytokine expression, but we're interested in all of them and trying to search among them for that set of agents which have the best properties, which leads us, of course, to PARP. The logic behind PARP is -- seems very clear. If you have an agent which should, particularly in the setting of any impediment in DNA repair mechanisms, further permit fixation of mutations and, hence, the production of neoepitopes, PARP should work pretty well in combination with KEYTRUDA. And that's what led us to charter these original combination studies with TESARO, and we started those a long time ago. We're very interested in the question of whether those 2 will work well in combination. I think the data from the PARP inhibitors in ovarian cancer that we've seen from a variety of different settings are clear and strong and have enabled registrations. There's no doubt that PARP agents are active in those settings, and they may turn out to be active in other settings as well despite the recent setbacks that were reported by Lilly. So we're interested in PARPs and we're interested in the fundamental mechanism because we do think it will combine well with KEYTRUDA.

Operator

It's from David Risinger of Morgan Stanley.

David Reed Risinger - *Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst*

So I guess I'd like to start with Roger. Roger, could you talk about your level of conviction in the approval of the KEYTRUDA/ALIMTA combo on May 10? And I just wanted to ask about the upcoming KEYNOTE-189 trial. So it would make sense to me to provide access to the FDA to take a private look at that data to give them comfort approving on just Phase II data and eliminate any risk that they end up with egg on their face by approving on a small Phase II and then having the Phase III disappoint in the fall, even though that seems extremely unlikely. And there would obviously be no statistical penalty for Merck to allow FDA to have access to 189. So I'd love to get your thoughts on that. And then for Rob, if the FDA doesn't approve the chemo combo on May 10, should we assume that 2017 guidance needs to be lowered? I know that the guidance assumes that approval.

Roger M. Perlmutter - *Merck Research Laboratories - President*

Yes. David, first, with respect to 021G, we've been working closely with the agency. There's been good dialogue on the results and analysis. I will not predict what FDA will do on the PDUFA date. They need to make their own decisions. But I would say that we have a very strong dataset that stands on its own. There's every reason to expect that, based on our discussions with them, that they'll be able to see their way clear for that. And frankly, it doesn't make a lot of sense to start opening up additional clinical trials at this point. Although the 189 trial is underway, it is just that, underway. And we would have to do a lot of data cleaning again, analysis in order to provide those kinds of results. So really, 021G stands on its own. I should point out that while 021G is one cohort of the 021 study, it's not the first time that we've seen results like this in combination with chemotherapy. The earlier cohort in 021, a single arm, showed that. As well as -- so in essence, 021G is a confirmatory study that shows the results of a true comparison with chemotherapy. So that's important. We are not the only ones, of course, who have seen favorable results for a PD-1, PD-L1 blockade in combination with chemotherapy, all of which is to say that I think that results are substantive.

Robert M. Davis - *Merck & Co., Inc. - CFO and EVP of Global Services*

David, this is Rob. With your question on guidance, as we build the guidance, obviously, we take in a whole range of scenarios across all of our products, with each one clearly having its own distinct risk and opportunity. And while we do have a risk-adjusted sales assumption for the 021G in our guidance, we do not anticipate -- I wouldn't anticipate that if it failed, we would change guidance. So you should assume our guidance is unchanged with or without 021G approval based on what we've given today.

Operator

It's from Tim Anderson with Bernstein.

Timothy Minton Anderson - *Sanford C. Bernstein & Co., LLC., Research Division - Senior Analyst*

Going back to 021G, you guys have made it clear in the past you need to submit additional data from that trial, and I'm wondering if that data has been submitted. And if so, any color to add in terms of what it showed? And one of the key elements, of course, would be if there's any separation of the OS curves, which we did not see in the ESMO data. So a separate question is, is the separation of any OS curves required for FDA approval in your opinion? Another question on KEYNOTE-189. Have you done any interim looks at that trial thus far? And then last question, KEYTRUDA plus YERVOY, should we still continue to expect that you'll advance the program into Phase III in lung?

Roger M. Perlmutter - *Merck Research Laboratories - President*

Right, okay. So first of all, with respect to 021G, we did submit additional data to the FDA shortly after our filing, which provided -- it's fairly standard actually in these kinds of settings to provide an update on the results from the original report, and there will be data that provides that kind of update. That will be presented at ASCO next month, so you'll have a chance to see some of the data related to that and have a chance to look at PFS and the OS curves in those data. So that will be of some interest. We have not internally reviewed any data from 189. The study is continuing as before. And with respect to CTLA-4, again, CTLA-4 is -- the CTLA-4 antagonist, clearly an active agent. Ipilimumab is an active agent. And there is reason to hope that a combination of those 2 will provide improved efficacy and should do so in lung cancer, and we have our own internal data from that. We have worked hard to try and get the dose and schedule right, as I've mentioned to you before, with respect to a CTLA-4 combination. And we are looking still further at the recently reported data from AACR from our colleagues at Bristol-Myers with respect to melanoma, where, again, the evidence that there is activity in terms of overall survival versus monotherapy with nivolumab was less profound than perhaps one might have thought. So we're looking at all of that, but we're -- there's no doubt about the activity of CTLA-4 antagonist.

Operator

It's from Steve Scala with Cowen.

Stephen Michael Scala - *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

I have a couple of questions. First, KEYTRUDA fell a bit short of consensus in Q1. Do you attribute that to not gaining as much share in second-line lung as anticipated, that expectations were simply too high? Or was there some sort of stocking issue in the quarter? And the second question is for Dr. Perlmutter. Letermovir in CME -- CMV prophylaxis, you noted that the data was presented from the first Phase III trial. I think Merck is only running one trial. Does this mean you have to run another trial to file the drug?

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

Yes. So this is Adam. First of all, we're pleased with the progress of KEYTRUDA. And the $584 million in sales, if you look at the U.S., which is the first market where we're really launching lung, because we're still working on reimbursement outside the U.S., we saw 170% increase versus the same

quarter prior year. And if you look at quarter-over-quarter growth and you adjust it for the $40 million that we told you about last quarter, you get over 30% quarter-over-quarter growth in the United States. So -- and if you look at the data from some of the other areas, you would have gotten to about the number that we achieved. In addition to that, to provide additional context, if you look at the sales in the United States, right now about 40% of it is coming from lung. So you've seen a very significant increase in the amount of sales coming from the lung indication. And in fact, the first quarter of this year is the first quarter in which lung is the largest percent of our total sales. So we remain optimistic about the progress of KEYTRUDA. We think that there are opportunities to continue to grow with all the indications that we have, and we look forward to seeing what happens with 021G.

Roger M. Perlmutter - *Merck Research Laboratories - President*

And thanks very much for listening so closely to my comments on letermovir. Yes, there's a single study in heme transplant for letermovir in terms of suppressing CMV reactivation. It has always been the plan, which is well formulated, to do the second Phase III study in solid tumors, where there's also a meaningful need to suppress CMV reactivation. And frankly, we're in a 3-point stance to begin that Phase III study in solid tumors, eager to move forward with that, and that's the study I was referring to.

Operator

It's from Umer Raffat with Evercore ISI.

Umer Raffat - *Evercore ISI, Research Division - Senior MD and Fundamental Research Analyst*

I have 2 for Roger, if I may. Roger, first, perhaps on KEYNOTE-189 trial design. So one of the things your competitors are doing in first-line trial is they're not enabling PD-1 "as part of the trial." Are you allowing pembro as part of the trial for crossover on the chemo arm, number one? And secondly, on 021G, was the PFS data -- in the subgroup of PD-L1-positive 1% to 49%, was the PFS beating the I-O chemo versus chemo for that specific cohort? I know that wasn't presented at ESMO, but you may have that in-house.

Roger M. Perlmutter - *Merck Research Laboratories - President*

Right. So first, for the second one, we're not breaking out the 021G data. We showed at ESMO the sets of patients with respect to PD-L1 expression, and there's a similar trend overall that, frankly, in such a small number of patients, I wouldn't try and draw any conclusions with respect to PD-L1 expression. The totality of the data was pretty much the same across the entire set. And with respect to KEYNOTE-189, crossover is permitted, and that obviously will have an effect. And more and more, as we've said, in all studies, there will be a meaningful effect of crossover, both the same PD-1/PD-L1 directed agent into other PD-1/PD-L1 directed agents. We see that, and that will make overall survival harder to see, although so much depends upon the timing of the crossover.

Operator

It's from Jeff Gilbert (sic) [Gregg Gilbert] with Deutsche Bank.

Gregory B. Gilbert - *Deutsche Bank AG, Research Division - MD and Senior Analyst*

First, for Rob, can you comment on the gross margin outlook for the rest of the year given the very strong growth we saw on gross margin in Q1 versus last year? Not sure if I missed you quantifying the customer purchase timing for the JANUVIA franchise. And then for Roger, I'm sure you've studied MYSTIC and all that's known about it. Can you frame the importance of that event for Merck? Is this simply about CTLA-4 and is relevant in lung? Or are there other key questions that you know are likely to be answered here?

Robert M. Davis - *Merck & Co., Inc. - CFO and EVP of Global Services*

Yes. So with regards to the gross margin, as we look at the full year gross margin, we continue to expect that we will see a moderate increase over 2016. And obviously, while we had a very strong first quarter gross margin, as we mentioned, driven largely by FX and discards in the quarter, our gross margin fluctuates quarter by quarter. So we are not changing our outlook for the full year gross margin guidance. And then on your second question around the JANUVIA stocking, it's about $70 million. So if you look at the decline in JANUVIA in the United States, it's virtually all due to the stocking.

Roger M. Perlmutter - *Merck Research Laboratories - President*

And Gregg, it's Roger. With respect to MYSTIC, of course, it's probably a question better addressed to our colleagues at AstraZeneca. But I would say that, as with all of the agents now, there are 5 PD-1/PD-L1 directed agents, the details of response across tumors and across populations are pretty important. It's nice to know what the level of activity is. MYSTIC will provide a large dataset and shows the activity of durvalumab in combination with tremelimumab, and we don't have a lot of data on those 2 agents, certainly not data in large studies. And so I think that will be important to see. Again, the goal for everyone is to try and improve treatment for cancer patients. That's what we're trying to get to. So every additional piece of information that we get helps us to understand how better to sequence these agents in treating patients with a variety of malignancies.

Operator

It's from Jami Rubin with Goldman Sachs.

Jamilu E. Rubin - *Goldman Sachs Group Inc., Research Division - Equity Analyst*

I have a few. Rob, first for you, can you quantify where the guidance raise is coming from? It seems that it's all FX, but I just wanted verification from you. Secondly, for you Roger, just on what's we should expect in terms of labeling for KEYNOTE-021. Obviously, this is a small study with just ALIMTA. Should we expect that the label will be restricted to just ALIMTA use? And then, Adam, how much -- what is ALIMTA's share in the front-line non-squamous market?

Robert M. Davis - *Merck & Co., Inc. - CFO and EVP of Global Services*

Jami, this is Rob. So if you look at the top line guidance that we provided, the midpoint of the range increased by about $350 million. If you look at about roughly 0.5 point of FX against that, it's about $200 million. So actually, on the sales line, we did have obviously the benefit of FX, but we also had an increase due to strength of sales of about $150 million. So it's both. On the bottom line, we increased the midpoint about $0.02, and that is largely FX. As we now continue to look at the full year and with the great opportunities we see with 021G and with continuing to support KEYTRUDA in general, we want to make sure we're also making the right investments behind our clinical spend and our promotional spend in advance of the opportunities we hope to see. So as a result of that, largely the bottom line is FX.

Roger M. Perlmutter - *Merck Research Laboratories - President*

And Jami, it's Roger. With respect to 021G labeling language, again, can't speculate on precisely how FDA would choose to label 021G, except to say that, as you know, in general, you tend to get what you study. There's little reason for the agency to reach outside of that.

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

And Jami, if you look at the share, it's about 25% in non-small lung cancer. And as I said in my remarks, I think that it'll start off with physicians using it within whatever the indication is. So if it's with ALIMTA, they'll use it with ALIMTA. We'll obviously continue to promote based upon the label that

we have. I do believe that over time, physicians will begin to use it with other chemotherapy, irrespective of label. But again, that's nothing that we would promote.

Operator

It's from Tony Butler with Guggenheim Securities.

Charles Anthony Butler - *Guggenheim Securities, LLC, Research Division - Senior Analyst*

Roger, briefly on REVEAL, which you stated would be revealed in the middle of the year, is -- would that simply be a press release? Would the European heart meeting be too soon for any data readout? Or would it need to be at the cardiology meetings later in the fall? And then briefly, Adam, the GARDASIL franchise, obviously being strong on government purchases, but it was stated that price did have an effect. To what degree did price have an effect in the quarter?

Roger M. Perlmutter - *Merck Research Laboratories - President*

Yes. Tony, on REVEAL, the study data are being managed by Oxford. So at some point, when they pull the early results memo together, I expect that I'll get a call. I can't specify exactly when that's going to be, but we're -- our expectation is midyear. The dataset is very large, of course, 30,000 patients, many years of study. So it will take a while to pull that together into a presentable form. Given the importance of the data, we'll likely provide top line information. But it will take until the fall until I think we probably have a good presentation pulled together. All depends on what we get to see and when we get to see it.

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

And then if you look at GARDASIL, we have $530 million of sales. The 2 things I'd point out is, one, there's about $45 million of CDC purchases in the quarter that was due to timing. The second thing is there's about $50 million of sales from Europe because we dissolved the joint venture with Sanofi. Outside of those 2 things, I would say demand remains strong, and we continue to see increased penetration rates not just in males but even in females as well. And right now, Tony, our market share is greater than 90% globally, almost 100% in the United States. So we remain optimistic about demand. To me, the key thing is, is what happens with the 2-dose regimen. So we're seeing increased demand right now, a lot of people getting their first doses. The question will be, do they come back for their second dose in 6 months? Or will it be next year, a year later? And we still have to wait to see how the 2 doses plays out.

Operator

It's from Chris Schott with JPMorgan.

Christopher Thomas Schott - *JP Morgan Chase & Co, Research Division - Senior Analyst*

First, can you just elaborate a little bit more on your expectations in the HCV market from here as we think about your launch, how that's ramping as well as additional competition coming in the space? And my second question is coming back to kind of chemo combo and just how that fits in the I-O landscape. To the extent your chemo combo is approved based on 021G, with potentially other chemo combos coming to market in 2018, how do you think about IDO and other I-O/I-O combo agents factoring in the market relative to chemo combo given the time-to-market kind of dynamics playing out here as you think about both the lung cancer setting and other indications?

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

Yes. So for HCV, we continue to see good progress with ZEPATIER, and we saw not just in the U.S. but we've seen good progress in Europe, but also in Japan. As you look at the HCV market, there's no doubt that it's a large market and it's a large opportunity, but it's going to play out over many years. And as we look at the market, we see a reduction in number of patients being treated this year versus last year, and we think that, that's going to continue to be difficult as it's harder to get new patients into the market. Many of the tough-to-treat patients or those that were already previously diagnosed have been treated. Although there's still a lot of patients, we have to work harder to get those patients into the buying process. That's particularly true in the United States, but it's also true in countries like Japan, where there's less patients each and every year and there's not a lot of new patients coming into the Japanese market. So with that, we believe that it's still a significant opportunity. As we look at increased competition, we'll have to see what final labels look like, and we'll have to see pricing strategy and those types of things. But my expectation is that this continues to be a large market, albeit a declining market.

Roger M. Perlmutter - *Merck Research Laboratories - President*

And Chris, with -- this is Roger. With respect to the impact of IDO and other agents, I mean, it's worth stepping back and remembering what the goal has been from the beginning, which is -- we see KEYTRUDA, which is the first really broad-spectrum antineoplastic agent introduced into clinical practice, we see it as foundational and transformational for oncologists. And while we recognize that chemotherapy has evolved over a period of decades, it's effective in a lot of different tumor types, provides meaningful responses, the goal has been to actually change the shape of the survival curve for patients with malignant disease. And it's both the high response rates and the durability of those response rates that we see with KEYTRUDA that's so impressive. And the thought is that in combination with other immuno-active agents, particularly those that have relatively little toxicity, we'll be able to change those curves still further. In the best circumstance, ultimately, the role would be to have KEYTRUDA in combination with these other agents end up being first line across a broad spectrum of malignant disease, anticipating that chemotherapy would be used in a relapse setting as a second- or third-line therapy. We'd like to get rid of the toxicity of chemotherapy, but we also recognize that chemotherapy has been used for a long time. Oncologists have become very comfortable in using chemotherapy. They know how to administer it, and they get results that are meaningful with it. So I don't see chemotherapy being displaced completely or going away. My hope is that we're going to find the combinations of agents that work better.

Operator

It's from Vamil Divan with Credit Suisse.

Vamil Kishore Divan - *Credit Suisse AG, Research Division - Senior Analyst*

So first one, more on the -- a commercial question on KEYTRUDA. Can you just give a sense of the adoption you're seeing in academic centers versus community-based centers, just given community docs may be more general oncologists as opposed to being subspecialists who may have incentives to see patients more frequently? Just wondering if the difference in terms of the breadth of indications or the dosing frequency for KEYTRUDA versus the other drugs is making any difference on how different doctors are using the product. And then second one, maybe if I could bring Ken into the Q&A here, around business development. It's something, when I look back at some of your prior earnings releases, I mean, you've mentioned it as a top priority. We haven't seen Merck pull any significant sized deals. Just if you could give an update on what's maybe the limiting factor on pulling the trigger in terms of -- is it the availability of assets? Is it the price for the assets? Or is there any of the unknowns around drug pricing, tax reform and some of those things that might be making Merck wait a little bit?

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

Yes. Vamil, let me give you some additional context on KEYTRUDA. So first of all, we're seeing pretty broad adoption. As I mentioned, the vast majority of patients within our approved indication for lung cancer are being treated. So that tells you it has to be both on academic but also outside of academic centers. So for our first-line share to be what it is, you would have to see a pretty broad utilization. And if you look now, melanoma is 30% of our total sales, but head and neck is also 15% of our sales. So we're seeing increased utilization in head and neck as well, which

we're seeing fairly broad-based for physicians that treat that type of cancer. In addition to that, as you look at what we're seeing, physicians are using the products primarily based upon the indications that we have. In terms of looking at the dosing regimens, I do think that we may have an advantage there with our dosing regimen and scheduling versus competition, but it really is about efficacy, it's about what indications you have and it's about ensuring appropriate utilization based on your indications. So I think that's what's allowing us to win in the marketplace as we sit here today.

Kenneth C. Frazier - *Merck & Co., Inc. - Chairman, CEO and President*

And on business development, I would just reiterate that this is an important priority based on our innovation strategy, and we're going to continue to seek the best scientific innovations to enhance our pipeline. The challenge really is that we have to be diligent about finding the right assets at the right valuation. And we're confident that if we remain disciplined, we will be able to identify and acquire the kinds of assets that could create long-term value for our shareholders. So that's -- nothing's changed. We continue to look for the right assets, and we think, in time, we'll be able to find them.

Operator

It's from Alex Arfaei, BMO Capital Markets.

Ardalan Alex Arfaei - *BMO Capital Markets Equity Research - Pharmaceuticals Analyst*

Adam, I think you mentioned 40% of KEYTRUDA sales in the U.S. were in lung. How should we think about the breakdown of that in first- and second-line setting? And what is the rate of PD-L1 screening that you're seeing out there? And a follow-up for Roger, if I may. When can we expect data from your own IDO inhibitor, which I think you acquired early in 2016? How should we think about the potential of that given the breadth of your activity with Incyte?

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

Yes. So Alex, as you look at the utilization of KEYTRUDA in the U.S., and this is, again, a rough estimate with the data we have, about 40% is lung, 30% melanoma, 15% head and neck and then 15% is all other utilization of the product. And if you look to PD-L1 testing, the vast majority of patients are being tested somewhere between 75% to 80% in the United States. If you look at our share in first-line lung, our share is about -- if you look at early data, 1 in 4 patients or so are being treated for first-line setting. And then if you look at second-line lung patients, we have a share of about 15%, which has been pretty stable over time. Outside the U.S., PD-L1 testing is increasing significantly in Japan. It's remarkable how fast they've begun to adopt PD-L1 testing. And frankly, even in Europe, about 2/3 of physicians are already testing PD-L1, including about 80% in Germany and 60% or so in the U.K. So we're seeing PD-L1 test being picked up around the world, frankly.

Roger M. Perlmutter - *Merck Research Laboratories - President*

And Alex, it's Roger. Yes, our program with epacadostat is quite broad. But we felt, in light of what we were seeing, that there were potentially opportunities both in the IDO1 inhibitor space and the TDO1 inhibitor space and maybe actually dual inhibitors to create agents that could be superior. We actually have a whole family of such compounds, which have different properties. They're just beginning to come into -- out of the preclinical space, soon into the clinic. So fairly soon, we'll have opportunity to see how those actually behave.

Operator

It's from Andrew Baum with Citi.

Andrew Simon Baum - *Citigroup Inc, Research Division - Global Head of Healthcare Research and MD*

A couple of questions for Roger, please, relating to the combination of KEYTRUDA with chemo. As you further experience the use of chemo together with pembrolizumab, do you have any further insights into what we're seeing is addition rather than synergy through some kind of immunopotentiation? The reason I asked is there's been another dataset published recently from human ovarian showing that you get an increase in TIL, but they look like they may be anergic, suggesting that you're seeing an [absolute] effect. And obviously, I'm thinking about the implications of that long term in terms of the size of TIL versus other approaches. And then second, in relation to your ongoing IDO expansion trials, could you talk to patient selection? Are you selecting patients with a certain cutoff point for PD-L1 expression? Or do you believe there's a role for IDO to actually increase [fusile] infiltrate in [culvert] tumors?

Roger M. Perlmutter - *Merck Research Laboratories - President*

Right, okay. Andrew, with respect to the chemo combination and the mechanism of action, it is -- it does appear, and here I'm getting a little bit beyond the data but just sort of the sense of it, that, more or less, anything that kills tumor cells in a meaningful way introduces more antigen into the system. And through cross-priming effects, we believe that enables more stimulation of immune responses. With respect to whether or not one has an effect on the representation of TILs and whether those tumor-infiltrating lymphocytes are anergic, as you know, it's very difficult to characterize those cell populations, and that's one of the reasons why we wandered in the wilderness for such a long time trying to understand what the meaning was of lymphocytes that were present in tumors, were they good, were they bad, those kinds of things. So at this point, we believe that there is an effect on the immune component, and we're not just seeing a certain amount of tumor killing that comes from chemotherapy and then add on to it the immunologic response. But more work is needed to characterize that. And then with respect to patient selection, we have a broad range of tumor types that we're looking at. Some of those tumor types, of course, PD-L1 expression is very important, as in melanoma, where our first Phase III data will become available with epacadostat. In other tumor types, it's much less important. So the entry criteria for those patients are different in the different settings. And we will -- we have, in some cases, already described the nature of the study, and we will in publications describe what those studies look like.

Operator

It's from John Boris with SunTrust.

John Thomas Boris - *SunTrust Robinson Humphrey, Inc., Research Division - MD*

Just on the MSI high PDUFA date of June 9 that you referred to earlier, Roger, can you possibly just discuss the opportunity there, number of tumors that you file for? Are centers actually diagnosing for the MSI-high mutation? And what is the incremental commercial opportunity across those tumors? And then the second question, at AACR, we saw you initiated the KEYTRUDA plus YERVOY study in melanoma. Just your thoughts around initiating one with YERVOY in lung cancer. Are you waiting for MYSTIC and CheckMate 227 to read out before you consider that? What's really the gating factor in initiating that trial?

Roger M. Perlmutter - *Merck Research Laboratories - President*

Right. John, first, for the MSI high, we -- what we've tried to do with MSI high is to say that we believe, based on the studies that were done at Johns Hopkins and our own studies, that the observation that there is microsatellite instability, which can be demonstrated using standard available tests, by itself predicts responsiveness in a broad range of solid tumors to KEYTRUDA. And what we're trying to do is something different from what has been done before. And that is to get away from the question of what is the primary histology of the tumor and say, from a molecular point of view, if you've got a DNA repair defect, there's a much higher likelihood of response. So we're looking at a broad indication there. Now microsatellite instability is not present at a very high frequency in many tumors. We're talking about 5% to 10% typically in a variety of different tumor types, so it's not a gigantic opportunity. But the tests are available. They're used to characterize tumors or can be ordered by physicians, and hence, the drug can be used in those settings. I don't think we can characterize the commercial opportunity in much detail. But knowing that a small percentage,

typically 5% to 10%, of tumors might have such things and there would be some penetration, I think you can probably do the calculation. And then with respect to -- as I've said a little bit earlier, with respect to ipilimumab, CTLA-4-directed therapy, there's no question that ipilimumab is active. We are interested in the question of how best to use ipilimumab in combination with KEYTRUDA. We have been doing some studies previously in melanoma and also in lung, which are helping us to understand what dose and schedule would be. We've been a little bit slower getting those started than perhaps others, in part because we're seeing so many other signals in combination studies with a variety of other agents, particularly intra-tumoral injections, which have less associated toxicity. So we've got a lot of irons in the fire there, but we are intending to do those studies.

Teri Loxam

Thanks, Roger. Darla, unfortunately, we're out of time, so we're going to have to end the call here.

Operator

Ladies and gentlemen, this concludes Merck's Q1 2017 Sales and Earnings Conference Call. You may now disconnect.