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MRK - Q1 2019 Merck & Co Inc Earnings Call

EVENT DATE/TIME: APRIL 30, 2019 / 12:00PM GMT

OVERVIEW:

Co. reported 1Q19 total Co. revenues of $10.8b and non-GAAP EPS of $1.22. Expects 2019 revenue to be $43.9-45.1b and non-GAAP EPS to be $4.67-4.79.

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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 First Quarter 2019 Sales and Earnings Conference Call. (Operator Instructions)

I'd now like to turn the call over to Teri Loxam, SVP, Investor Relations and Global Communications. Please go ahead.

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Thank you, Darla, and good morning, everyone. Welcome to Merck's First Quarter 2019 Conference Call. Today, I'm joined by Ken Frazier, our Chairman and Chief Executive Officer; Rob Davis, our Chief Financial Officer; and Dr. Roger Perlmutter, President of Merck Research Labs, who will each have remarks. In addition, I'm also joined by Mike Nally, our Chief Marketing Officer; and Frank Clyburn, our Chief Commercial Officer, who will be available for the Q&A portion of the call.

Before I turn the call over to Ken, I'd like to point out a few items. You'll 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 have excluded these from our non-GAAP results and provided

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 uncertainty. 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 2018 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 publically update any forward-looking statements. You can see our SEC filings as well as today's earnings release on merck.com. Finally, similar to last quarter, we had posted a presentation to the Investors section of merck.com, which include some of our highlights from the quarter.

With that, I would like to turn the call over to Ken.

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

Thank you, Teri. Good morning, and thank you all for joining us today.

We had a very strong start to 2019, and we are seeing our fundamental strategy of investing thoughtfully in R&D and following the science pay off. Our current portfolio of assets continues to drive strong growth, and we are working to ensure that we capture the near-term opportunities in front of us to maintain this momentum while planning for the next generation of treatments.

Our first quarter performance with double-digit year-over-year sales and EPS growth are the results of portfolio and operational strength, driven by oncology, vaccines and select hospital and specialty products. We are confident that products within these areas, including KEYTRUDA, Lynparza, Lenvima, GARDASIL, BRIDION and others, together with our Animal Health franchise, will lead to strong growth over the coming years.

Our performance in the first quarter also speaks to our success globally as we have received a number of additional approvals and launched new products in various markets around the world. Our international business, which represented nearly 60% of our sales this quarter, has strong momentum. And we believe that we've only scratched the surface in terms of the opportunity in key markets such as China where we are seeing significant growth.

We foresee a stream of additional approvals from our current portfolio of products across markets globally. And we will look to maximize these opportunities powered by our commercial team's proven ability to execute.

In parallel, we are also focused on advancing our promising pipeline and continuing to augment our internal research and development efforts with external innovation. We are excited by the prospects of our pipeline, which include potential new treatments in vaccines, oncology, HIV and many other areas of significant and ongoing unmet need.

There is also impressive work underway in our discovery hubs in Cambridge, London and South San Francisco, where we are incorporating some of the most scientifically advanced modalities and technologies in the world. Importantly, these hubs are located where many of the best biotech and scientific minds are gathered, and we're benefiting from the vibrant academic and biotech communities in each of our respective hubs.

Finally, we're continuing to evolve in a rapidly changing industry environment to best position Merck for sustainable, profitable growth over the long term while helping to drive positive outcomes for patients.

The overall health care landscape remains dynamic as the industry grapples with complex issues such as the rising cost of health care generally, pharmaceutical pricing and access and the shift to more outcomes-based reimbursement systems. At the same time, we believe that demand for even better outcomes for more innovative medicines will continue around the world given the vast and growing unmet need in cancer, Alzheimer's disease, and in so many other areas as the global population continues to grow while countries -- certain countries age. As a result, we will remain

steadfast in going where the science leads us in order to bring forward transformative medicines and vaccines. We are confident in our strategy, our growth prospects and our ability to continue to deliver significant benefits for patients and value to shareholders in 2019 and beyond.

We look forward to discussing these matters in more detail with you at our Investor Day in June where we plan to give you a deeper understanding of our pipeline and company and provide you with the opportunity to meet a broader set of our scientists and business leaders.

With that, I'll pass the call over to Rob to go through the details of our quarterly results. Rob?

Robert M. Davis - *Merck & Co., Inc. - Executive VP of Global Services & CFO*

Thanks, Ken, and good morning, everyone. As Ken mentioned, Merck had one of its strongest quarters in recent history. Our first quarter results reflect broad-based strength across our portfolio and continued discipline in our resource allocation. We executed very well across our key growth pillars, and our updated guidance reflects confidence that we remain well-positioned to deliver strong growth this year and into the future.

Turning to the top line. Total company revenues were $10.8 billion, an increase of 8% year-over-year or 11%, excluding the negative impact from foreign currency. This quarter was led by our human health business with growth of 12% excluding exchange. Animal Health revenues grew 3% excluding exchange. The remainder of my comments pertaining to sales will be on an ex exchange basis.

The increase in human health revenues was led by key products in our oncology, vaccine and hospital and specialty businesses. Growth was strong in both the U.S. and international markets and especially in China, where sales increased 67% year-over-year driven largely by newly launched products.

In oncology, KEYTRUDA sales were nearly $2.3 billion this quarter, an increase of 60% versus the first quarter of 2018. Growth was primarily driven by higher use in first-line non-small cell lung cancer, both as monotherapy and with the rollout of the chemo combo. In addition, utilization remains strong across the breadth of indications, including melanoma, head and neck, bladder and MSI high cancers. With our recent approvals in adjuvant melanoma and renal cell carcinoma in the United States, we are now approved in 18 indications across 11 different tumor types plus a pan tumor approval in MSI high patients. We are also very excited by recent approvals in Japan and China and look forward to making additional indications available to patients and markets around the world.

In the U.S., first-line lung cancer remains a key driver of growth, given further penetration of the chemo combo in both nonsquamous and squamous non-small cell lung cancer. We also are encouraged by early feedback in adjuvant melanoma, which is our first approval in the adjuvant setting.

First-line lung has also become a larger contributor in ex U.S. markets with growth driven by further uptake of our monotherapy indication in PD-L1 high expressers, but also by the ramp of the chemo combo following regulatory and reimbursement approvals in select EU markets and Japan. In Europe, the uptake of the chemo combo in nonsquamous patients is strong in markets where we have gained reimbursement, and we look forward to potential additional reimbursement approvals later this year as well as the introduction of the chemo combo in the squamous setting. In Japan, KEYTRUDA growth accelerated this quarter given the recent approvals across 5 indications including lung, adjuvant melanoma and MSI high cancers with utilization of the chemo combo in first-line lung cancer as a particularly strong driver of growth.

Finally, in China, we are seeing strong sales of KEYTRUDA following our launch late last year in metastatic melanoma. And we're very excited by our recent approval in China in first-line lung cancer. Overall, we remain very confident in KEYTRUDA's benefit to patients and long-term growth potential given its established immuno-oncology leadership and increased utilization across many indications and in markets around the world as well as our expectation for many additional approvals going forward.

We also remain encouraged by the progress and potential of both Lynparza and Lenvima, which we are developing and marketing in collaboration with AstraZeneca and Eisai, respectively. Lynparza sales doubled this quarter driven by further uptake in ovarian cancer following the U.S. approval of SOLO-1 in December as well as uptake in new markets such as China and Japan. In the U.S., across all tumors, Lynparza continues to lead the PARP inhibitor class with over 50% total patient share. We remain excited by the long-term potential of Lynparza especially with the recent start of the initial Phase III KEYTRUDA combination studies.

Lenvima is another important product for our oncology portfolio. Sales this quarter reflected continued strong performance in hepatocellular carcinoma following recent launches around the world. The launch in China is still early, but we believe the opportunity there is large given the high prevalence of HCC in that market.

Now turning to vaccines. Our vaccines business reflected strong demand for GARDASIL, which achieved sales of over $800 million this quarter, representing growth of 31% compared to Q1 of 2018. Ex U.S. demand remains particularly robust with continued strong uptake in China following the GARDASIL 9 launch last May and increased gender-neutral vaccination in Europe.

The decline in the U.S. reflects timing of public sector purchases, which will more than offset underlying demand. The strong growth demonstrated across our overall vaccines portfolio was also helped by the performance of certain pediatric products.

Our hospital and specialty business was led by 30% growth in sales of BRIDION. U.S. growth reflects BRIDION's increased utilization in procedures where a neuromuscular reversal agent is used, including in robotic and minimally invasive surgeries.

Animal Health revenue increased 3% this quarter to just over $1 billion. Companion animal sales grew 6%, primarily driven by strong demand globally for the BRAVECTO line of products. Livestock sales grew 1% driven by volume growth, particularly from new poultry and swine vaccines. This was largely offset by lower ruminant product sales driven by distributor purchasing patterns and weather-related softness resulting in delayed movement of cattle into the feedlots in the United States. While Animal Health growth this quarter was light versus recent trends, we still expect our full year performance to again outpace the overall market.

Additionally, we are very excited by the recent closing of our acquisition of Antelliq, which establishes Merck as a leader in animal identification and monitoring, one of the fastest-growing parts of the animal health industry.

Turning to the rest of our P&L, my comments will be on a non-GAAP basis. Gross margin was 75.9% in the quarter, an increase of 30 basis points versus the first quarter of 2018. Favorable benefits of product mix and foreign currency were mostly offset by lower price, higher royalties and amortization of milestone payments.

Operating expenses of $4.4 billion increased 2% year-over-year, including a favorable 2 percentage point impact from foreign exchange. Our investments in research and development grew 9%, driven by clinical development spending in oncology and vaccines as well as our discovery and early development efforts.

SG&A spending declined 3% year-over-year as we continued to drive productivity and reallocate resources for our highest-value growth opportunities. Other income and expense reflected $21 million of expense this quarter versus $259 million of income last year. The negative variance was primarily due to a litigation settlement gain in last year's first quarter as well as lower income from certain investments and equity securities and higher net interest expense this year.

Our tax rate of 16.5% for the quarter was 350 basis points lower year-over-year largely due to favorable discrete items primarily related to foreign tax credits and prior year mix of income adjustments booked this quarter. Taken together, our earnings per share increased 18%, excluding exchange, to $1.22.

Turning to our outlook for the year, we are narrowing and raising both our revenue and non-GAAP EPS guidance ranges for 2019 reflecting our strong and continued operational performance. We remain confident in both our near- and long-term prospects for revenue growth, driven by expected demand for our innovative products across key growth pillars, which more than overcome expected headwinds from price, foreign currency and pressures on mature and LOE products.

For 2019, we now expect revenues of $43.9 billion to $45.1 billion, which represents 4% to 7% growth versus 2018 driven by strength across our oncology, vaccines, hospital and specialty and Animal Health businesses. This range assumes a negative impact from foreign exchange of just over 1 percentage point using mid-April rates, which is slightly above our former assumption.

We are also increasing our expected EPS range to be between $4.67 and $4.79, including a slightly positive impact from foreign exchange at mid-April rates down from the 1 percentage point positive impact we have previously assumed. The new range represents growth of approximately 8% to 10% versus 2018. Other elements of our guidance remain unchanged, including our expectation for roughly flat gross margins and low to mid-single-digit increase in operating expense, driven mostly by the meaningful investments we continue to make in R&D which we expect to increase in the back half of the year; an expectation for roughly 0 dollars in other income and expense; and finally, a full year tax rate of a range of 18.5% to 19.5%.

In summary, we are very pleased by our first quarter performance. We expect our operational momentum to continue throughout the remainder of 2019 with continued strength across our key pillars of growth. Strong revenue growth along with disciplined resource allocation will allow us to make important investments in our pipeline while at the same time, delivering a leveraged P&L and meaningful increases in earnings per share. We believe our ongoing efforts to develop and deliver innovative products that help meet unmet medical needs for patients worldwide, coupled with strong commercial execution and disciplined financial management, position us very well to generate strong short- and long-term value to society and to our shareholders.

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

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

Thanks, Rob. The first quarter saw continued progress across all aspects of the R&D portfolio. As has already been mentioned, early in the quarter, we obtained U.S. approval for KEYTRUDA when used as adjuvant therapy in the treatment of patients with malignant melanoma with lymph node involvement following definitive resection. More recently, we obtained approval for combined use of KEYTRUDA and Pfizer's axitinib in the first-line treatment of advanced renal cell carcinoma based on the results of our KEYNOTE-426 trial. The strength of this study in which improved overall response rates, progression-free survival and overall survival compared with traditional treatment with single-agent sunitinib were observed, led to a very rapid review with approval secured nearly 2 months prior to the PDUFA date. I should also note that the combination of KEYTRUDA plus axitinib yielded consistently favorable results versus sunitinib in all traditionally defined patient subgroups and irrespective of PD-L1 expression in the tumor.

KEYTRUDA acts on a very broad range of malignancies. The current FDA label includes indications from salvage to adjuvant therapy applied in different settings and spanning 11 different tumor types with more indications currently under review. During the quarter, we also gained approval for KEYTRUDA in China when combined with platinum plus pemetrexed chemotherapy in the first line treatment of nonsquamous non-small cell lung cancer. With this approval, we hope to bring the benefits of this combination regimen previously approved in the United States, the EU, Japan and other major jurisdictions, to the very large population of patients in China suffering from pulmonary malignancy.

We also obtained FDA approval for the use of KEYTRUDA monotherapy in patients with non-small cell lung cancer whose tumors expressed PD-L1 on 1% or more of tumor cells based on the results of our KEYNOTE-042 study. This indication broadens the use of KEYTRUDA monotherapy to a much larger set of patients. Previously, only those patients in whom 50% or more of tumor cells were shown to express PD-L1 were included in the monotherapy indication. This recent broader approval also includes Stage III patients who are not candidates for surgical resection of their disease or for treatment by definitive chemoradiation.

At this point, I should note at the end of the first quarter, we posted our 1,000th KEYTRUDA study on ClinicalTrials.gov. Unsurprisingly, the bulk of new studies examined combinations of KEYTRUDA with other regiments and at earlier stages of disease. Not all of these studies yield the results that we and our patients around the world hoped for. As we have previously announced, both our KEYNOTE-240 study in patients with hepatocellular carcinoma and our KEYNOTE-062 study in the first-line treatment of patients with gastric cancer, did not meet our expectations.

However, both of these studies, the results of which we expect to be discussed at the American Society for Clinical Oncology meeting in June, provided important information that will assist specialists in refining their treatment regimens. In addition, the aggregated results of our clinical programs to inform the selection of novel agents. As an example, we have more than 20 new molecular entities currently under study in early stage clinical trials.

Beyond this, together with our colleagues at AstraZeneca, we made significant progress in advancing the use of our PARP inhibitor, Lynparza, for the maintenance treatment of patients with malignancies that bear evidence of defective DNA repair. Just yesterday, we announced that the Committee for Medicinal Products for Human Use or CHMP of the European Medicines Agency has adopted a positive opinion recommending Lynparza as first-line maintenance treatment for women with advanced BRCA-mutated epithelial ovarian fallopian tube or primary peritoneal cancer who have responded to traditional first-line platinum-based chemotherapy. This recommendation for an indication that has already been achieved in the United States was based on the SOLO-1 study showing that Lynparza treatment reduced the risk of disease progression or death by 70% versus that of a placebo treatment.

The CHMP recommendation follows approval by the European Commission authorizing Lynparza for the treatment of germline BRCA-mutated HER2-negative advanced breast cancer based on the OlympiAD trial.

Also in the first quarter, we announced that Lynparza treatment improved progression-free survival versus placebo in patients with germline BRCA-mutated metastatic pancreatic cancer whose disease had not progressed on platinum-based chemotherapy. Pancreatic cancer is an exceedingly difficult disease to treat, and we were gratified to see both statistically significant and clinically meaningful improvement in patients with germline BRCA mutations.

On the infectious disease front, earlier this month we had the opportunity to describe the use of ZERBAXA to treat hospital-acquired and ventilator-associated pneumonia at the European Congress on Clinical Microbiology & Infectious Diseases meeting in Amsterdam. In this ASPECT-NP study, we evaluated increased dose of ZERBAXA, 3 grams per day, which provided improved intrapulmonary drug levels in infected lungs. The study met its primary and key secondary endpoints in this critically ill population, 92% of whom were accessed in intensive care units, including favorable efficacy in patients with key gram-negative pathogens. The results of ASPECT-NP are currently under priority review at the FDA as a qualified infectious disease product with a PDUFA date of June 3. The same indication is also under review by the CHMP in Europe.

Looking ahead and beyond ZERBAXA, we have multiple FDA PDUFA dates during the second quarter. In the infectious disease area, the first quarter saw acceptance with priority review for our new drug application detailing the activity of our novel beta-lactamase inhibitor, relebactam, to be used in combination with imipenem and cilastatin for the treatment of susceptible gram-negative infection with a PDUFA date of July 16.

In the oncology space, FDA has granted priority review for KEYTRUDA in the first-line treatment of patients with recurrent or metastatic head and neck squamous cell cancer either as monotherapy or in combination with chemotherapy based on the results of the KEYNOTE-048 trial, with a PDUFA date of June 10, and for KEYTRUDA in the third-line treatment of patients with advanced small cell lung cancer based on results from the KEYNOTE-158 and KEYNOTE-028 trials with a PDUFA date of June 17. We're also looking forward to a large set of Phase III results, including the first data from our registration-enabling program for the 15-valent pneumococcal conjugate vaccine, V114, which is intended to provide broad protection against invasive pneumococcal disease in susceptible populations. We will provide more information about this program and about our other areas of research at the Investor Day meeting on June 20.

Now my colleagues and I will take your questions.

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Thanks, Roger. Darla, we'll move to the Q&A portion. We're sensitive to the rest of our peers reporting this morning, so we'll end our call just before 9 a.m. (Operator Instructions) So Darla?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) And your first question from Jason Gerberry, Bank of America.

Jason Matthew Gerberry - *BofA Merrill Lynch, Research Division - MD in US Equity Research*

Just 2 for me. First, can you talk, Ken, maybe a little bit about the future of Merck's role as a primary care company? I know a lot of investors perceive the company as largely pivoting post-JANUVIA LOE away from primary care and becoming more of a specialty company. But you also have programs like MK-7264. So just -- if you can provide a little bit of color in terms of the company's commitment and thought process regarding being a primary care player longer term? And then just secondly, can you guys give a little bit of color, the KEYTRUDA lung opportunity in China? A little bit more specifics there would be helpful.

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

Well, let me start by just saying that as a company, we are focused on following the science and coming up with innovative products that make a big difference. We are not saying we're going to be totally a specialty company or a vaccines company or a primary care company. What we actually want to do is to make sure that we take advantage of the best opportunities. Right now in oncology, the current growth is largely driven by that. So if you look at our pipeline, things like, for example, the pneumococcal vaccines are things that are essentially primary-tier-type products. I would say we haven't committed ourselves to one area of medicine. It has always been helpful to us to follow the science, and we're going to continue to do that going forward.

Frank Clyburn - *Merck & Co., Inc. - Chief Commercial Officer & Executive VP*

And with regards to China, this is Frank. We are, one, very excited about the overall opportunity in China as we demonstrated, as Rob mentioned, 67% growth versus prior year. Specifically with KEYTRUDA, last year, we received our second-line melanoma indication in China. And as Roger mentioned, we just received our first-line lung indication with the combination with chemotherapy.

We're really excited about the opportunity in China. We'll be working through the NRDL listing process with the Chinese regulators. And given the timing of our lung approval, we'll have to see if NRDL listing is a possibility this year. A listing would open up an exciting opportunity to expand volumes.

But even without that, we feel as though we're very well-positioned with KEYTRUDA in China. We're the only PD-1 that has a first-line lung cancer indication, and we feel as though the breadth of our program, as you've seen in other markets, we plan to bring additional indications to China, which we think positions us very well for future growth.

Operator

It's from Umer Raffat with Evercore ISI.

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

I actually wanted to focus not on cancer today for a change, and perhaps on HIV for a minute. I just wanted to gauge your expectations into the drive to simplify a Phase II trial coming up this summer. I understand you have an Atripla-like regimen. And I guess my question really is what is it that we can learn about MK-8591 in the context of the combination pill? And what are you specifically looking for on deciding whether to take this program forward into larger Phase III?

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

8591 has extraordinary properties as you appreciate, both in terms of its potency and in terms of the duration of its effect. We've had the opportunity to present some of those data in the past but we're now getting -- we'll have a chance to look at significant Phase II studies of long duration. I'm quite optimistic actually that we're going to see very good responses in that setting and that that will lead to Phase III programs.

Over time, I think the real advantage of 8591 is its ability to be put into a long-term format as potentially an implantable that could provide enormous benefits from a pre-exposure prophylaxis point of view. But as well dramatically simplify the treatment regimen for patients who are already infected with HIV in order to achieve long-term viral suppressant. So we're going to be looking at those results, the Phase II results very soon and have the opportunity to present them. And I think that will lead to much larger studies. So we're quite enthusiastic about 8591.

Operator

It's from Chris Schott with JPMorgan.

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

I guess just 2 here. Maybe, first, can you just elaborate a little bit more on KEYTRUDA in front-line lung as you're thinking about Europe? Just where are we at this point in terms of reimbursement and market share? And how should we be thinking about kind of the ramp in that first-line lung business as we go through the rest of this year?

My second question was trying to get a better handle on longer-term margin dynamics. Could you just elaborate a little bit more on expense trends over time? Specifically, you've talked about R&D investments this year and next. But when we think longer term, can we think about expenses actually rolling over beyond 2020 and starting to decline? Or is the longer-term margin opportunity more about expenses just growing at a slower rate than top line?

Frank Clyburn - *Merck & Co., Inc. - Chief Commercial Officer & Executive VP*

With regards to KEYTRUDA outside the U.S. and Europe in particular, first, we're very pleased. We sold close to $985 million this quarter and had growth with almost 69% versus prior year outside the U.S. So we're very pleased with our progress. In lung specifically, lung represents about 70% of our sales outside the U.S. We have access right now in Germany in many of the mid-European markets. We're still working on access in several of the other large European markets for reimbursements, which we expect will come online hopefully in the second half of this year.

So our overall momentum, where we have first-line lung approval for monotherapy is very strong. We're the leader clearly in lung in that setting. The chemo combination has helped us to ramp, as I mentioned, and we have market-leading shares in the markets in Europe there. And then we look forward to the second half of the year, where we'll see additional reimbursement, additional markets come on board for access. So we're very pleased with where we are in Europe and outside the U.S. with regards to lung.

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Great. And Rob, if you'd comment on margins?

Robert M. Davis - *Merck & Co., Inc. - Executive VP of Global Services & CFO*

Yes. So with your question on margin, maybe just an overall comment then the specifics on what's happening in the operating expense line. We have said and we continue to believe, we do expect meaningful operating margin expansion over time driven by revenue growth, the changing mix of our business, our continued focus on efficiencies and ultimately a moderation of our R&D growth over time. So I just put that out there to

set context. But specifically, when you look at what will be driving the margin expansion, into your question, we will continue to see R&D grow over the next couple of years, and we would expect that to be at a rate faster than sales. But after that, we do expect to think -- to see R&D moderate. It will still grow. And our overall OpEx, we believe, will continue to grow. It just will be growing at rates lower than sales. That should allow for the margin expansion we've been talking about.

So it's not that you're -- we expect absolute reduction in spend, but just a moderation of growth as we move through the bolus of investment and the really expansive and, frankly, impressive clinical program that our MRL colleagues have put together in the near term here.

Operator

It's from Navin Jacob with UBS.

Navin Cyriac Jacob - *UBS Investment Bank, Research Division - Equity Research Analyst of Specialty Pharmaceuticals and Large Cap Pharmaceutic*

If I may, on KEYTRUDA, the administration will be -- or the OMB will be putting out regulations on -- or draft guidance on IPI. Just wondering, to the extent that you can share with us, what the average net price is in Europe relative to the net price here in the U.S. Is the administration's characterization of EU to U.S. pricing differential of -- or U.S. to EU pricing differentiation of 1.3 to 1, is that fair? And then number two, just on the China market, how large is KEYTRUDA right now, roughly annualizing that in China? That would be very helpful to us.

Frank Clyburn - *Merck & Co., Inc. - Chief Commercial Officer & Executive VP*

Yes, so on the first question -- this is Frank. With regards to KEYTRUDA, we're really focused on our overall strong underlying demand in the U.S. and outside the U.S. and our strong data. We haven't shared with regards to net pricing outside the U.S.

With regards to China, we see the opportunity as very significant. If you look at the lung market, in particular, there's 600,000 to 700,000 lung cancer patients in China. Half of them have a driver mutation, and we think a couple hundred thousand of those patients are available for treatment with our overall KEYNOTE-189 regimen. So we see China as a very significant opportunity of growth going forward, and we're very pleased that we're rolling out our new lung cancer indication.

Operator

It's from Vamil Divan with Crédit Suisse.

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

So one, maybe just on the lung side. You mentioned the KEYNOTE-042 approval. Can you maybe just quantify sort of your expectations on the use of monotherapy in patients with PD-L1 between 1 to 50? And then also the Stage III opportunity, I think maybe because some people were, like, surprised with that label expansion, just if you can talk about the commercial opportunity there. And then maybe Ken, just building on the earlier question around primary care and sort of business development priorities, can you maybe just comment broader on sort of the size of deal? I know you say you want to sort of focus on the science. But I think a lot of investors also are curious on just as you think about bolt-on versus larger transactions or any changes in your priorities there.

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Right, let's start with Frank.

Frank Clyburn - *Merck & Co., Inc. - Chief Commercial Officer & Executive VP*

Yes. So KEYNOTE-042, we see as a very positive advancement for our position in non-small cell lung cancer. As Roger mentioned, our new indication is based on -- for patients who are not candidates for surgical resection or definitive chemoradiation. So it gives us an entrée into Stage III patients. It's a smaller subset of Stage III patients based on our indication, but an important indication for us to expand into non-small cell lung cancer.

The other aspect that 42 does allow us, it allows, for now, all PD-L1 positive patients in the metastatic setting that would look for a monotherapy option. And there are patients that look for monotherapy options, maybe based off of their performance status or other comorbidities. We see this as an important opportunity as well. So we're very pleased that KEYNOTE-042 helps to round out our overall lung story and positions us very strong for future growth in lung.

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

Okay, and on the business development side, I would just say that, first of all, last year we were very active. We did about 60 transactions spanning licensing, technology deals and clinical collaborations. As we said before, our goal is to find the best scientific opportunities that we can. Our balance sheet gives us the opportunity to look across the entire spectrum of opportunities, but we've also been very clear that while we look at everything, what's most appetizing to us are the bolt-on deals because we believe they're the least disruptive thing from an R&D standpoint.

I would also comment that while at the end of last year we felt valuations were going in the right direction, with the first quarter 2019 market recovery, assets seem more fully valued. And as we look forward, we continue to say we have to be disciplined and look for those opportunities where we can create value going forward.

Operator

It's from Andrew Baum with Citigroup.

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

A couple questions, please. The first one for Roger on V114. Simplistically, one could say, well, your competitor is in market experience that has a great number of stereotype areas, precious replacement strains, and so on. I underline the word simplistically. But what is it that you believe Merck brings to the table apart from speed to market which you think is going to make sure that Merck is a major participant to both pediatric and adult segment?

And then second, in relation to the IPI proposals, and this is addressed really to Ken or Frank, what do you think is the ultimate impact of IPI given the ability to negotiate in Europe provides nontransparent discounts but increased lift? Because what is the complexity of -- attacks this pricing for 340B hospitals? How does that all shake out? And do you think it's actually feasible to find a solution that works?

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Let's start with -- thanks, Andrew. We'll start with Roger on V114.

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

Right. Andrew, thanks. So first of all, we're not inexperienced in the pneumococcal disease market, and we have had Pneumovax on the market for decades. This is an area that we know extremely well. The pneumococcal conjugate vaccines have been in development for more than 20 years in our laboratories. In fact, I started these programs during my first tour of duty a long time ago. And so we've learned a great deal about how to

make these vaccines to make them very efficacious. In particular, we've learned about balancing serotypes in order to provide the broadest possible response.

Over time, our program, which includes not just V114 but others as well, will become an important contributor to human health and to protection from pneumococcal disease, invasive pneumococcal disease, both in adults and in the pediatric population. So you will see that evolve over a period of years. It's going to be an important contributor, no doubt.

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

On the international price index situation, so we have -- first of all, we submitted our comments. We continue to see this as not the best approach to dealing with a major problem that we have with patient out-of-pocket costs. We think there are much better approaches.

I think it's still early days. I don't know exactly how these kinds of things will be implemented. There are a number of proposals out there, as you know, involving health care reform in this country.

I would say that we negotiate as much as we can in ex U.S. markets for the value that we believe that we can bring. And I don't think anyone's supposition that by doing that, it's going to improve our ability to negotiate in Europe is really the right thing.

Finally, I would say that we've looked at some of the calculations in the report about KEYTRUDA. We're not sure they're actually the right ones. But I will tell you this, that we continue to focus on the strong data that makes KEYTRUDA a unique product across many indications.

Operator

It's from Steve Scala with Cowen.

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

A couple of questions. KEYTRUDA numbers were impressive but a touch below expectations. Just wondering if there were any onetime factors that impacted the Q1 number.

And secondly, on gefapixant, it looks like an effective drug and a safe drug but I don't believe the Phase II data in OA or OA pain ever was presented. Neither were other smaller studies that completed some time ago. So can you elaborate on the data set supporting gefapixant?

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Great. Let's start with Frank on KEYTRUDA.

Frank Clyburn - *Merck & Co., Inc. - Chief Commercial Officer & Executive VP*

Yes. So KEYTRUDA sales, as we've mentioned, were $2.3 billion this quarter, 60% growth year-over-year ex exchange. And what I tend to look at is what's happening from an underlying demand perspective. And when you look both versus prior year and sequentially, we're seeing very good continued underlying demand. You will see quarter-to-quarter some fluctuations based on some inventory movements. But overall, I think that we feel very good about how we're seeing the demand ramp. And in particular, we're seeing strong overall demand with regards to our lung cancer indications, both in nonsquamous and squamous cell carcinoma non-small cell lung cancer. In fact, in squamous cell lung cancer, we're seeing our market shares exceed 75% for new patients. So we've become the standard of care in that subset of patients.

We also are feeling very excited about the opportunities outside of lung. In the U.S., as Roger mentioned, we have our new indication now based off of KEYNOTE-426 in renal cell carcinoma. We see that as a very significant opportunity for future growth. As well as Roger also highlighted KEYNOTE-048 with a PDUFA date coming up in June for head and neck cancer. And we have market leadership position in head and neck in later lines of therapy, and we're very excited about KEYNOTE-048.

In addition, the last thing I'll mention is outside the U.S. As we've been saying, we see significant opportunities based on some of the continued rollouts in Japan, in China and in Europe. So we're very confident about the KEYTRUDA ramp and future growth prospects going forward.

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Thanks, Frank. We'll move to Roger.

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

Right, Steve. On 7264, gefapixant, the underlying logic of this is the belief, based on a variety of preclinical studies that the purinergic receptors, and particularly P2X3, contribute to a neuronal hypersensitivity syndrome. So in the setting of chronic stimulation, there's sort of a feedforward phenomenon, and it contributes to allodynia and other sensitivity syndromes.

That's true, we believe, in the first case in the chronic cough setting, where an early stimulus usually the result of inflammation leads to a cough syndrome that does not resolve after 8 weeks. And in that setting, as we've demonstrated in Phase II studies, gefapixant has dramatic effects but as well in some other chronic stimulation syndromes. And we're looking at a number of those, including as you know, in endometriosis. There's a lot of preclinical data that supports the conjecture, but fundamentally, we need better clinical data, and that's what we're going to get.

Operator

It's from Geoff Meacham with Barclays.

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

Frank, I wanted to ask about lung trends in the U.S. When I look at brand impact data, that it shows first line share that's stable at around 60% in 1Q. So the question is, are you seeing any moderation in sequential share gains in the U.S.? And where do you think the ceiling share could be in first-line lung?

And then, and the recent Immune Design deal, Roger, can you talk maybe more broadly about how you can leverage your technology optimally -- and now that it's in-house? And how do you guys view a new engine approach in IO more broadly?

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Right. We'll start with Frank.

Frank Clyburn - *Merck & Co., Inc. - Chief Commercial Officer & Executive VP*

Geoff, in the U.S. in lung, what we're seeing is with regards to share, you have to take out patients that do not have an EGFR or ALK genomic tumor aberration. So we see our market shares somewhere in the low 70% share for the nonsquamous non-small cell lung cancer segment. So we see very strong penetration, Geoff, within PD-L1-positive patients, the 15-above segment, which we're pretty much getting all of those patients; in the 1 to 49, we have penetrated very significantly. We still have opportunity for growth in the PD-L1-negative patient population, and that's a focus

for the commercial team. So I do see that as being the opportunity. We'll continue to educate, in particular, the community physicians in the U.S. with regards to lung.

As I mentioned with regards to the squamous non-small cell lung cancer patient population, we have penetrated that very rapidly. Over 3/4 of those patients and are being treated with a chemo combo regimen or with monotherapy. So we still see growth for squamous. But clearly, we have penetrated that segment very rapidly. And as I mentioned before, we're very excited, not only about lung, but all of the other indications that I spoke about and that Roger spoke about that are upcoming new launches for us in the U.S.

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Thanks, Frank. We'll move to Roger on Immune Design.

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

Right. Geoff, thanks for the question. So in Immune Design, there were 2 principal assets, both of high interest to us. I mean, the first is a molecular defined adjuvant, the GLA adjuvant, which we believe could be beneficial for some of our newer vaccines that require adjuvant and as well for some of the older vaccines where there's a desire to get to less -- a fewer -- a smaller number of vaccinations. So we're looking at those things very carefully. The adjuvant has been in thousands of people, and so we already understand its safety profile quite well. So that's good.

And the second thing is the lentivirus vaccine, which is unique in -- from several prospectives. The first is it's selective targeting of dendritic cells. The second is its high carrying capacity. And the third is that it has already a substantial amount of clinical exposure demonstrating that it actually stimulates an immune response. That can be applied to neoantigens, but it can also be applied, as they have, to more conventional cancer testis antigens, which are often forgotten about, but I think may someday have their day in the sun. So we're looking forward to pursuing those kinds of approaches in combination with other immune modulators that we've already developed.

Operator

Your next question is from Louise Chen with Cantor.

Louise Alesandra Chen - *Cantor Fitzgerald & Co., Research Division - Senior Research Analyst & MD*

So my first question is on China, and do you think that individual drugs have blockbuster potential? And if so, what has to change in the market for this to happen? And then just a follow-up question on V114. If it's approved, what is your go-to-market strategy in light of competition that's in the market now and potentially coming? For example, will you target children first and then go after adults? And then what do you anticipate the ACIP recommendation may be?

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Let's start with Frank in China.

Frank Clyburn - *Merck & Co., Inc. - Chief Commercial Officer & Executive VP*

So with regard to China, we see China as a very significant opportunity for us. As we mentioned, we're seeing very strong growth. And I think for us, what's important is we have pivoted to innovation in China. And this has always been a part of our overall strategy at Merck. So when you think about the launches right now in China of GARDASIL, of KEYTRUDA, Lynparza, Lenvima, BRIDION, JANUVIA has just now received NRDL listing, we see significant opportunity for China across a number of products within our innovative portfolio.

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Great. Thanks. We'll move on to Mike Nally for V114 outlook.

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

When you think about V114 and the opportunity going forward, we think there's a great opportunity in both the pediatric and adult segments. Obviously, we've had a presence in the adult segment, as Roger noted, with Pneumovax 23 for over 35 years. And as we think about the pediatric segment, clearly we're touching all pediatric offices basically around the world with our existing vaccines. And so when we look at the opportunity for 114, a lot of it comes down to really understanding the underlying epidemiology and how that's evolving over time with 114 at a market level that is different. But also across pediatric and the adult segments, the epidemiology is evolving quickly.

So as we think about the ultimate recommendations, it's clear that customers want choice in this market. And with 114, we think we provide a really valid alternative, especially given the fact that we have a very balanced immune response across all 15 serotypes that we're covering in our vaccine. And what we've seen to date is that there are some serotypes that are inadequately covered, and we're seeing breakthrough with those from the existing vaccines.

Operator

It's from Dave Risinger with Morgan Stanley.

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

I have a couple questions, and if I repeated anything from -- repeating anything, I apologize. First, with respect to Animal Health, the constant currency growth was 3% including 1% in livestock. Was the issue in livestock just at the end of the quarter in the U.S.? I think that -- there were the Midwest floods and other weather issues at the end of the quarter, but I don't know if there were other things that held back the livestock business. And I think that you said that for the full year, you expect growth to be greater than the market for Animal Health. What is the market expected to grow in 2019? And then separately, could you just quantify the inventory swings for KEYTRUDA in the first quarter? And for GARDASIL, if there were any for GARDASIL?

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Thanks. We'll start with Rob on Animal Health.

Robert M. Davis - *Merck & Co., Inc. - Executive VP of Global Services & CFO*

Thanks for the question. Yes, as you look at what happened with Animal Health in the first quarter, your numbers you're quoting are correct. And really, what we were seeing is an impact of the cold weather. It's not necessarily the flooding that went through the middle part of the country. It's really more due to the cold weather patterns, which caused the cattle to stay in the fields longer and not move into the feedlots as quickly. And given that a lot of our products are more focused to the feedlots, that mix dynamic of just how it played out affected us in the quarter. So that was part of it.

We also did see some buyout from our distributor partners due to some consolidation going on in the distributor space. So it was really a combination of a change in channel and buy down to pull down inventory in the channel and the seasonality impact that affected the business in the first quarter.

As we look to the full year, we do expect to grow above market. And if you look at where the Animal Health market has been over the last couple of years, it's in the roughly, I will say, low to mid-single digits of growth. So we expect to outpace that, and that's before we layer in the impact of the Antelliq acquisition.

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Well I'll pass over to Frank really quick on inventory.

Frank Clyburn - *Merck & Co., Inc. - Chief Commercial Officer & Executive VP*

Yes. And Dave, with regards to KEYTRUDA, as I mentioned, with a brand that is now of this size, you're going to see some slight movements with regards to channel quarter-to-quarter. We're focused, as I mentioned, really on the strong underlying demand that we're seeing in our major indications as well as the future indications we're prepared to launch.

Operator

It's from Alex Arfaei with BMO Capital Markets.

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

Frank, a follow-up, if I may, on the KEYTRUDA opportunity in China given that it sounds like it's going to become increasingly important. As I'm sure you know, there are Chinese companies that are also working on PD-L1s, some of them moving to late stage. And these could compete with you on price. So as you look at China longer term, what's the outlook from a competitor perspective in immuno-oncology? And do you also see a future where these PD-1s compete with KEYTRUDA in the U.S. in developed markets? And if I may, could you provide your estimated KEYTRUDA sales by indications in major markets?

Frank Clyburn - *Merck & Co., Inc. - Chief Commercial Officer & Executive VP*

Yes. So on the -- let me start with the estimated sales in the U.S. by indication. We usually provide that out. So 65% of our sales in the U.S. are lung; 10% percent are approximately melanoma; head and neck represents about 5%; and as I mentioned, we're very excited about the opportunity we have upcoming in head and neck. Bladder represents about 5%. MSI high has become a very important indication for us, represents about 5%; and all other is approximately 10%.

Going back to your question on China, we believe oncology is really a data-driven area, Alex, given the severity of the disease. If you look right now at what's been accomplished with KEYTRUDA, and we've always said that this wall of data is going to be important, and I think it's going to be very important for us in China as well. When you think about 18 indications across 11 different tumor types, we believe that this continues to differentiate us in the marketplace. China will clearly be a competitive market, but our first-mover advantage with the first-line lung cancer approval, we think, sets us up very well. And the local players in China do not have an approved indication right now on first-line lung nor have they conducted or achieved the results of a trial like KEYNOTE-189.

So our strategy, as we've seen in the U.S. right now, there are 5 additional competitors there. And we believe our clinical execution and commercial execution and our significant amount of data will help us to compete in China as well as any other market around the world.

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

All right. We're going to try and get at least one more in if we can squeeze it in.

Operator

It's from Tim Anderson with Wolfe Research.

Timothy Minton Anderson - *Wolfe Research, LLC - MD of Equity Research*

Just a broader question on China in general. Big growth in the quarter, but they've implemented certain policy changes, like this 4+7 tendering process that a lot of industry participants think is going to slow down overall Chinese growth for multinationals. What is your outlook for that for Merck's overall book of business?

And then second question is KEYTRUDA, the triple-negative breast 522 adjuvant trial, just an update. Are we likely going to see data this year? Is that still possible? And if it is, is that just going to be pCR? Or could we actually see clinical efficacy being reported out?

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Right. So we'll do, Frank, comment quickly on China; and then Roger on 522.

Frank Clyburn - *Merck & Co., Inc. - Chief Commercial Officer & Executive VP*

So as I mentioned in China for us, we have pivoted to more of the innovative products that are driving our growth: GARDASIL, KEYTRUDA, BRIDION, Lynparza, Lenvima. So we feel as though we're very well-positioned, and that's going to help us to continue to see growth. We will likely see some impact from some of the older products based on some of the pricing initiatives that are underway in China in some of the provinces. So while we may see some bumpiness along the way, we have shifted the majority of our portfolio, approximately 60% to 70% of it is now focused on innovative products. So we feel as though that positions us very well, not only in the near term but for the long-term growth in China.

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Real quick on 522.

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

On 522, yes. The -- of course, the study is supervised by an external data monitoring committee, and they will be evaluating it. It's event-driven. My expectation is that it is possible for sure that we could see some review from them. There was a previous interim which led to the study continuing. And our expectation is that there will be an opportunity to see additional data, but I can't speak to what those data will be. And soon as we know, we'll have the opportunity to announce it. That's basically -- they're in control.

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

So thank you for joining the call today. We are executing well across our business, and we remain confident in our performance for the year and the long term. We look forward to discussing our pipeline and business in more detail at our Investor Day in June. Thank you.

Operator

This concludes Merck's First Quarter 2019 Sales and Earnings Conference Call. You may now disconnect.