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Merck & Co., Inc. (MRK) CEO Kenneth Frazier on Q2 2019 Results - Earnings Call Transcript

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Q2: 07-30-19 Earnings Summary

Press Release *10-Q* *Slides*

EPS of $1.3 beats by $0.14 | Revenue of $11.76B (12.37% Y/Y) beats by $817.42M

Earning Call Audio

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Merck & Co., Inc. (NYSE:MRK) Q2 2019 Results Earnings Conference Call July 30, 2019 8:00 AM ET

Company Participants

Teri Loxam - Senior Vice President of Investor Relations and Global Communications

Kenneth Frazier - Chairman, Chief Executive Officer

Robert Davis - Executive Vice President of Global Services & Chief Financial Officer

Roger Perlmutter - Executive Vice President & President of Merck Research Laboratories

Mike Nally - Chief Marketing Officer

Frank Clyburn - Executive Vice President & Chief Commercial Officer

Conference Call Participants

Terence Flynn - Goldman Sachs

Seamus Fernandez - Guggenheim

Andrew Baum - Citi

Chris Schott - JPMorgan

Navin Jacob - UBS

Umer Raffat - Evercore

David Risinger - Morgan Stanley

Tim Anderson - Wolfe Research

Jason Gerberry - Bank of America

Steve Scala - Cowen

Louise Chen - Cantor

Mara Goldstein - Mizuho

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 the Merck & Company Q2 Sales and Earnings Conference Call. All lines have been placed on mute to prevent any background noise. After the speakers' remarks, there will be a question-and-answer session. [Operator Instructions] Thank you.

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

Teri Loxam

Thank you, Darla and good morning. Welcome to Merck's second 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 read our prepared 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 will see that we have items in our GAAP results, such as acquisition-related charges, restructuring costs and certain other items. You should note that we 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 US 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 1A 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 forward-looking statements made this morning. Merck undertakes no obligation to publicly update any forward-looking statements. You can see our SEC filings, as well as today's earnings release on merck.com. We have also posted a presentation to the investor section of merck.com which includes some of our highlights from the quarter.

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

Kenneth Frazier

Thank you, Teri. Good morning and thank you all for joining the call. Our science-led strategy together with our clinical and commercial execution drove another quarter of accelerating revenue growth with strength across our global portfolio.

Our results demonstrate the continued momentum of our business through the first half of the year and further show that our focus on the kind of innovation that significantly improved health outcomes is paying off.

As highlighted at our recent Investor Day, we are confident that our innovative portfolio of product and significant pipeline opportunities supported by unparalleled R&D and commercial execution will continue to drive strong growth while we invest in cutting edge science to deliver breakthroughs over the next decade and beyond.

Over the past quarter, we continue to advance our pipeline and presented encouraging data across our programs, including two additional regulatory approvals and a filing acceptance for KEYTRUDA. Two new regulatory approvals in infectious diseases, as well as new clinical data on the V14 - V114 pediatrics trial, MK-8591 and many others.

Our clinical and regulatory progress reflects Merck's unwavering commitment to biomedical research aimed at bringing forward products that can make a meaningful difference in the lives of patients around the world.

In addition, we continue to strategically invest in business development to strengthen our pipeline through value enhancing external opportunities. This quarter alone, we announced two acquisitions that will bolster our oncology pipeline with Peloton Therapeutics and Tilos Therapeutics respectively.

We also successfully completed our tender offer for Immune Design and closed on the acquisition of Antelliq and animal health. We remain confident that our strategy, growth prospects, outstanding scientific and commercial talent and leadership team, together with our focus on execution will enable us to drive significant value for patients and shareholders this year and for years to come.

And with that, I'll now turn the call over to Rob to review the details of our quarterly performance. Rob?

Robert Davis

Thanks, Ken. And good morning, everyone. As Ken mentioned, our performance in the second quarter is a clear testament to the strong momentum and growth potential of our business. Our result over the last several quarters continue to reinforce the confidence we have and our ability to drive sustained long-term revenue growth and meaningful operating margin expansion, while maintaining a disciplined capital allocation strategy focused both on investing in the business and returning capital to shareholders.

Now turning to our results. Total company revenues were $11.8 billion, an increase of 12% year-over-year or 15% excluding the negative impact from foreign currency. This growth was led by our Human Health business which increased 17% this quarter excluding exchange. Animal Health grew 9% excluding exchange. The remainder of my comments pertaining to sales will all be on an ex-exchange basis.

The increase in Human Health revenues was led by key products in our oncology, vaccines and hospital businesses. In oncology, KEYTRUDA sales exceeded $2.6 billion this quarter, an increase of 63% year-over-year. Growth was driven by increased adoption globally in the first-line lung setting, as well as uptake in recently approved indications.

In the US, strong demand across all indications continues to drive performance. KEYTRUDA is firmly established as the standard of care for indicated patients in first-line lung and we continue to further penetrate segments of the population, including low and

non PD-L1 expressing patients.

In addition, we are encouraged by our recent launches in metastatic renal cell carcinoma and adjuvant melanoma where we are already seeing strong adoption by oncologists.

We're also excited about our opportunity in first-line head and neck cancer for which we received approval in June. With 20 indications currently approved in the United States we are further establishing KEYTRUDA as a foundational cancer treatment. Outside the US, KEYTRUDA sales grew 73% driven by long as we continue to gain reimbursement for the chemo combo in more countries in the EU.

In Japan, we are now the leading anti PD-1 agents, which speaks to our execution and the breadth of our indications. And in China, we have seen very strong growth given the recent launch in first-line lung and continued uptake in melanoma and our growth should continue as we reach more patients and expect to launch additional indications.

KEYTRUDA is changing the way in which cancer is being treated and we are still in the early days of the KEYTRUDA journey. We remain very confident in the long-term growth potential, given our established IO leadership and our expectation for many additional approvals around the world.

Our results also reflect continued strength in both Lynparza and Lenvima, products we market in collaboration with AstraZeneca and Eisai respectively. Lynparza revenue more than doubled this quarter driven by further uptake in ovarian cancer based on the results of SOLO-1 in the United States, as well as strength in Europe, China and Japan.

Lynparza continues to lead the PARP inhibitor class in the United States, with nearly 60% total patient share. We look to further establish Lynparza as the PARP inhibitor of choice in additional tumor types and in combination with KEYTRUDA.

Lenvima revenue also more than doubled as we continue to drive sales in HCC in the United States in China and launch in several other markets. We believe the Lenvima will be an important product for our oncology portfolio and look forward to the potential for additional indications, across our broad development program.

Turning to vaccines. Our vaccines business reflect strong growth in our pediatric portfolio, as well as strength in GARDASIL which was driven by public sector purchases and greater demand in the adolescent cohorts in the United States, as well as continued demand across Europe and the emerging markets, especially China.

Our hospital business benefited from 20% growth in BRIDION which is annualizing at over $1 billion, reflecting strong performance in the United States as we continue to increase share within the reversal market.

Animal Health revenue increased 9% this quarter to $1.1 billion. Livestock grew 13% primarily due to the contributions from the products acquired in the Antelliq acquisition. Companion animal sales grew 4%, as volume growth in vaccines and insulin products were partially offset by the timing of customer purchases in the prior year for BRAVECTO.

Turning to the rest of our P&L, my comments will be on a non-GAAP basis. Gross margin was 75.4% in the quarter, an increase of 100 basis points year-over-year. Recall that the sizable catch-up adjustment for an accrued sales milestone related to Adempas was included in the second quarter of 2018.

Operating expenses of $4.8 billion increased 9% year-over-year. R&D drove a large portion of the increase in spend and reflects higher expenses in support of our discovery in clinical development efforts, as well as business development transactions during the quarter. SG&A also grew year-over-year, reflecting continued investments to accelerate our key growth drivers and the launch of new indications.

The decrease in other income this quarter reflected the unfavorable year-on-year impact of mark-to-market income on equity securities, as well as higher net interest expense.

Taken together, we earned $1.30 per share, an increase of 25% excluding exchange. This growth demonstrates the continued momentum in our business as we drive strong top line growth combined with disciplined resource allocation enabling operational leverage.

Turning to our outlook for the year. Given the confidence we have in our strong continued performance we are narrowing and raising both our revenue and non-GAAP EPS guidance ranges for the full year of 2019. We now expect revenues of $45.2 billion to $46.2 billion, which represents 7% to 9% growth versus 2018 driven by strength across our key growth pillars.

This range assumes a negative impact from foreign exchange of just over 1 percentage point using mid July rates. We expect OpEx to increase by mid-single digits, primarily driven by investments in R&D. We now expect non-GAAP EPS to be in the range of $4.84 to $4.94, which represents growth of approximately 12% to 14% versus 2018. We now expect a slightly negative impact from foreign exchange. All other elements of our guidance provided in April remain unchanged.

In summary, we are operating from a position of strength as reflected in our second quarter results and our updated guidance. We are confident in our ability to drive strong revenue growth in the near and long term, and we remain committed to delivering a leveraged P&L, while balancing the need to invest in innovation, all of which we expect will deliver significant and sustainable value to patients and our shareholders.

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

Roger Perlmutter

Thanks, Rob. The second quarter was a very important one for Merck Research Laboratories with meaningful progress made in every part of our organization. First, we received numerous approvals from the US Food and Drug Administration, including as previously mentioned supplementary approval for the use of KEYTRUDA both as monotherapy and in combination with chemotherapy in the first-line treatment of squamous cell carcinoma, head neck, and supplementary approval of KEYTRUDA as monotherapy for third-line treatment of small cell lung cancer.

We also received supplementary approval for ZERBAXA in the treatment of hospital-acquired and ventilator-associated pneumonia caused by sensitive bacterial strain. This represents an important advance in the treatment of a life-threatening illness especially when caused by for example resistant pseudomonas species.

More recently we obtained approval of RECARBRIO, our combined independent cilastatin, relebactam therapy for complicated urinary tract or intra-abdominal infections.

Relebactam was specifically engineered to enable extended activity of imipenem against certain otherwise resistant bacterial species expressing the form of beta-lactamase, and as part of our efforts to address the increasing threat of antimicrobial resistance.

During the second quarter, we also had the opportunity to review exciting new data from our anti-retroviral program including 48 week data from the combination of Doravirine with our new nucleoside reverse transcriptase translocation inhibitor, islatravir for the maintenance of low-viral burdens and patients infected with the human immunodeficiency virus.

These data which were presented last week at the International AIDS Society meetings in Mexico City were complemented by studies of a subcutaneous islatravir implant that might permit long term perhaps once a yearly prophylaxis against HIV infection.

In the infectious disease space, we also presented data on the immunogenicity [ph] of V114, our new 15-valent pneumococcal conjugate vaccine in pediatric populations. We are very enthusiastic about the V114 for which Phase 3 data from our comprehensive development program will become available beginning towards the end of this year.

Returning to the oncology space, just yesterday we announced that the data monitoring committee supervising our KEYNOTE-522 Phase 3 studies of neoadjuvant and adjuvant KEYTRUDA combined with chemotherapy found that KEYTRUDA treatment was associated with an improvement in pathologic complete response rates, one of two dual primary endpoints of this study as compared with chemotherapy alone.

I wish to make two key points regarding this study. First, neoadjuvant therapy occupies an increasingly important role in the treatment of breast cancer, especially in the triple-negative subset, which represents between 15% and 20% of breast cancers. In this setting, the use of neoadjuvant therapy can reduce tumor burden from a less aggressive surgical resection and provide improvement in long-term outcomes.

Second, achievement of a pathological complete response in which examination of the surgical specimens shows the tumor cells have been eliminated has been repeatedly associated with improved of event-free survival and overall survival and is often quite aggressive malignancies. Hence we are very encouraged by the interim analysis demonstrating successful achievement of this endpoint.

In this context, the KEYNOTE-522 data monitoring committee recommended that the study continue unchanged. And so the data become mature enough to assess event free survival. In the meantime, we look forward to discussing the KEYNOTE-522 data with regulatory authorities and to presenting our data in an upcoming scientific meeting.

Finally, I wish to notice that we anticipate risk pace of regulatory approvals in major jurisdictions that we have achieved during the first six months of the year will continue, especially in the oncology space. I look forward to sharing these notifications with you in due course.

Now, my colleagues and I will take your questions.

Teri Loxam

Thanks, Roger. Darla, we'll turn it over to the Q&A portion. And I'd like to remind everyone if they can keep their questions to a maximum of two to allow as many questions on the call as possible.

Question-and-Answer Session

Operator

[Operator Instructions] And your first question is from Terence Flynn with Goldman Sachs.

Terence Flynn

Hi. Thanks for taking the question. Ken, there's obviously been a more significant focus on larger deals in this space following some of the recent announcements. I would just welcome your latest thoughts here on Merck's capital allocation strategy. I know you touched on this a little bit at your Investor Day about a month ago, but just wondering if you could provide us an update there. Thank you very much.

Kenneth Frazier

Thank you very much for the question, Terence. We have launched some of the activity around us in the sector. I think each one of those companies is evaluating their own growth prospects over the next few years. We feel very, very confident in our growth prospects going forward.

As we have said in the past, given all of that, we are not interested particularly in a large merger that we believe could be disruptive to the company, including R&D. We continue to look at bolt-on deals. We do look across the spectrum in terms of size for bolt-on, we don't divide it by $1 amount. But at the end of the day, we think the operational complexity, the cultural disruption, the R&D disruption, that has been associated with large mergers counsel that we should not go there, particularly, because we feel very confident about our ability to grow our company organically supplemented by bolt-on deals.

Teri Loxam

Great. Thank you. We'll take the next question please.

Operator

It's from Seamus Fernandez with Guggenheim.

Seamus Fernandez

Thanks very much for the question. So maybe just two very quickly. On the first one, some spectacular growth in the pediatric vaccines across the board, as well as GARDASIL, could you guys just help us more fully understand the sustainability of the kind of growth

that we saw this quarter. And then, and just incremental to that, if you could just comment on what happened with NuvaRing this quarter in particular?

And then the second question, just broadly speaking for Roger, 8591, the data looks solid for the doravirine combination. Obviously the PrEP information is quite impressive and exciting, particularly if you can get to annual dosing with the implants. But just wanted to better understand how you guys are working towards finding a better partner than doravirine for 8591. And if you're willing to work with other companies and collaborate on those programs.

That was -- those were some concerns raised by physicians that other great products are out there and that unfortunately it doesn't look like the companies are collaborating with each other on that front. So I just wanted to ask on that front. Thanks so much.

Teri Loxam

Great. Thanks, Seamus. We'll start with Frank.

Frank Clyburn

Sure, Seamus. So let me start first with NuvaRing. No really new news there, no generic entry this quarter. Seamus, so we continue to promote NuvaRing as we have done in the past. With regards to vaccines, a couple of things.

Let me start with GARDASIL. GARDASIL had a very strong quarter growth of 50% if you were to exclude exchange on a global basis. We did see in the US, we did see CDC purchases in Q2 of this year, which actually took place in Q1 of last year. So, you do see some bumpiness with some of our vaccine sales. But I would ask them to take a look at Seamus, on a year-to-date basis vaccines for GARDASIL globally is up about 35%.

So we're seeing very strong demand expressing 11 year to 12 year-old cohorts in the US and some in the 19 to 26 cohorts. We're also seeing very strong ex-US demand as we talked about our Investor Day in particular in China, in Europe and a lot of the general neutral programs are rolling out. So we're still very confident in our growth prospects for GARDASIL.

The pediatric vaccines did also see a very strong quarter, this quarter. That was driven by demand as well. There was some buoyant to the private sector within the US. This quarter based on some of the Measles outbreaks that you've read in the news and we do believe that we'll continue to see growth for our pediatric vaccines going forward.

So the durability of our vaccine business, we feel very good about both for near term and long term growth as we mentioned just on Investor Day.

Roger Perlmutter

All right. Seamus, this is Roger. With regard to islatravir MK-8591, I mean, first of all, I would say, again, the performance of islatravir is quite remarkable and especially in the implant setting the durability is remarkable. And it's important to note that the very long intracellular half life of islatravir and the very impressive resistance profile.

I would take nothing away from doravirine in terms of its capabilities for many in the market that used the previous non-nucleoside reverse transcriptase inhibitors, in particular, which had a lot of adverse events associated with them. Doravirine is superior to those and is a very effective agent. And I think the combination of islatravir, doravirine will be good.

That said, we are also considering a lots of other combinations and lots of other conversations. And over time you will have the opportunity to see the broader impact of islatravir in a variety of different settings.

The important thing to emphasize is, it can be administered on a daily, weekly or monthly or even a longer duration regimen, which offers great possibilities. I think for change in treatment patterns in HIV infected individuals. Thanks.

Teri Loxam

Thanks. We'll take the next question please.

Operator

It's from Andrew Baum with Citi.

Andrew Baum

Thank you. Couple of questions, please. Firstly interested in your thoughts on the tenant proposal to fund catastrophic coverage given your exposure to Lenvima, Lynparza, Januvia and others.

Second on, islatravir, question for Roger, thinking about PrEP, both with the implants as well as the once-monthly, do you think the FDA is ready to accept anything other than traditional non-inferiority trials or what do you think that could do to the timelines in order to bringing islatravir to market as PrEP? Thank you.

Kenneth Frazier

Okay. So let me just comment generally about what's happening with the various things that are going on and some of these proposals that were included in the Senate finance package.

Let me start by saying that as a company, we are very supportive. The kinds of changes that will relieve patients in terms of their out-of-pocket costs. I think the catastrophic changes are step in the right direction, but that's a very small number of people who actually progress through the system and get the catastrophic.

So we continue to work with people as part of the legislative process and the administration, because we support lowering costs for seniors at the counter and not just at the catastrophic portion and so with respect to the impact on our own portfolio. I'm going to turn it over to Frank.

Frank Clyburn

Yeah. So just on the oncology front, I think you heard from our colleague at AstraZeneca, Lynparza for Part D is, approximately 25% of our business flows through Part D.

To remind everyone with regards to KEYTRUDA, that is reimbursed through Part B. So it is not a Part D product. So we feel as though we're balanced across our oncology portfolio going forward. Roger?

Roger Perlmutter

Yeah. And Andrew with respect to PrEP regimens. I think it's a great concern to the community as a whole that if one has to do active comparator controls, because of [indiscernible] that's understandable. The event rates are so low that you will need very, very large populations and very difficult to execute clinical trials.

FDA and other regulatory agencies are not aware of this. There have been discussions among a variety of sponsors and particularly in the very active patient community about this and what could be done.

And we have a lot of ideas in mind that thus far, we don't really have a novel trial design that would permit more rapid registration, watch this space, I mean, we're very concerned about decision.

Teri Loxam

Thanks. We'll move on to the next question.

Operator

It's from Chris Schott with JPMorgan.

Chris Schott

Great. Thanks very much for the questions. Just two here. Maybe first elaborate a little bit more on the China dynamics that are driving that 51% growth. I guess what products in particular behind this and can you just remind us the overall size of your China business at this point?

My second question was just KEYTRUDA in RCC, could we just get a quick update in terms of - uptake you're seeing so far. Where in the market you're seeming to get the most traction with the data, et cetera. Just, I know it's obviously an important new indication for you guys. Thank you.

Frank Clyburn

Hi, Chris. It's Frank on China. And China is about $725 million this quarter and it grew to 0.50%, really being driven by a number of products. As we mentioned we have pivoted to innovation. So our oncology portfolio, Lynparza, Lenvima, KEYTRUDA is driving the growth.

GARDASIL has had a significant uptake in China. We have NRDL listing also for Januvia. So it's a broad base innovative portfolio that is driving that 50% growth and we believe that will continue in China. With regards to RCC we're very excited, Chris about where we are to-date.

As we mentioned when we rolled out the data for RCC, it's important to note that KEYTRUDA plus axitinib shows a benefit across all three risk groups, which differentiates us from the competition. So we are seeing uptake across all three risk groups and it's really based on the strong overall survival, progression-free survival and very strong response rates.

80% of our chartered accounts in the US have adopted this regimen into their guidelines, which I think is a very strong early indicator. And we're seeing and hearing very strong feedback from both community and academic physicians.

So I feel really good Chris about RCC in the US. And as you know, we also plan to be rolling that out around the world. So we see this as a key indication, key growth drivers for us going forward.

Teri Loxam

Great. And Roger, on 522? My bad, sorry. I thought - I missed out the question, apologies. Next question, please.

Operator

It's from Navin Jacob with UBS.

Navin Jacob

Hi, thanks for taking the question. Two, sorry if I missed this. But, would it be possible to quantify how much of the US GARDASIL public sector buying pattern was if you could actually quantify, that amount that would be helpful.

And then just on KEYTRUDA plus Lynparza and first-line lung, could you remind us where those trials are when we could expect to see readouts there. And as a corollary to that KEYTRUDA in prostate cancer, you're going to be starting a three Phase 3 trials there as well. I'm wondering when we could hear updates from those trials as well. Thank you very much.

Teri Loxam

We'll start with Roger.

Roger Perlmutter

Right, okay. So as we have discussed and we've showed some data from our Investor Day, this is quite a large opportunity for combinations KEYTRUDA with Lynparza and in one of those cases, it's prostate cancer. We have indicated that we will study registration enabling studies for those. And US as we're starting to move forward obviously they take some time to conduct, we'll then have a chance to update you on the results.

But we are enthusiastic about the opportunity of the combination and believe that there will be many circumstances. I should point out that not only, the Lynparza combination, but the Lenvima combination as well - we're, we just received breakthrough designation for the hepatocellular carcinoma first-line indication 2. So there is an awful lot going on in combination studies with both agents.

Frank Clyburn

Yeah. And on GARDASIL as I mentioned, we had a CDC purchase in Q2 which was not purchased in Q2 of 2018. It was actually purchased in Q1 of '18. So the way in which I would characterize GARDASIL is in the US, year-to-date we have grown 20%, when you look on a six month basis.

I think that's the best way to look at it from a GARDASIL perspective. So think of the US growing about 20% right now versus prior year for the half year mark, because you are going to see different timing with regards to the CDC purchases.

Teri Loxam

Thank you, Frank. Next question please.

Operator

It's from Umer Raffat with Evercore.

Umer Raffat

Hi, thanks so much for taking my questions. I had two if I may. First can you mentioned low complexity as being a key consideration for bolt-ons, you're looking at. And in that vein, I guess my question is, are you open to therapeutic areas like orphan and also if there is a company with let's say $50 billion market cap or value, is that still a tuck-in, as long as the complexity is low?

And secondly on gross margin, so I see two big drivers going forward. One, of course, being KEYTRUDA's Bristol-Myers royalty reduction in 2023. But also anything you may be baking in on pricing reform. I was curious if you could add numbers around each of those. Thank you very much.

Kenneth Frazier

So I'll start with the PD question. Thanks, Umer for your questions. I don't think the size is the issue necessarily for complexity. I think it has to do with whether or not the two companies overlap and whether or not we are spending a lot of our time integrating IT systems manufacturing systems.

So if it's a true add-on, a separate kind of business, a true both-on, then I don't think that the size drives the complexity at all. As it relates to orphan versus other types, our preference is to do the most good for the most people.

But having said that, we are not against the right kind of therapy, even including orphan indications or orphan approaches to therapy. What we care about is are we getting good science that we can leverage together with our internal efforts to actually create value for our shareholders as well as patients.

Robert Davis

Good morning, Umer. This is Rob. To your question, just to remind everyone, for gross margin, over time, as we indicated at the Investor Day, we do expect to see gross margin generally flat, because while we do see product mix benefits flowing from products like KEYTRUDA and our vaccines business, we also, as we mentioned have assumed negative price going forward.

The impact of royalties, you've had, obviously, the one with KEYTRUDA that does step down in 2023 and the impact of the collaborations, which in the near-term will be a drag on margin or the long term, they become accretive.

We haven't given specific dollar numbers to those. And frankly, we don't want to give that specific guidance, but clearly how those interplay will determine whether you see our product gross margin slightly up, slightly down or flat over the period with most of what's driving our operating margin expansion, as we've talked about coming from reducing growth in operating expense relative to sales.

Teri Loxam

Thanks, Rob. Next question please.

Operator

It's from David Risinger with Morgan Stanley.

David Risinger

Yes. Thanks very much. I guess first I'd like to start with, actually the last comment and I know that this was mentioned previously, at the analyst meeting. But in terms of Merck's projection of negative price going forward that's a bit different than some of your peers. I think for some of your peers, talk about flat pricing, so maybe you could provide some more color regarding what you see as the biggest downward pressures on price for Merck going forward.

And then second, could you just provide an update on the - growing meningitis concerns. I jumped on the call late, so I don't know if this is addressed, but wanted to hear about that topic. And then also the durability of Merck's PROQUAD MMR-II revenue line strength. Thank you.

Teri Loxam

Great. We'll start with Rob.

Robert Davis

And morning, David. So thanks for the question. With regard to the pricing, again, I think the important thing to focus on is, how we see the mix going forward. And I can't speak to what our competitors are implying that, recall we've actually seen negative price quite some time outside the United States.

So that's not a new phenomenon. We've been absorbing headwinds and price outside the United States for several years. Historically that was offset by price increases in the United States.

As we look going forward, we no longer see the benefit of those price increases in the United States because of obviously the changing dynamics. And so as you look in total, we do continue to believe we're going to see declining price as we look forward, impacting our margins.

Teri Loxam

Thanks. And Frank on the pediatric vaccines.

Frank Clyburn

Yeah. So on the pediatric vaccines, we are continuing to see very good demand within the pediatric vaccines. And clearly the measles outbreak has driven some of that demand expression in the private sector. We also did see buy-in this quarter in Q2. We do anticipate that some of that buy-in will come out in Q3 and Q4.

But as I mentioned before, we see our pediatric vaccine business as a very strong part of our growth story. And we see it as a very durable business going forward.

Teri Loxam

Thanks. We'll take the next question please.

Operator

It's from Tim Anderson with Wolfe Research.

Tim Anderson

Thank you. A couple of questions. A longer-term question on KEYTRUDA, we published an analysis while back claiming that cancer drugs, very often ultimately sell much more outside the US and in the US as they mature to the tune of 50% more or so, when I look at how we and the analyst community at large models KEYTRUDA and other PD1s for that matter. No one ever really seem to have ex-US even surpassing the US.

And I'm wondering if you can tell us what your long-term model assumes from this regard, could ex-US markets eventually kind of blow away, the US market over time. It could be billions of dollars more potentially.

Second question, Bristol recently top-lined part 1 of 227 as positive, which I think was a surprise. Can you remind us where you are with your CTLA-4 combination program specifically what are the latest stage trials and then what tumor types. I guess as you may have kind of backed off this initiative that you started maybe a couple of years ago? Thank you.

Teri Loxam

So let's start with Frank on KEYTRUDA.

Frank Clyburn

Yeah. So for the KEYTRUDA as we look long term, we do see significant opportunity outside the US in particular markets like China, especially when you look at some of the GI malignancies in the actual prevalence there. We are seeing obviously very strong uptake in Japan as well, not going to give a specific number, but we clearly do see ex-US opportunity is very significant in fact this quarter alone, we sold $1.1 billion outside the US and grew 73%. So we see both ex-US and US KEYTRUDA opportunities. But clearly, China is the one I would highlight as significant potential growth for us going forward.

Teri Loxam

And Roger?

Roger Perlmutter

And Tim, with respect to CTLA-4 directed therapy, our interest has been in demonstrating or assessing whether or not adding CTLA-4 directed therapy actually has an impact over KEYTRUDA alone, that is powering the study to see whether CTLA-4 plus KEYTRUDA is in fact superior to KEYTRUDA in any setting and we have done that both with adalimumab and also with MK-1308, our own CTLA-4 directed therapy.

And so registration enabling studies are going on in both setting and with both kinds of combinations, which includes, for example, the KEYNOTE-598 study and a couple of others, and we could go through the details with you, I think, find them usually on clinicaltrials.gov.

Teri Loxam

We'll move on to the next question please.

Operator

It's from Jason Gerberry with Bank of America.

Jason Gerberry

Hi, good morning. Thanks for taking my question. First, just a follow-up on the Bristol Opdivo, Yervoy data, just curious, Roger, how do you think oncologists are going to benchmark the CheckMate-227 data against the already approved either Merck combination or KEYTRUDA monotherapy in the PD-L1 greater than 1% populations?

And then my second question maybe just for Frank, can you frame the importance of NRDL listing for KEYTRUDA in the lung setting? And what I'm specifically curious about is the percent of the market accessible with and without the listing? Thanks.

Teri Loxam

We'll start with Roger.

Roger Perlmutter

Well, Jason. It's pretty hard to comment on the data from the CheckMate-227 program, because we haven't actually seen it. We have the top line announcement that one part of it was in the PD-L1 greater than 1% did succeed in the combination with adalimumab, but we don't know what that success looked like in overall survival. We don't know the hazard

ratios look like and there is a - it's complicated study as you appreciate because the study was broken down into most parts and a part of it was predicated on a tumor mutational burden analysis and then subsequent PD-L1 directed such that.

So we're not actually seeing the data, pretty hard to know how oncologists will respond with time, the data will become available. And I think people will want to have a look at it and understand what the meaning of that might be.

I think our own data, I think are extremely strong of course, with KEYTRUDA and the combination of KEYTRUDA plus traditional chemotherapy with typically on the order of a doubling of overall survival.

So there is an important value that can be gained there and we are optimistic that we're going to continue to be able to advance therapies that will improve overall survival of this disease.

Teri Loxam

Thanks, Roger. Will go to Frank on the NRDL.

Frank Clyburn

Yeah. And just one additional pointed to what Roger was saying commercially with regards to lung, I do believe we're in a very strong position with our data. And as you mentioned with monotherapy on the PD-L1 high population with very strong overall survival as well as KEYNOTE-189 reducing the risk of death in half.

That data is playing very well around the world, and it has helped us to penetrate now 8 out of every 10 new eligible patients in lung. So we feel as though will - there'll be a lot of data readouts here from competition, but we feel as though our data positions us well in lung today and in the future.

NRDL, we are waiting to see if we'll be invited to - actually participate for next year. It is an important potential listing. It does expand the population in China fairly significantly. There is 5 to 600,000 lung cancer patients in China. There is probably 300,000 of those that are a part of our labeled indication and NRDL gives us a chance if invited to expand into that patient population.

We'd also like to highlight, we expect to expand our label in China. China is going to be important for us, not only for 2020, but 2020 and beyond and we are also seeing good self-pay market uptake in China as well, but clearly we will keep you informed as the

NRDL process unfolds.

Teri Loxam

Thanks. We'll move on to the next question please.

Operator

It's from Steve Scala with Cowen.

Steve Scala

Thank you. A couple of questions, both for Roger. If you could clarify your KEYNOTE-522 comments, I think you said you needed EFS to file, but that you would share the PCR data with regulators. So were you implying you would seek to file and potentially garner approval on PCR? That is why you're going to share in the first place, or are you saying you absolutely definitely need the EFS.

And then secondly if Bristol's 227 delivered a percent of patients alive greater than the 69% that KEYNOTE-189 reported at 12 months, just wondering how Merck would respond or do you think that is extremely unlikely? Thank you.

Roger Perlmutter

All right, Steve. So with respect to KEYNOTE-522 you know the goal I'm discussing, the data with regulatory agencies is to ask whether or not they think that represents a finding of sufficient importance to consider making the drug available for patients in that setting. So that's the reason to do it.

As I indicated pathological complete response is associated with favorable outcome, particularly in the breast cancer setting and his been repeatedly demonstrated to have that impact in the triple negative breast cancer setting. On the other hand, this is something that agencies have to look at, and with regard to the totality of the data. So that's -- that's basically where we are there.

And with regard to 227, pretty hard to respond to hypothetical without actually seeing what the data look like. I really, I don't know what to say about that. I know I'm - I think there is some interest in seeing what the subset data look like, obviously there - the flip side of that was, but, and maybe unsurprisingly that in light of what we've seen, beginning with the CheckMate-026, I mean, the combination of nivolumab plus chemotherapy was not successful.

In part 2 which for us KEYTRUDA plus chemotherapy, obviously gives very impressive results in terms of overall response rate, progression-free survival, overall survival. As we've demonstrated repeatedly and in non-squamous and squamous cell, non-small cell lung cancer. So you know those of these are behaving differently in these settings for whatever reason.

Teri Loxam

Thank you. We'll move on to the next question please.

Operator

Your next question is from Louise Chen with Cantor.

Louise Chen

Hi. Thanks for taking my questions. My first question is on KEYTRUDA in China. Just curious if you will disclose sales there. We get that question a lot, seeing if you can provide any color. And then how will you compete with the local players that are much less expensive on a price basis at least for now?

And then second question is just on potential competition for KEYTRUDA from some of the upcoming trial readouts in second half ' 19 and beyond that will be a non-small cell lung cancer RCC and melanoma? Thank you.

Teri Loxam

Frank?

Frank Clyburn

Yeah. So we don't intend to actually share our sales number for KEYTRUDA in China. As far as competing with the local players, we feel as though oncology is a data-driven market there, clearly our local players that are entering the market at a lower price, they are penetrating into some segments of the market.

However, we're continuing to see very good penetration and very good growth in China there are clearly, patients that are in the self-pay market is where we compete today, they can afford KEYTRUDA. We have our patient assistance programs and we have a very strong commercial presence in China. So I feel really, really good that we'll be able to compete with the local players going forward.

Teri Loxam

Great. And then the KEYTRUDA positioning in the US given peer file.

Frank Clyburn

Yeah. I think as we mentioned, it is going to be a lot of competitive data readouts in lung and across many different cancer types. What I would say is, right now we are in a very strong first mover advantage in many of those cancer types. When you think about 20 indications across 12 different tumors, we right now have build a wall of data that we feel very comfortable with, and in fact many of the community oncologists are getting significant real world experience using KEYTRUDA.

So we'll have to see how the data unfolds with the competition, but as Roger and I have just mentioned, we feel as though our data right now, strong overall survival across many different cancer types, bladder, renal, cell carcinoma. I haven't even spoken about adjuvant melanoma, which is a very important launch for us right now. Head and neck, the teams are just launching that indication of strong overall survival in the first-line setting.

So we know it's going to be competitive, we feel as though we're very well positioned based on our strategy and the data that we have as well as what you heard at our Investor Day, the significant amount of data to come, not only in the metastatic setting, but also in the neoadjuvant and adjuvant setting going forward.

Teri Loxam

Thanks, Frank. We'll take the next question please.

Operator

It's from Mara Goldstein with Mizuho.

Mara Goldstein

Yeah. Thank you, can you --

Teri Loxam

Mara we can't hear your - we couldn't hear your question. If you wouldn't mind, repeating that.

Mara Goldstein

Sure. Thank you very much. I have two questions. And the first is on the KEYTRUDA plus Lynparza trials and non-small cell lung cancer. And I'm just wondering what the expectation is in terms of expanding patient population based on that clinical trial.

And then the second question is one around regulatory strategy in Europe, just understanding that yesterday or the day before heard that the CHMP had removed accelerated status for Novartis' Zolgensma, but we've also seen this is not an isolated incident with other drugs and in particular oncology drugs being taken off that accelerated track. And I'm wondering if the Company can share any thoughts around this dynamic and any potential impact on your own regulatory plans in Europe?

Roger Perlmutter

Right. Mara, the underlying logic behind KEYTRUDA plus Lynparza and a whole variety of settings is that where there are defects in DNA repair and there are - those are included a whole variety of different defects, not just the BRCA 1, BRCA 2 indication for the whole variety of different molecular defects.

The effect of Lynparza can be to increase the representation of epitopes that potentially could be recognizable by immune cells and release of constraints with KEYTRUDA and combination with that should be beneficial. Thus far hypothesis that's being tested, whole variety of different settings and quite broadly. So we are enthusiastic about it. We're encouraged that this could be extremely important.

As one of the things I would point out with respect to Lynparza is it's extraordinarily well tolerated, people stay on it for years, and the ability to maintain a treatment effect as has been shown for example in the ovarian setting is really quite remarkable. So that's extremely promising.

With regard to EU strategy, the regulatory strategy really hasn't changed there. The EU has a prime program for - within CHMP in order to permit more rapid review. In general a good thing about EU reviews is that they now go along a very well defined timeline which we understand extremely well. And at this point, we are moving forward with those EU reviews as we've announced, even just this week. So all of that is going very well for us.

Teri Loxam

Thanks, Roger. And we were able to get to all of the callers' questions. So I'll turn it over to Ken for some closing comments.

Kenneth Frazier

Okay. I want to thank you again for joining us today. As you can see our strong second quarter results reinforce, why we're still confident in our ability to deliver sustained strong growth not only this year, but beyond. And as we mentioned in Investor Day, we have a de-risked portfolio of innovative asset, together with our differentiated, scientific commercial, our capabilities and our ability to execute, we believe that uniquely positions Merck to deliver strong results for patients and shareholders well into the future. So, thanks again. We look forward to joining you in the future.

Operator

This concludes the Merck & Company Q2 sales and earnings conference call. You may now disconnect.