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MRK - Q3 2018 Merck & Co Inc Earnings Call

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OCTOBER 25, 2018 / 12:00PM, MRK - Q3 2018 Merck & Co Inc Earnings Call

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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 the Merck's Third Quarter 2018 Sales and Earnings Conference Call. (Operator Instructions) I would 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 Third Quarter 2018 Conference Call. Today, I'm joined by Ken Frazier, our Chairman and Chief Executive Officer; Rob Davis, our Chief Financial Officer; Adam Schechter, President of Global Human Health; and Dr. Roger Perlmutter, President of Merck Research Labs.

Before I turn the call over to Ken, I'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 U.S. Private Securities Litigation Reform Act of 1995.



OCTOBER 25, 2018 / 12:00PM, MRK - Q3 2018 Merck & Co Inc Earnings Call

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 2017 10-K, identify certain risk factors and cautionary statements that could cause the company's actual results to differ materially from those projected in any of our forward-looking statements made this morning.

Merck undertakes no obligation to publicly update any forward-looking statements.

You can see our SEC filings as well as today's earnings release on merck.com.

Finally, in an effort to further improve our communications and transparency, we have posted a presentation to the Investors section of merck.com. This includes some of our highlights from this quarter, and we will -- throughout this morning's discussion, we will reference certain slides of the presentation.

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

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

Thanks, Teri, and good morning, everyone. The strong performance of our business demonstrates that our innovation strategy is working and that Merck is on the right track to deliver sustainable value to shareholders and patients.

In addition to delivering solid results in the third quarter, we also continue to advance our pipeline with exciting new data readouts and milestones. While there are many aspect of the business to highlight this quarter, I would like to turn first to KEYTRUDA's performance.

This drug continues to lead the IO field with the breadth and depth of indications across multiple tumor types. We've executed well, both in the clinic and commercially, and we are seeing firsthand how KEYTRUDA is making a tremendous difference to cancer patients around the world.

We're very confident in KEYTRUDA's near- and long-term growth prospects as we continue to launch existing indications and look towards future approvals. We believe that our approach of following the science throughout KEYTRUDA's development has and will continue to successfully differentiate the medicine as a foundational cancer treatment.

We're also encouraged by Lynparza and Lenvima, both targets of our strategic business development as well as our other Oncology assets in the pipeline that position us to further expand our leadership in Oncology.

Beyond Oncology, Merck has the strongest vaccine portfolio in our company's history led by GARDASIL, which continues to experience healthy demand and growth. The hospital specialty business is performing well, and our Animal Health business is an industry leader.

We have great momentum as we close out the year and prepare for 2019, given our existing portfolio and pipeline. And we are confident about our long-term outlet -- outlook, I apologize.

As a reflection of our confidence in our future growth prospects, today, we announced a dividend increase along with an accelerated share repurchase program, which Rob will talk about in more detail in a moment. These actions are driven by our commitment to a balanced capital allocation strategy and supported by our strong balance sheet and cash flow generation that provide us the flexibility to return cash to shareholders while also investing in our pipeline, innovation and growth.

Even with these actions, we continue to have ample capacity for business development, which remains a major priority. Looking ahead, we're confident in the strength of our business. We believe that our well-balanced portfolio will continue to drive sustainable growth and value creation.

OCTOBER 25, 2018 / 12:00PM, MRK - Q3 2018 Merck & Co Inc Earnings Call

Along with the rest of Merck's world-class team of scientists and employees, I'm excited to build on our strong performance as we achieve our objective of delivering innovative and urgently needed medicines and vaccines to serve the critical needs of patients while enhancing shareholder value.

And with that, I'd like to turn the call over to my colleague, Rob Davis, to provide more detail on the quarter.

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

Thanks, Ken, and good morning, everyone. Please note that my comments today will be on a non-GAAP basis.

In the third quarter, we delivered both top and bottom line growth, and we're well positioned to finish the year strong. Total company revenues were \$10.8 billion, an increase of 5% year-over-year.

Excluding the impact of exchange, third quarter revenues grew 6%. Our Human Health business grew 7% excluding exchange, and Adam will provide more color on those results in a moment. Animal Health sales totaled \$1 billion in the quarter, an increase of 2%, and excluding the impact of exchange, sales grew 6%, with companion animal growing 7% and livestock growing 5%.

We continue to see strong demand for our products. However, this quarter's revenue growth rate was unfavorably impacted by timing of purchases as well as a shorter flea and tick season. Animal Health segment profits were \$409 million in the third quarter, an increase of 5% compared to prior year.

Turning to the expense lines. Gross margin was 76.7% for the quarter, an increase of 100 basis points versus the third quarter of 2017, with the increase primarily driven by favorable effects of exchange. Recall, manufacturing variances related to the cyberattack negatively impacted gross margins in the third quarter of 2017.

Operating expenses of \$4.5 billion increased 6% year-over-year, including a favorable 2 percentage point impact from exchange. The increase was driven by R&D, which was comprised of higher Oncology clinical spend; investments in discovery and early development; as well as licensing costs.

Our tax rate of 18.9% for the quarter was roughly flat year-over-year. Taken together, we earned \$1.19 per share, an increase of 8% excluding exchange.

Turning to the outlook for the year. We are now narrowing our revenue guidance range and narrowing and raising our EPS guidance range for 2018, reflecting our strong operational performance throughout the year.

For the full year, we now expect revenues to be between \$42.1 billion and \$42.7 billion, including a minimal impact of foreign exchange at mid-October rates. We now expect our tax rate to be between 19% and 20%. We now expect EPS to be between \$4.30 and \$4.36, including a roughly 1 percentage point negative impact to foreign exchange at mid-October rates. All other aspects of our guidance provided on our second quarter call remain the same. A summary of our guidance can be found on Slide 7 of our earnings presentation.

Before concluding, let me spend a few moments speaking about our capital allocation strategy, through which we are able to deliver for our patients, grow the business and ultimately, create meaningful shareholder value. As Ken mentioned, we are committed to maintaining a balanced approach to capital allocation, which you can see on Slide 8.

Our first priority continues to be to appropriately invest in R&D and support our key brands and launches in order to drive value creation. As we've stated, funding opportunities in our portfolio that drove revenue remains our primary focus. Consistent with this focus, we also see significant opportunities to drive growth from increased market demand, and we will continue to allocate resources to position ourselves for success.

We now plan to spend roughly \$16 billion on capital projects through 2022. This is up from our prior estimate of \$12 billion that we announced in February. Our primary focus through these projects is to increase manufacturing capacity across our key businesses, including Oncology, vaccines

OCTOBER 25, 2018 / 12:00PM, MRK - Q3 2018 Merck & Co Inc Earnings Call

and Animal Health, where demand continues to be higher than originally projected as well as to invest in our discovery and development operations and IT infrastructure.

We also continue to prioritize value-creating business development opportunities. We believe building a best-in-class pipeline will ultimately create long-term growth and value for shareholders. With our strong balance sheet, we have the financial flexibility to pursue all forms of business development, including acquisitions, partnerships and collaborations. We will continue to actively look at and evaluate those opportunities to create the strongest portfolio and pipeline.

While our primary objective is to fund the business, we have a strong track record of returning meaningful cash to our shareholders. Over the past year, we have returned approximately \$10 billion to shareholders in the form of dividends and share repurchases. Given the increasingly strong confidence we have in our pipeline, long-term revenue growth, cash flow projections and overall balance sheet strength, we've decided to grow our dividend above historical levels and increase our share repurchases.

Today, we announced that we will increase our quarterly dividend by 15% or by \$0.07 to \$0.55 per share beginning in the first quarter of 2019. In addition, the board has approved an additional \$10 billion share repurchase authorization, giving us approximately \$18 billion in share repurchase capacity.

As a first step, we entered into a \$5 billion ASR, with the remainder providing us the opportunity to flex our regular share repurchase program over the next 2-plus years. Given the strength of our balance sheet, we were able to return this cash to shareholders today while retaining the ability to execute on any value-creating business development opportunities that further our growth strategy. We believe we have the ability to drive significant additional value to shareholders over the long term, and these actions are a reflection of that confidence.

With that, I'd like to turn the call over to Adam to provide more detail on our Human Health business. Adam?

Adam H. Schechter - Merck & Co., Inc. - Executive VP & President of Global Human Health

Yes, thank you, Rob, and good morning, everyone. This morning, I'll provide highlights on the performance of Global Human Health in the third quarter of 2018. My comments will be on a constant currency basis.

We continue to execute very well, both in the U.S. and ex U.S. markets. Sales this quarter grew 7% to \$9.7 billion driven by the strong performance of key products in our Oncology, vaccines and hospital and specialty franchises. We have overcome loss of exclusivity and competitive pressures in certain significant products, and we are optimistic about our future revenue growth prospects.

I'll now focus on key franchises starting with Oncology. With nearly \$1.9 billion in sales this quarter, KEYTRUDA's performance after 4 years on the market is unprecedented, not only in the field of Oncology but also in the pharmaceutical industry more broadly. KEYTRUDA is now the leading IO therapy in the U.S. in both new patient starts and total patient volumes and has become a foundational Oncology treatment. Five applications are now on file with the FDA, and numerous registration-enabling readouts are expected over the next 18 months.

We look forward to launching additional indications and tumor types such as renal cell carcinoma where last week, we announced strong trial results. Our clinical results have demonstrated KEYTRUDA's benefit across a wide range of cancers, and our vast global regulatory and commercial capabilities have enabled us to rapidly bring this treatment to patients around the world.

KEYTRUDA's growth this quarter was driven by higher use in first-line, non-squamous, non-small lung cancer patients, those whose tumors do not express EGFR or ALK.

In the U.S., the robust survival benefit seen in KEYNOTE-189 is convincing more and more physicians of the benefits of using KEYTRUDA's in combination with chemotherapy across all of their newly diagnosed patients, including patients whose tumors expressed low levels of PD-L1 or nonexpressers. We see continued growth of KEYTRUDA in this setting as we further establish the benefits of the combination in the community setting.



OCTOBER 25, 2018 / 12:00PM, MRK - Q3 2018 Merck & Co Inc Earnings Call

Additionally beyond the line, we see strong usage in our other proved indications and have leadership positions in head and neck, bladder and MSI high cancers. Merck's extensive global presence is helping to drive strong growth of KEYTRUDA in ex U.S. markets. Use in first-line lung continues to increase driven by further uptake of our monotherapy indication upon reimbursement approvals. In Europe, lung now represents a majority of our KEYTRUDA sales in all major markets. We received European approval in early September for the chemo combo and believe that our addressable market of first-line, non-squamous, metastatic lung cancer patients in Europe has now tripled.

Use of the chemo combo began immediately upon approval as some large markets such as Germany have already begun reimbursing. And reimbursement discussions are beginning in other major markets as well.

Beyond KEYTRUDA, the strong growth in sales of Lynparza and Lenvima add to our confidence in the potential of both of these Oncology therapies to be meaningful contributors to Merck's revenue growth. Lynparza leads the park inhibitor class in both new and total prescriptions. U.S. sales grew significantly driven by growth in ovarian cancer as well as uptake in breast cancer. We are also excited by the first-line maintenance opportunity in BRCA-mutated advanced ovarian cancer given the very impressive SOLO-1 data presented this past weekend. And we look forward to the potential approval of this important indication.

Separately, we're making great progress in building our partnership with Eisai for Lenvima, which continues to grow strongly. Following hepatocellular cancer approval in Japan earlier this year, we have seen rapid adoption of Lenvima in that indication. Additionally, the recent hepatocellular approvals in the U.S. and Europe add to the existing indications in differentiated thyroid and renal cell carcinoma.

Now moving to vaccines. Global vaccine sales were nearly \$2.2 billion this quarter, up 13% from a year ago. GARDASIL achieved over \$1 billion in sales, reflecting strong demand worldwide. The China launch has been very successful and is a meaningful contributor to ex U.S. growth. GARDASIL is increasingly viewed as an anticancer vaccine for certain HPV-related cancers.

Countries like Australia have increased vaccination rates to levels that could potentially help attain the goal of cervical cancer elimination, driving demand and awareness as well as serving as a model for others. In the United States, demand remains strong, and the recent expansion in our approved age cohort to include men and women up to the age of 45 represents an exciting opportunity. We believe that GARDASIL has a very long runway of growth ahead.

Moving to our diabetes franchise. Our diabetes franchise continues to be relatively stable, with global sales of nearly \$1.5 billion, about equal to year-ago levels. Increased demand in ex U.S. markets was offset by pricing pressure in the U.S.

Finally, our overall hospital specialty business performed well led by BRIDION, which again grew strong in this quarter. ZERBAXA is also growing with exciting future potential given the recent Phase III success in hospital-acquired bacterial pneumonia.

In the HIV space, we launched doravirine in August and believe it represents an opportunity for patients looking for alternative NNRTI therapies and a great bridge to our exciting HIV pipeline.

In summary, our Global Human Health business is very strong, and we remain confident in our growth prospects due to a solid performance in our Oncology, vaccines and hospital specialty franchises. We believe we are very well positioned and look forward to the future with great optimism.

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

Roger M. Perlmutter - Merck Research Laboratories - President

Thanks, Adam. So let's summarize on Slide 10 of our presentation. The third quarter saw a very important regulatory activity for KEYTRUDA, including the approval in Europe for the first-line treatment of metastatic, non-squamous, non-small cell lung cancer in combination with platinum-based therapy in ALIMTA, reflecting the integrated results of the KEYNOTE-021C, 021G and 189 studies.



OCTOBER 25, 2018 / 12:00PM, MRK - Q3 2018 Merck & Co Inc Earnings Call

The KEYNOTE-189 results were also incorporated in the revised label for KEYTRUDA in the United States. As previously announced, KEYTRUDA was also approved in China for the treatment of advanced melanoma, the first such approval in China for a PD-1-directed therapy.

Slide 11 provides a summary of important regulatory and clinical catalysts. KEYTRUDA is under regulatory review in the United States for the first-line treatment of squamous cell carcinoma of the lung in combination with appropriate chemotherapy based on the KEYNOTE-407 results, for the second-line treatment of hepatocellular carcinoma based on the KEYNOTE-224 trial, for the first-line treatment of Merkel cell carcinoma based on KEYNOTE-017, as monotherapy for non-small cell lung cancer in an expanded population of patients with PD-L1 expression in at least 1% tumor cells based on KEYNOTE-042 and for the adjuvant treatment of cutaneous melanoma following definitive surgical resection based on KEYNOTE-054. The European committee on human medicine -- medicinal products adopted a positive opinion for this adjuvant melanoma medication last week, and many of the other indications are under review in Europe and in other jurisdictions.

We've also made substantial progress in identifying new tumor settings where KEYTRUDA can be used to advantage. At the European Society for Medical Oncology meetings earlier this week, Dr. Barbara Burtness at the Yale University School of Medicine reported the results of the KEYNOTE-048 study, which address the first-line treatment of squamous cell carcinoma of the head and neck with KEYTRUDA given either as monotherapy or in combination with platinum-based therapy in 5-fluorouracil. This study included an active comparator, the extreme regimen, which includes cetuximab added to platinum-based chemotherapy in 5-fluorouracil, and this is the standard of care for this disease in many areas and employed a comprehensive statistical analysis plan to control type 1 error.

The improvement in overall survival scene with KEYTRUDA monotherapy in patients with PDL-1 expressing tumors is judged by a combined proportional score of hazard ratio of 0.61 in the CPS 20 or greater population. And the improvement in overall survival human KEYTRUDA was administered with chemotherapy hazard ratio of 0.77 in all patients as compared with the extreme regimen, suggest that KEYTRUDA has the potential to become the new standard of care in the first-line treatment of squamous cell carcinoma of the head and neck.

As a result, we intend to incorporate previously filed data from our second-line head and neck cancer study, KEYNOTE-040, in the U.S. filing for KEYNOTE-048. In Europe, the CHMP adopted a positive opinion for the use of KEYTRUDA as second-line therapy in appropriate patients with squamous cell carcinoma of the head and neck based on the overall data and as we will submit a separate file containing the new KEYNOTE-048 data.

Meanwhile, important new data continued to emerge as shown on Slide 11. At the ESMO meeting, we presented the results of our Phase II KEYNOTE-057 study, which showed that more than 40% of patients with persistent or recurring nonmuscle invasive bladder cancer achieved a complete response following KEYTRUDA monotherapy.

And just last week, we announced the results of a Phase III KEYNOTE-426 study in which the combination of KEYTRUDA plus axitinib, marketed by Pfizer as ALIMTA, improved overall survival, progression-free survival and the overall response rate in the first-line treatment of locally advanced or refractory renal cell carcinoma as compared with cetuximab. These data will be presented at an upcoming scientific meeting, and we intend to seek regulatory approval for this first-line indication around the world.

Beyond KEYTRUDA, our Oncology programs are advancing in important ways that are also shown on Slides 10 and 11. At the ESMO meeting, we joined our colleagues from AstraZeneca in presenting the results of SOLO-1, the study addressing the maintenance use of Lynparza in patients with newly diagnosed BRCA-mutated ovarian cancer, who are in complete or partial remission following treatment with platinum-based regimens.

In SOLO-1, Lynparza reduced the risk of disease progression or death compared with placebo by an astonishing 70%, such that at the 3-year time point, 60.4% of women receiving Lynparza remained progression free compared to just 26.9% of women receiving standard-of-care placebo. Numerous future studies will address expanding opportunities for Lynparza in breast, prostate and pancreatic cancer, and we eagerly await data from combination studies of Lynparza with KEYTRUDA, which will emerge in the near future.

During the third quarter, our partnership with Eisai led to the approval of Lenvima for the first-line treatment of advanced hepatocellular carcinoma in the United States, the European Union and in China. We also received breakthrough designation from the FDA for the combination of Lenvima with KEYTRUDA in the treatment of advanced or metastatic microsatellite stable endometrial carcinoma.



OCTOBER 25, 2018 / 12:00PM, MRK - Q3 2018 Merck & Co Inc Earnings Call

Lenvima is a very attractive partner for KEYTRUDA across a broad range of malignancies. As an example, our KEYNOTE-581 trial exploring the combination of KEYTRUDA and Lenvima in the first-line treatment of renal cell carcinoma is well underway.

At the ESMO meeting, we also had the opportunity to highlight some newer programs in our Oncology portfolio, including MK-1454, our STING agonist for tumor injection and MK-1308, CTLA-4 directed checkpoint inhibitor. Both drugs would be developed in combination with KEYTRUDA. And, indeed, in light of the positive impact of KEYTRUDA across a broad range of tumor types, we anticipate that most of our new programs will seek in the first instance to expand the impact of KEYTRUDA still further.

Our teams are also active in other therapeutic areas. During the third quarter, we gained FDA approval for PIFELTRO, our second-generation nonhepatocellular protease inhibitor for HIV infection, which was also proved in combination with lamivudine and tenofovir under the brand name DELSTRIGO. The European Committee for Medicinal Products for Human Use also adopted a positive opinion for PIFELTRO and DELSTRIGO in September, meaning that marketing authorization can be expected in late November. We're also studying PIFELTRO in combination with MK-8591, our first-in-class nucleoside derivative that durably blocks reverse transcriptase translocation as well as polymerase activity. Data from this Phase II study will become available towards the end of this year.

Our antimicrobial efforts include ZERBAXA for which we reported positive results from our large Phase III study in patients with hospital-acquired or ventilator-associated bacterial pneumonia using an investigational dose. This data will be submitted to regulatory agencies in the new future as well data supporting our new beta-lactamase inhibitor relebactam, which we have shown to improve clinical responses to imipenem and patients infected with carbapenemase expressing bacteria.

Also in the infections disease arena, the FDA granted approval for GARDASIL 9 in women and men ages 27 to 45 as a means to reduce the incidence of certain HPV-related malignancies and dysplastic syndromes. We continue to see high interest around the world in developing strategies with the goal of broader control or even elimination of HPV infection.

We have many other important vaccine initiatives underway including V114, our 15-valent pneumococcal conjugate vaccine currently under investigation in Phase III trials and V160, our novel vaccine for the prevention of primary CMV infection in healthy seronegative women, which is currently being evaluated in a large Phase II study.

More broadly as shown on Slide 12, we have a large set of late-stage clinical assets in cardio metabolic disease and neuroscience for which data will become available in a relatively near future.

I will now turn the call back over to Teri.

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

Thanks, Roger. Darla, we'll be getting started with questions. (Operator Instructions) So Darla, let's start off the Q&A portion, please.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) And your first question is from Vamil Divan with Crédit Suisse.

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

So maybe my first one is just a broader question for Ken. There's obviously announcement recently that you'll be -- you won't be retiring at the end of next year, and I'm just curious how we should think about how that might impact your views on the longer-term outlook for Merck or the

OCTOBER 25, 2018 / 12:00PM, MRK - Q3 2018 Merck & Co Inc Earnings Call

company's strategy as we think about business development or a lot of questions around Animal Health and how you guys see that business in your company. Does the fact that you're staying on longer as a CEO impact how you guys are thinking about maybe like something more transformational from a strategic perspective? And then the second one is a more specific question for Roger, and it's just around your STING asset that you presented data for last week, and I'm just curious how are you thinking about I think the data we saw, the monotherapy impact was more limited than I was expecting. So how do you think about the need for monotherapy impact before moving forward with a combination approach, whether it's for STING or some of the other approaches you have in your pipeline?

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

Okay. Thanks, Vamil, for the questions. Let me start by talking about whether or not my extended tenure will affect how I think about transformational deals one way or the other. So our responsibility as a management team is to continue to focus on the best opportunities to put together the best portfolio to drive sustainable value. That remains our focus. While we remain disciplined in our approach, we're also committed to identifying and acquiring assets that will create sustainable value. And as we've said in our comments earlier today, we have the capacity to do deals of all sizes and all types. The question is are they the right deals for Merck? And that's what our management team debates. That's what we discuss. That's what our board debates and discusses. So to answer your question, no. I don't believe the fact that I am expected to stay a little bit longer is going to change the fundamental analysis of all of these people about what makes sense from a sustainable value-creation standpoint.

Roger M. Perlmutter - Merck Research Laboratories - President

Yes. And Vamil, it's Roger. On MK-1454, the STING agonist that we presented at ESMO, I think it's important to remember that this was our first opportunity to describe this molecule. It's in the matter of a birth announcement. Birth announcements are important because they speak they potential, but the important thing to recognize is that 1454 can be given into tumor lead effectively, it stimulates inflammation. That was clear. And if you looked at the pattern of tumor response, the injected tumors had more response than the abscopal effect in combination with KEYTRUDA, which suggests that there's something going on there besides just KEYTRUDA itself. But boy, it's early days. So we have very few patients. And as I indicated, we see these kinds of therapies as being adjunctive. What we're thinking to do is to improve still further the response to KEYTRUDA. So, so far, so good. Let's see how we do. And we're enthusiastic about these kinds of approaches, not just 1454 but other inflammatory mediators, including oncolytic viruses, including TLR agonists and other things that we are studying in the setting.

Operator

It's from Chris Schott with JPMorgan.

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

Just a couple of questions here. Maybe first, first-line renal. Just would be interested in your perspective with some data at ESMO and, obviously, your data pending, how you see the PD-1, TKI combo spitting into the treatment landscape, particularly relative to Opdivo, YERVOY. The second question I had was on KEYTRUDA in the first-line lung in Europe. I know you've got a recommendation there, but could you just sort of elaborate a bit more in terms of where we stand today in terms of penetration and how quickly you are expecting a ramp given the positive recommendation on 189 as we think about the rest of this year and into 2019. And if I can slip a third really quick one in there, could you just update on KEYTRUDA usage by tumor type in U.S. and ex U.S. as you've done in the past?

Roger M. Perlmutter - Merck Research Laboratories - President

So Chris, this is Roger. Let me try the renal first, and then Adam can take on the other issues. With respect to the first-line renal, of course, we haven't presented the KEYNOTE-426 data. We announced top line results. And it's important to recognize that those top line results came from the first interim analysis, where KEYTRUDA in combination with axitinib met its endpoints in terms of progression-free survival and overall survival both as well as the key secondary endpoint and response rate. Those are important results at this first interim, and they speak to the power of the combination.



OCTOBER 25, 2018 / 12:00PM, MRK - Q3 2018 Merck & Co Inc Earnings Call

Obviously, what people are going to be interested in is, how much treatment effect is there and at what level are there adverse effects. In this setting, in renal cell carcinoma as is typical, efficacy is extremely important. And I think people are going to be very, very interested therefore in looking at the efficacy results of the overall survivor results that we've obtained with this combination. Well, it's suffice to say that we're enthusiastic about it.

Adam H. Schechter - Merck & Co., Inc. - Executive VP & President of Global Human Health

Chris, this is Adam. Let me start by giving you the percent break out by tumor type, and I've always provided this for the U.S. and outside the U.S. The caveat is it's very hard to get data, and it does differ by country. But in the U.S., if you look at non-small cell lung cancer, it's about 65%, about 10%, melanoma; 5%, head and neck; 5%, bladder; 5%, MSI high; and then about 10% all other indications. When you look at Europe and lung, as you know, we've been launching the monotherapy for patients with PD-L1 greater than 50, and we're making significant inroads. And as I said now in the major European markets, lung is the larger -- largest tumor type versus all the other tumor types. So we are seeing significant growth there. With the combo, that will triple the size of the eligible market. So, obviously, that's going to be a much bigger market for us. But as I've always said, when it comes to first-line lung, ramp up is lower because you're not getting a lot of patients that have been treated before failed and coming in a bolus. It's each person comes in is diagnosed that the chemo combo will be considered. Also in countries like Germany, we have reimbursement right away, you'll start to see sales come in quickly. But in other markets, we're working on reimbursement to get that as soon as possible

Operator

It's from Jami Rubin with Goldman Sachs.

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

Just a couple for you, Ken. I noticed that at a recent competitor conference, you characterized margin expansion potential as being meaningful. And I think that's the first time you've actually used the word meaningful. Can you just elaborate a bit on what you mean by that. And if at any point in time you would expect the company to provide a line in the sand in terms of where you see that going? And second question you won't be at all surprised I'm asking. But while we recognize and you've been very clear that Animal Health is a strong pillar of Merck's growth and diversification, based on the math that we done -- we have done we see an approximate \$12 per share upside if the market were to value your Animal Health business in line with Zoetis and Elanco, both of which have obviously been hugely successful. If you don't consider spending this business, which it sounds like you're not, what steps can you take to highlight its value? And what conditions are you looking for in order to consider changing your mind? Or should we expect an Animal Health will be part of Merck indefinitely?

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

So the thing I would say about that, Jami, is that, first of all, we actively evaluate our portfolio on an ongoing basis. So you shouldn't expect that any decision that we are making today will necessarily be the decision that we make forever, but we are actively evaluating our portfolio to decide what we think makes sense in terms of our overall strategy of driving sustainable value and growth for our shareholders. I also want you to know that we do pay attention to what happens on the outside world. In fact, we share the market's excitement around Animal Health value as a sector and our business in particular. In fact, we believe that we run this business very well inside the company compared to its competitors. So if you look at our business, it's a global leader. We continue to view it as one that we can be a good owner of. We look at it in our industry-leading growth and margin, and so as we think about it, again coming back to what I said at the beginning, we have to actively review our portfolio looking at multiple factors, including market development to decide whether or not a particular asset, not just Animal Health, should remain in our portfolio. And we'll continue to do that on an ongoing basis. With respect to the issue around margin expansion, we did say that we expect meaningful operating margin expansion over time. We see the growth of certain parts of our business like Oncology as being very helpful to driving that kind of margin expansion. But as it relates to being more specific and putting numbers around that and time periods at this time, we don't know that that's the right thing for us to do. We will continue to give guidance in the way that we normally do it on an annual basis. But I don't really think it makes sense for us today as we're seeing this business grow and expand for us to try to say a specific number in terms of what the margin expansion



OCTOBER 25, 2018 / 12:00PM, MRK - Q3 2018 Merck & Co Inc Earnings Call

will be. What I can tell you is that we will continue to work very hard to drive that margin expansion at the same time, making the right kinds of investments that we need to make to drive our growth over the next few years.

Operator

It's from Alex Arfaei with BMO Capital Markets.

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

Ken, given your demonstrated confidence in your long-term growth prospects now, why do you still see business development as a priority? I appreciate that you have the capacity. But just because you can doesn't mean you should. So is business development a key -- are you looking at it as a priority because of risk management reasons given your KEYTRUDA exposure? Or is something else driving this? And if I could, a follow-up for Roger. Just wondering about your updated CTLA-4 data, some interesting activity. Seems to have better safety than what we're seeing with the YERVOY combination, but just as this field evolves and as you get more information from CheckMate 227 and other competitive agents, I'm just wondering where your CTLA-4 ranks as a priority for you.

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

So on business development. Let me start by saying that we're pleased with the way in which our business is growing now, particularly in the Oncology field. But that doesn't make us comfortable. At the end of the day, we know that we have to continue to build our portfolio and build on our pipeline. And that's why it's an important priority for us going forward. Going back to the question that was asked a few questions ago, that's a situation that we faced as a company. Our pipeline is never going to be strong enough. We can always add to our pipeline. And that's not just a question of derisking. It's a question of driving on future growth.

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

And Alex, on 1308, you're right. I mean, the -- our molecule looks pretty good. I mean, we've worked quite hard to select a CTLA-4 directed molecule and to try and establish what the appropriate dose and schedule would be for such a molecule. And we are interested in the question, not sure why. But the combination looks a little promising. And so we think that there may be a possibility for it. We're still sort of still stepping through it, haven't made explicit decisions, but it looks like there may be an opportunity there. We wanted to make sure that people were aware of what we were seeing, and we did present the data at ESMO for that reason.

Operator

It's from Seamus Fernandez with Guggenheim.

Seamus Christopher Fernandez - *Guggenheim Securities, LLC, Research Division - Senior Analyst of Global Pharmaceuticals*

Maybe first question is really around business development. A number of times on the BD -- in your prepared comments, I think about 6x, you mentioned business development as a priority. So maybe, Ken, if you can just give us a little bit of an incremental sense or perhaps, Roger could opine as well on the areas where you think adding to the pipeline and really targeting the time frame, the sort of post JANUVIA time frame as a key.

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

I'm sorry. Go ahead, finish. I'm sorry.



OCTOBER 25, 2018 / 12:00PM, MRK - Q3 2018 Merck & Co Inc Earnings Call

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

No, no, that's okay. I'll follow-up on my second question after you go.

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

No, I think you should go ahead and ask it. So that way, we can have it all.

Seamus Christopher Fernandez - Guggenheim Securities, LLC, Research Division - Senior Analyst of Global Pharmaceuticals

Then you can proceed. So -- and then maybe, Roger, just 2 quick questions for you. Maybe you can just give us a sense of -- in the wake of the first-line kidney cancer results as you've seen it, do you see a meaningful opportunity to improve upon the data with other TKIs like Lenvima in the same setting? And then just my last question, the 522 study, we're on the cusp of it. Maybe could just help us understand the opportunity in the adjuvant and neoadjuvant TMBC setting.

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

Okay. Thanks, Seamus, and I apologize for interrupting. So with respect to business development, it remains an important priority for us because it's our job to find the best scientific innovations that will enhance our pipeline. We think building best-in-class pipeline is ultimately what generates long-term growth value for shareholders, and that's what we intend to do. And let me turn it over to Roger now.

Roger M. Perlmutter - Merck Research Laboratories - President

Right. Well, I mean, if I could on the business development side, I think everybody recognizes that for any pharmaceutical company at our scale, it will always be the case that business development contributes materially to our pipeline. It must be the case. And typically, something over a majority of the molecules that we developed are licensed from the outside or acquired in some way. If we can acquire those in a way which also adds meaningful revenue right from the beginning, terrific. But we're fundamentally interested in the best science, the best opportunities that could have the biggest impact on patient care. I think that should be clear. With respect to first-line renal, I don't want to prejudge any data that we would see from other combinations we've had. We've had data that we presented previously and discussed after ASCO the combination of KEYTRUDA with axitinib and with lenvatinib, and those data are both -- both datasets were extremely interesting. We're charging ahead in the lenvatinib story. Every single one of the protein tyrosine kinase inhibitors will have slightly different characteristics. I don't think there's any way to predict exactly what those are going to look like. But certainly, the success of Lenvima and hepatocellular arena is very promising and, of course, the work that we've done in endometrial as well. So we're enthusiastic about those combinations. And lastly, you're right. 522 is getting close to the point where there would be DMC review. We are expecting that, that will happen this quarter, fourth quarter. And in principle I mean, it's very hard to predict what those data will look like. But in principle, anything that can add, improve responses in the triple-negative breast cancer population, obviously, would be extremely welcome in a very aggressive disease, concerning disease. And so we're looking forward to seeing those data.

Operator

It's from Andrew Baum with Citi.

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

A couple of questions for -- well, one for Roger and then a couple for Adam. So you recently, Merck published a paper in the JCO commenting on inflammatory signatures and TMB as biomarkers for responsiveness. In light of the recent disclosure from 227 around TMB as a protective factor



OCTOBER 25, 2018 / 12:00PM, MRK - Q3 2018 Merck & Co Inc Earnings Call

for overall survival, how does that influence how you're thinking about the future role of TMB in various combinations within your own studies? Second, for Adam, Ken has referenced business development as being critical part of Merck's focus. Obviously, the reimbursement outlook of the U.S. is great dynamic. The President is going to address what looks like Part B this afternoon. I'm interested how you think about that dynamism and valuation in light of business development and where you're leaning in terms of where you see the most risk from proposed and potentially enacted reform. And then finally, just a couple of quick comments on the future expansion of GARDASIL that you alluded to, both from China but also from vaccination of males throughout Europe and the time lines of that.

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

All right. Let's start.

Roger M. Perlmutter - Merck Research Laboratories - President

Yes. Andrew, thanks for the question. With respect to TMB, I have to say I'm not much influenced by reports from a single study like 227 where there was relatively modest ascertainment. We didn't have a lot of information from patients as patient subsets. We've done quite large studies on TMB comparing TMB to inflammatory signature, the JCO paper you referenced is one of those. There's quite a large series coming out in Frontline journal very soon that describes a more comprehensive analysis. You and I could talk about the underlying science here. It's quite interesting. I think that the question of how it is that mutation influences response rate, which it clearly does, is important to understand. People jump to the conclusion that that's neoepitopes and improved immune response. Not so clear for a whole variety of reasons. And, nevertheless, it's -- something that's very important to study and to understand the depth. And we continue to do that. We do not see tumor mutational burden as a test that could be implemented in any near term as a way of selecting patients will be appropriate to treat with KEYTRUDA monotherapy, for example. And as we know, in the combination therapy setting, the utility of KEYTRUDA with chemotherapy is quite broad.

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

Adam?

Adam H. Schechter - Merck & Co., Inc. - Executive VP & President of Global Human Health

And Andrew, with regard to business development in the U.S. specifically, obviously, the U.S. remains extremely important as we think about the future. And I believe that when we find products that make a significant difference in the world and those that there's nothing that competes in new areas that the U.S. will continue to have good reimbursement for those types of products. I would not want to be a late entry nondifferentiated product, and I wouldn't want to necessarily be a new mechanism that doesn't give a significant additional benefit. So when we're looking at business development, we're looking for real breakthroughs that can increase the health of large numbers of patients. With regard to GARDASIL, we're seeing growth, very strong on a global basis. And if you look, we sold just over \$1 billion. A lot of that was due to demand. But it's also from the CDC stockpile borrowing. The thing with vaccines is it's very lumpy, and you have to be careful looking at any 1 quarter. But if you look over time, we believe GARDASIL represents a very significant growth opportunity. If you look at the new indication in the United States, that's a big additional cohort. But also if you look at China and even in Europe, where we've taken back GARDASIL from the joint venture last year, we're seeing real big growth opportunities there. And then lastly, I'd say other countries are looking at what Australia has done. And they're already beginning to think about whether or not to implement those types of programs. So we see a real long runway of growth for GARDASIL over time.

Operator

It's from Tim Anderson with Wolfe Research.



OCTOBER 25, 2018 / 12:00PM, MRK - Q3 2018 Merck & Co Inc Earnings Call

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

A few questions. You talked about spending more in capital projects with part of that going towards manufacturing one of those products is KEYTRUDA, the other is GARDASIL. And my question is whether as you look forward over the next couple of years is there the change that demand will outstrip supply? I know with vaccines, for example, manufacturing can be very tricky. So is there any sort of risk we should anticipate in terms of sales kind of being kept until manufacturing is fully up and running? And then going back to GARDASIL, you guys seem to be flagging that, that could be an underappreciated opportunity. So you just touched on those, I think, in your last comment. But can you just talk about where you are with health authorities and payers in the various markets in terms of a broad embrace on vaccinating both boys and girls as a way of preventing different cancers? And if that product this year is going to sell \$3 billion, is it unrealistic to think that over time, it could do something like double in size? I'm trying to quantify what you think is opportunity that you guys keep highlighting.

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

Great. We'll start with Rob on the CapEx.

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

Tim, thanks for the question. So if you look at where our capacity is expanding, you're correct. It is around vaccines. GARDASIL in particular, frankly, our broader vaccines portfolio, KEYTRUDA and Animal Health. So it is really spread across all of the key growth areas of the company. And it's important to point out, and I'll let Adam to speak specifically to the -- what we see as the long-term demand in the marketplace but as we look at the supply, and we've been able to bring to the market, we have meaningfully increased our GARDASIL supply over the last several years, including coming into this year as we look forward, we also have the ability to continue to increase supply on a meaningful basis going forward. So we are making the necessary investments to ensure we can drive growth in this product and are very confident in that fact. And I'll turn it over to Adam to maybe give some specifics beyond that.

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

Yes, thanks, Rob. Hi, Tim. Yes, so we really are seeing unprecedented increase in worldwide demand for the HPV vaccines, and it's doubled in the last year alone in terms of demand necessarily. A lot of the increase in demand is driven by the policy change for GAVI countries and many countries are moving from demonstration programs to multiage cohorts. So as Rob said, we are really working hard to increase the global supply of the HPV vaccines. And it's a top priority for us, and we have plans in place to really significantly increase the global supply from our 2017 base as we look over the next 3 years. And I do think the demand is going to really continue to grow. So we're going to need that supply. As you look around the world, different countries are putting in place different mechanisms to ensure vaccination. So if you look at Brazil, you have a very different profile than, say, a country like France. So it's hard to give generalizations. But I would say the highest level is that people are really beginning to understand the importance of vaccinating both men and women, for the approved cohorts in the countries in which we're launched. And the demand will continue to grow, and after 9 years in the market to see the growth that we're seeing is really unprecedented. And I believe that, that growth will continue to be very, very strong.

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 had 3, if I may. First, we're seeing some proposals come out of Trump administration, not formally proposed but KEYTRUDA and the other IOs are being proposed at some of the top Part B priorities where they are seeing a price disconnect between U.S. and ex U.S. So I'm just curious how you guys see this play out, one. And secondly, Ken, for you on margins. I guess the question really is when investors hear you speak about margin



OCTOBER 25, 2018 / 12:00PM, MRK - Q3 2018 Merck & Co Inc Earnings Call

expansion, there's this assumption perhaps what it's implying is a margin expansion that may be beyond what's in consensus already, because consensus has it going up 500, 600 bps from current levels. I'm not sure how much granular you want to get there, but I just wanted to get your temperature on that in general. And then finally, Roger, we noticed for your upcoming neoadjuvant triple-negative breast trial that powering was increased by 35% a few months ago. I just wanted to get some color on the thought process behind that decision.

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

So let me start with the pricing question. So let me start by saying I think right now, there's a lot that's being talked about in Washington, but we really need to see further details to better understand how all of this is expected to be implemented. What we do agree with is that we need to find ways of getting patients more meaningful access to these Part B drugs. But at the end of the day, while we're open to that, we would be opposed to anything that would actually create a problem from the standpoint of patient access or innovation. But again, it's really early to try to comment on some of the things. I know the President will be speaking this afternoon, and we'll just have to continue to interact with the administration and Congress on those issues.

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

Right, Rob, maybe you can take the margin expansion?

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

Yes, Umer, thanks for the question. I don't want to comment specifically on how we look relative to consensus. I think the key message here is that we want to make sure people understand is that we do expect to see a meaningful margin expansion due to the mix of the business and our ability to continue to drive leverage through a productive use of our investments to drive faster top line growth over time. So really, that's the message. How that compares to consensus, we're not going to comment.

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

And Roger, do you want to finish up?

Roger M. Perlmutter - Merck Research Laboratories - President

Yes, Umer, on product 22, I'm a huge believer in adequately powering studies. I really am, and Roy and I spent a lot of time thinking through the issue of how to ensure that the results that we get from the study will be as definitive as possible. The important point to recognize is sort of I know you know this, but we don't see data that result in our change in the study. The study is going on, and we don't know what the results are. What we do is we simply look at everything that we've learned from everything that everyone is doing and ask questions about how we should improve the way in which the study proceeds. And so we'll see where we get to. We're not always want to do it exactly right, but we do it as best we can.

Operator

It's from David Risinger with Morgan Stanley.

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

I will follow the instructions from Teri very closely, unlike some of my competitors. So my 2 questions are number one, could you please provide the percentages of U.S. sales that Merck generates from Medicare, including Medicare Part B? And second, could you talk a little bit more about Animal Health growth? It was 6%, which is solid organically. But I just don't have a sense for what we should expect going forward in that business.



OCTOBER 25, 2018 / 12:00PM, MRK - Q3 2018 Merck & Co Inc Earnings Call

I think there was some moderation in the organic growth. And if you could give us a sense for how we should think about future organic growth prospects, that would be great.

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

We'll start with Adam.

Adam H. Schechter - Merck & Co., Inc. - Executive VP & President of Global Human Health

Yes. So, David, thanks for the question. Yes, we don't really break out segment growth, and the reason why is because if you look at our portfolio, it's changing every quarter and growth is coming from different areas, some of which are much bigger in Medicaid and Medicare, and we -- it's very hard because a lot of the data you also get is retroactive versus where you are today. But in general, you know that KEYTRUDA is reimbursed through Part D. You can tell the vaccines are reimbursed differently. And I think as we go forward, obviously, oncologists are going to play a much bigger role for us.

Roger M. Perlmutter - Merck Research Laboratories - President

And to your question about Animal Health, as I commented in the prepared remarks, I wouldn't look at what you see as the what could appear to be the slower growth in the quarter as any indication of what's going on in the business as I said. There really are some timing impacts. We actually had some customer purchases in the companion animal space that positively impacted the second quarter. It was a buy ahead of a price increase. That is affecting the comps. If you adjust it for that in the third quarter, you'd actually see Animal Health growth very much in line where it's been consistently. And as we look longer term, as we said in the past, we see this business driven by our innovative pipeline, which comes from the synergies we get with our Human Health business to continue to drive strong, above-market growth for this business over the long term. So that hasn't changed and our confidence in this growth pile profile continues to be very strong.

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

Thanks, Rob, and unfortunately, I think we're going to have to close the questions there. Dave, I really appreciate you listening to the instructions, and hopefully, next time, we'll be able to get more questions in. I'll pass it over to Ken to close.

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

So I want to thank you all for your continuing support and interest in Merck. We are energized by the momentum in our business right now, and we believe our portfolio of opportunities is better than it has been at any time since I've been here at Merck. We look to the future with great confidence about what we can deliver for our patients and shareholders, and we look forward to updating you on our progress. Thank you.

Operator

This concludes Merck's Third Quarter 2018 Sales and Earnings Conference Call. You may now disconnect.

OCTOBER 25, 2018 / 12:00PM, MRK - Q3 2018 Merck & Co Inc Earnings Call

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