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MRK - Q4 2017 Merck & Co Inc Earnings Call

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## FEBRUARY 02, 2018 / 1:00PM, MRK - Q4 2017 Merck &amp; Co Inc Earnings Call

## CORPORATE PARTICIPANTS

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

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

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

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

**Teri Loxam** Merck & Co., Inc. - SVP Investor Relations and Global Communications

## CONFERENCE CALL PARTICIPANTS

**Alex Arfaei** BMO Capital Markets U.S. - Pharmaceuticals Analyst

**Alexander Man** Sanford C. Bernstein & Co., LLC., Research Division - Research Analyst

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

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

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

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

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

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

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

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

**Yan Li** Citigroup Inc, Research Division - Senior Associate

## PRESENTATION

## Operator

Good morning. My name is Darla, and I will be your conference operator today. At this time, I would like to welcome everyone to Merck's Fourth Quarter 2017 Sales and Earnings Conference Call. (Operator Instructions)

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

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**Teri Loxam** - Merck & Co., Inc. - SVP Investor Relations and Global Communications

Thanks, Darla, and good morning, everyone. Welcome to Merck's Fourth Quarter and Full Year 2017 Conference Call. Today, I'm joined by Ken Frazier, our Chairman and Chief Executive Officer; Rob Davis, our Chief Financial Officer; Adam Schechter, President of Global Human Health; and Dr. Roger Perlmutter, President of Merck Research Laboratories.

Before I turn the call over to Ken, I'd like to point out a few items. You will see that we have items in our GAAP results such as acquisition-related charges, 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.

In addition, you will note that we have included a table in the supplemental financials on the Investors section of the Merck website which provides information on the new accounting standard related to the allocation of pension costs on the income statement. This standard, which is effective



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January 1, 2018, requires pension components other than service costs to be reflected in other income and expense. As a result of this standard, Merck's 2017 cost of goods sold, operating expenses and other income and expense will be restated for 2018 reporting purposes. This change has no impact on net income or EPS but will result in an increase to expense and an offsetting increased other income. The supplemental table shows that the new 2017 amounts will be what they will be when we report in 2018. Our 2018 guidance for gross margin and operating expense is relative to these restated 2017 amounts.

I would also like to remind you that some of the statements that we make during today's call may be considered forward-looking statements within the meaning of the Safe Harbor provision of the U.S. Private Securities Litigation Reform Act of 1995. Such statements are made on the current beliefs of Merck's management and are subject to significant risks and uncertainty. If our underlying assumptions prove inaccurate or uncertainties materialize, actual results may differ materially from those set in -- set forth in the forward-looking statements. Our SEC filings, including Item 1a in the 2016 10-K, identify certain risk factors and cautionary statements that could cause the company's actual results to differ materially from those projected in any of our forward-looking statements made this morning. Merck undertakes no obligation to publicly update any forward-looking statements. You can see our SEC filings as well as today's earnings release on merck.com.

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

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

Thank you, Teri. Hello to everyone, and thank you all for joining the call today. Last year, 2017, was another successful year for Merck as we continued pursuing our mission of advancing the most promising science across our Animal and Human Health business.

Our full year results demonstrate underlying strength as we were able to grow despite a challenging year with the loss of exclusivity of several key products and other pressures.

The year's highlights include: ongoing and significant progress for KEYTRUDA, Lynparza and our expanding oncology portfolio; advancement in vaccines, especially with continued uptake of GARDASIL; and progress within our specialty medicines business, including the submission to the FDA of doravirine for HIV and advancement of our next-generation HIV pipeline. Animal Health also continued its strong performance and remains a core growth driver for Merck.

We are entering 2018 with good momentum behind these pillars and anticipate that they will drive solid top and bottom line growth for the company.

We continue to invest significantly in R&D, and at the same time, we're actively engaged in finding the best external science to further augment our portfolio and pipeline through business development.

We believe that bringing forward innovation that meaningfully addresses unmet medical needs is the key to Merck's long-term success, and we are actively building such a pipeline. In addition to efforts behind our pipeline, including focused work to reshape our discovery capabilities, we continue to evolve our operating model in line with our changing portfolio and the evolving health care environment. I'm excited for what lies ahead this year and in future years.

We expect our pipeline to continue to deliver medically important breakthroughs, and we remain dedicated to finding innovative ways to demonstrate the value of our products and to increase patient access. Finally, we are pleased that Congress and the administration enacted tax reform, which helps to level the playing field for U.S.-based companies and increases our financial flexibility by providing us access to overseas cash.

I will now turn the call over to Rob to go through more details on tax reform, our fourth quarter and full year results as well as our 2018 guidance. Rob?



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

Thanks, Ken, and good morning, everyone. As Ken noted, we're pleased with the newly enacted tax reform. The impact of the new legislation to Merck in the fourth quarter was a \$2.6 billion provisional charge. This reflects a onetime transition tax of approximately \$5 billion on foreign earnings deemed to be repatriated, partially offset by changes in deferred tax liabilities. While tax reform does not fundamentally change our capital allocation priorities, it does improve our flexibility and enhances our ability to deploy capital in support of our strategy to invent new medicines that address key unmet medical needs, benefiting patients and driving sustainable long-term shareholder value.

To that point, in addition to funding our growing investment in R&D as well as seeking value-creating business development opportunities, we are also planning roughly \$12 billion of capital investments over the next 5 years, with approximately \$8 billion in the United States, to add capacity for our key growth drivers of oncology, vaccines and Animal Health as well as additional investment to enable ongoing discovery efforts. We also remain committed to our dividend, which we increased for the seventh year in a row last November. Finally, to the extent we don't deploy capital towards business development deals over time, we look to return it to the shareholders.

Now let's turn to the fourth quarter results. My remarks will mainly focus on our non-GAAP financials. In the fourth quarter, we grew the top line on both a nominal and ex-exchange basis, driven by strength in KEYTRUDA, BRIDION and Animal Health. This more than offset the headwinds from LOEs for the products like ZETIA, VYTORIN and REMICADE; competitive pressure for ZOSTAVAX; and the negative sales impact of approximately \$125 million due to the June cyber incident.

Total company revenue of \$10.4 billion grew 3% in the quarter, including a 1 percentage point benefit from foreign exchange. Our Human Health business grew 3% excluding exchange, and Adam will provide additional detail on that in just a moment. Our Animal Health business delivered 8% growth excluding exchange, driven by continued strength in our companion animal, ruminants and poultry businesses.

Looking to the other parts of the P&L. Non-GAAP gross margin was 74.6% in the quarter, roughly flat year-over-year. Non-GAAP operating expenses of \$4.6 billion were higher year-over-year, reflecting increased R&D spending. The increase in R&D was driven by the timing of business development transactions as well as higher clinical development spending. The cost of goods sold and the operating expense lines also reflect approximately \$145 million in costs related to the June cyber incident.

Non-GAAP effective rate was 15.3% in the quarter, roughly 8 percentage points lower year-over-year, resulting in a full year tax rate of 19.1%. Increased income and lower tax jurisdictions and certain onetime items resulted in the lower full year tax rate versus last year. Taken together, we earned \$0.98 per share on a non-GAAP basis, an increase of 10% versus the prior year or 6% excluding the positive impact of foreign exchange. While there was some benefit from the lower tax rate in the quarter, our true operating strength was somewhat masked by several items that hit the fourth quarter, including the impacts of cyber, natural disasters and the timing of BD deals. On a GAAP basis, EPS was a loss of \$0.32, reflecting the provisional charge related to the enactment of U.S. tax reform legislation I described earlier.

Now let's turn to guidance and our outlook for 2018. We expect full year 2018 revenues to be in the range of \$41.2 billion to \$42.7 billion, mainly driven by strength in our growing pillars of oncology, vaccines and Animal Health. This range assumes an approximately 1 percentage point positive impact from foreign exchange using mid-January rates.

Before going into the remaining guidance, I'll remind you that the gross margin guidance and operating expense growth rates are relative to the restated 2017 amounts, which Teri mentioned at the beginning of the call. We expect our non-GAAP 2018 gross margin to be slightly lower year-over-year, driven primarily by product mix across the portfolio. We expect our non-GAAP operating expenses to increase year-over-year at a low to mid-single-digit rate. This is primarily driven by an increase in R&D spending as we continue to make the investments necessary to drive our many pipeline opportunities, such as our oncology pipeline, including KEYTRUDA and Lynparza; as well as our vaccines and other specialty care programs.

Regarding tax, we anticipate the full year non-GAAP tax rate to be in the range of 19% to 20%, which reflects the favorable impact from tax reform of a few percentage points relative to what our rate would have been absent reform. Despite the tax reform benefit, the 2018 rate will generally be flat compared with 2017 due to onetime benefit in 2017, which I referenced earlier, that will not repeat in 2018. Beyond 2018, we anticipate some additional favorability.



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We project average diluted shares outstanding of approximately 2 point billion -- 2.7 billion for 2018, reflecting a decrease versus the prior year, as we continue our share repurchase program. Taken together, we expect non-GAAP EPS to be in the range of \$4.08 to \$4.23, which reflects an approximately 1 percentage point negative impact from foreign currency at mid-January rates.

In summary, 2017 reflected a year of strong execution resulting in top and bottom line full year growth and a leveraged P&L. We expect our momentum to continue into 2018 and anticipate delivering meaningful revenue performance driven by our growth pillars of oncology, vaccines and Animal Health. We will remain disciplined in our capital allocation of resources, continuing to invest in our pipeline to drive long-term growth while balancing the need to fully fund near-term opportunities, enabling us to both invest for the future while delivering solid EPS growth in the year. We believe this approach best positions us to maximize the long-term trajectory of our business and deliver shareholder value.

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

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

Thank you, Rob, and good morning, everyone. This morning, I'll provide highlights on the performance of Global Human Health for the fourth quarter and for the full year of 2017. My comments will be on a constant-currency basis.

2017 was another year of solid execution for Global Human Health. Sales of \$35.4 billion grew 1% despite headwinds of more than \$3 billion from LOEs. I'll now highlight a few of our key franchises and launches, and I'll start with oncology.

2017 was an exceptional year for our oncology franchise. Global sales of KEYTRUDA nearly tripled versus 2016, surpassing \$3.8 billion. In the U.S., KEYTRUDA continues to lead new patient starts across nearly all indications. In metastatic lung cancer, KEYTRUDA remains the leading treatment option across I-O and non-I-O therapies. We continue to build on that leadership position with an increased adoption of the combination with ALIMTA and carboplatin in non-squamous patients, and our recent announcement of the success of KEYNOTE-189 trial should catalyze even broader use of this combination.

KEYTRUDA is the only I-O agent to show an overall survival benefit in the first-line setting as a monotherapy in high expressers and as combination therapy with ALIMTA and platinum chemotherapy in non-squamous patients in an all-comers population. Anecdotal feedback from physicians has been very positive, and they are looking forward to seeing the full results from the KEYNOTE-189 study.

KEYTRUDA is also leading across many tumor types outside of the U.S. In addition to our leadership in melanoma, recent approval for additional tumor types in key markets, including lung and bladder cancers, are expected to drive incremental growth. Altogether, we see an extraordinary opportunity for KEYTRUDA in 2018 and beyond as we continue to establish KEYTRUDA as a foundation in the treatment of cancer.

We also see great opportunity for Lynparza, which we are codeveloping and co-commercializing with our colleagues at AstraZeneca. Lynparza regained class leadership following approval of the broader ovarian cancer label in the U.S., and we are currently launching the new metastatic breast cancer indication. The Merck field force is now being deployed in the U.S., and additional reps will be brought onboard in other top markets in 2018. We see significant long-term opportunity for Lynparza.

Now moving to diabetes. Global sales for the JANUVIA franchise were nearly \$6 billion for the full year, with volume trends remaining strong in most markets around the world. As I've discussed over the last several years, we face continued pricing pressure, particularly in the U.S., but we do maintain market-leading access. We expect the growth opportunity in international markets will be of increasing importance for the JANUVIA franchise moving forward.

Beyond JANUVIA, we're looking to build on our leadership in diabetes with the launch of STEGLATRO and STEGLUJAN. We believe JANUVIA will remain the first add-on to metformin in a majority of patients. But we are also pleased to provide additional options to help patients lower their A1c as disease progresses.



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As we look at our hospital specialty portfolio, products like ZEPATIER and BRIDION helped to offset the headwind from several LOE products in 2017. ZEPATIER sales were nearly \$1.7 billion for the year. As anticipated, sales in the U.S. in the fourth quarter reflected a significant reduction in share and volume due to the competitive landscape. We expect this dynamic to continue in 2018 with most markets outside of the U.S. also coming under pressure.

Conversely, we continue to see an important growth opportunity for BRIDION in many markets around the world. Global sales grew nearly 50% in 2017 to just over \$700 million. We expect BRIDION to remain a key growth driver for the hospital and specialty portfolio given the growing trend toward minimally invasive and robotic procedures and customers' continued positive experience with the product.

Now moving to vaccines. Our broad vaccines portfolio of pediatric and adult vaccines continue to perform well and reached \$6.5 billion in 2017. Sales of ZOSTAVAX reached nearly \$670 million for the full year. In the fourth quarter, we saw significant decrease in our ZOSTAVAX business in the U.S. as U.S. market reacted to new ACIP recommendations.

Sales of GARDASIL reached \$2.3 billion in 2017, with increased global demand for gender-neutral vaccination driving growth for the product year-over-year. Underlying growth and increased coverage rates remained strong in the U.S. Outside of the U.S., we saw growth in Europe with the JV termination as well as increased demand in Asia Pacific and our GARDASIL launch in China. We are excited about the growth opportunities for this important brand in both the U.S. and outside of the U.S. in 2018.

In closing, we are well positioned for growth in 2018. We expect our diabetes franchise to be relatively stable and growth from key products including KEYTRUDA, Lynparza, GARDASIL and BRIDION to more than offset the headwinds that we face.

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

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

And thank you, Adam. My colleagues in Merck Research Laboratories made progress on numerous fronts during the past 3 months.

Beginning with product approvals. In the fourth quarter, PREVYMIS, our cytomegalovirus terminase inhibitor, was approved by the FDA for the prophylaxis of CMV infection and disease in adult recipients of allogeneic hematopoietic stem cell transplant. And this is the first new drug registered for prophylaxis and treatment of cytomegalovirus infection over 15 years. And as described in our recent publication in the New England Journal of Medicine, the use of PREVYMIS as opposed to placebo was associated with the reduction in all-cause mortality in allogeneic hematopoietic transplant recipients.

Marketing authorization for PREVYMIS was also obtained in the European Union in January, and the product is under review in other jurisdictions, including Japan.

In December, we received FDA approval for a family of products containing the SGLT2 inhibitor ertugliflozin, which is presented as monotherapy with the brand name STEGLATRO or in combination with metformin or with JANUVIA for the treatment of type 2 diabetes. As a result of a worldwide collaboration with colleagues at Pfizer, these 3 products also received the positive opinion from the CHMP last week and are under review elsewhere.

Progress in the approval segment was nowhere more evident than in oncology. First, together with our colleagues at AstraZeneca, we have gained FDA approval for Lynparza, our poly ADP-ribose polymerase inhibitor, for the second-line treatment of HER2-negative metastatic breast cancer in patients with a germline BRCA mutation. This is the first approval for a PARP inhibitor in the breast cancer setting, and it's a component of our strategy to broaden the utility of this important new drug. Lynparza was also approved in Japan for the maintenance treatment of ovarian cancer, irrespective of BRCA status, in patients who have previously responded to platinum-based chemotherapy. Lynparza is the first PARP inhibitor approved for any indication in Japan.

Beyond Lynparza, we also made meaningful strides in further characterizing the activity of KEYTRUDA in a variety of malignancies. Based on data from our KEYNOTE-045 study, KEYTRUDA was approved for the second-line treatment of urothelial malignancies in Japan. This approval mirrors



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what we had previously achieved in the United States and in the European Union. Moreover, the FDA accepted for review our filing of KEYTRUDA for the treatment of primary mediastinal B cell lymphoma, a rare but typically aggressive tumor.

These accomplishments were overshadowed, however, by the results of 2 studies that together contribute importantly to our understanding of the ability of KEYTRUDA to influence the treatment of malignant disease. In early January, the European Organization for Research and Treatment of Cancer or EORTC announced the results from our KEYNOTE-054 cooperative study, showing that KEYTRUDA treatment as compared with placebo significantly improved recurrent-free survival in patients with previously resected, high-risk melanoma. Based on an interim analysis, KEYTRUDA-treated patients were 43% less likely to experience recurrence of their disease. KEYNOTE-054 will continue under the direction of the EORTC, thus permitting analysis of other key endpoints, and the results will be presented at an upcoming scientific meeting.

More recently, interim analysis of the KEYNOTE-189 study revealed that first-line treatment of non-squamous, non-small cell lung cancer patients with the combination of KEYTRUDA plus standard therapy, including either carboplatin or cisplatin, together with pemetrexed, resulted in statistically significant improvement in both progression-free survival and overall survival. This study extended the results obtained in our KEYNOTE-021G study, which, as you will remember, resulted in accelerated approval for combination treatment of non-squamous, non-small cell lung cancer in the United States in May of last year.

The KEYNOTE-189 study enrolled more than 5x as many patients as the KEYNOTE-021G and was structured such that overall survival and progression-free survival were co-primary endpoints. We are certainly encouraged by the strength of the KEYNOTE-189 data, details of which will also be presented as soonest as possible in an appropriate scientific venue.

Our clinical development and regulatory affairs teams are interacting with regulatory agencies regarding a number of new filings. Earlier this month, we announced that the FDA has accepted 2 New Drug Applications for doravirine, a second-generation non-nucleoside reverse transcriptase inhibitor for use in combination with other antiviral agents and as a complete regimen in combination with tenofovir and lamivudine for the treatment of HIV infection. The agency has established a PDUFA date of October 23 for these reviews. We believe that doravirine will prove to have broad utility, especially when used in combination with other new agents that we have advanced for the treatment of HIV infection.

For example, we are studying combinations of doravirine with MK-8591, a novel and highly potent anti-retroviral agent.

Unsurprisingly, our broadest efforts in the development and regulatory space were directed towards KEYTRUDA. A few weeks ago, we announced that KEYTRUDA was recognized with yet another Breakthrough Therapy Designation, the 12th, for the treatment of advanced and/or metastatic renal cell carcinoma in combination with Lenvima, a multi-kinase inhibitor discovered and marketed by Eisai. We are collaborating with Eisai in pursuing the development of this novel combination.

Clearly, given the large amount of clinical development activity underway with KEYTRUDA, including more than 700 registered clinical studies, of which more than 400 involved combinations, our regulatory affairs groups are exceptionally busy. We look forward to sharing more information about the clinical data supporting these regulatory activities at the many scientific meetings that will occur in the late spring and early summer, and I will provide details regarding the cadence of these presentations during our April earnings call.

I'll now turn the call back over to Teri.

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**Teri Loxam** - Merck & Co., Inc. - SVP Investor Relations and Global Communications

Thanks, Roger. Darla, we'll move on to the Q&A portion of the call. (Operator Instructions) Darla, could we get started, please.

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## QUESTIONS AND ANSWERS

### Operator

(Operator Instructions) Your first question is from Tim Anderson with Sanford Bernstein.

**Alexander Man** - *Sanford C. Bernstein & Co., LLC., Research Division - Research Analyst*

This is Alex Man on for Tim Anderson. I have 2. First, on KEYNOTE-189, while I understand you're limited in what you can say now, how should we think about the benefit of a combination occurring to more than just the high-expresser subgroup? And second, on Echo 301 in melanoma with KEYTRUDA plus epacadostat, some investors have felt sounded a bit cautious in the past. What's your latest thinking around the degree of risk for this trial as we head into the readout?

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

Right, Alex. Well, first of all, with respect to KEYNOTE-189, just as you say, with our -- we are quite limited in terms of what we will describe about this study. Our highest priority has to be to ensure that the KEYNOTE-189 data are presented as soon as possible in the appropriate scientific forum. And of course, we also would like to see the data published in an appropriate scientific venue as soon as possible. I would just reiterate that we are certainly encouraged by the strength of the KEYNOTE-189 data, and we're optimistic about the way in which those data will be received by practitioners. And so the most important thing is that practitioners need to have that information in front of them in a such a way that it can guide their thinking about how best to treat cancer patients. And with respect to Echo 301, I would say that, again, the important question is, do we see meaningful benefit that endures to patients when the combination of epacadostat is used with KEYTRUDA? We are -- have been very pleased, as I've said before, that epacadostat has an adverse effect profile such that it combines very well with KEYTRUDA. But the question is, how much benefit does one get from an efficacy standpoint? And until we actually see the data, we just don't know.

**Teri Loxam** - *Merck & Co., Inc. - SVP Investor Relations and Global Communications*

Thanks.

### 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*

So I have 2 questions. First, could you please provide some color on KEYTRUDA sales mix in the U.S. by cancer type and also ex U.S.? And then second, with respect to ZOSTAVAX, I'm hoping you can provide a little bit more color on the competitive pressures and the outlooks -- outlook for ZOSTAVAX sales.

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

David, so if you look at KEYTRUDA, first of all, we had very strong growth year-over-year in the U.S. and outside the U.S. In the U.S., it grew more than 50 -- 150%, and outside the U.S., it grew more than 175%. If you try to break down the data by indication, it's not perfect, as I've said before. But we believe more than 55% of the sales in the U.S. are in lung, about 15% melanoma, about 5% in head and neck, another 5% in bladder and then the rest in other. International market, it's not easy to get the data to break it out. Right now, the majority of our sales still remain in melanoma. However, we are seeing increases as we launched new indications around the world. So I don't have the precision that I have in the U.S. because the data is not easily available. But melanoma is still a driver outside the U.S., and lung is becoming more and more important and more and more





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of a growth driver. With regard to ZOSTAVAX, as I've said before, with the ACIP recommendations in the United States, it makes it very difficult. I think that we'll continue to see pressure in the U.S. based upon those guidelines. And then I think as the product launches outside of the U.S., we'll see similar pressure over time, and it's really because the recommendations are really recommending a preferential vaccination of a competitor versus ZOSTAVAX. So we expect very strong pressure competitively as we move forward.

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**Teri Loxam** - Merck & Co., Inc. - SVP Investor Relations and Global Communications

Thanks, Adam.

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**Operator**

It's from the line of Andrew Baum with Citi.

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**Yan Li** - Citigroup Inc, Research Division - Senior Associate

It's Yan Li on for Andrew Baum. Two questions, please. First question, going back to KEYNOTE-024, can you inform us, out of the total patients originally enrolled on to KEYNOTE-024, what was the percentage of them that did not manage to receive treatment because their disease had progressed or performance status worsened whilst obtaining their, obviously, results? A second and broader question on your oncology strategy. Given the recent FDA PMS gene assay approvals as well as tissue-agnostic MSI approval for KEYTRUDA, what is Merck's strategy and appetite for materially expanding your small molecule position that is an exposure in oncology to take advantage of the new NGS paradigm?

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

Right. Okay. So first of all, for KEYNOTE-024, the question, I guess, is how many individuals were enrolled in the study, randomized in the study who didn't receive treatment presumably because they -- their disease progressed very rapidly. I'm not sure what exactly you're getting at. I don't have the numbers in front of me. Obviously, the -- well, first of all, of course, the study has been published, and you can look at the table that describes the patient allocation. But we can provide additional data, and I guess we'll do that offline. But I don't think there is any aspect of that, that affects the interpretation of the KEYNOTE-024 study, which, again, was -- demonstrated dramatic treatment effect in those patients whose tumors expressed a high level of PD-L1. And with regard to the strategy for small molecule exposure and more generally, I guess, the strategy for advancing therapies in oncology, I guess, I would say again that it's important to recognize that KEYTRUDA is really the first broad spectrum -- truly broad-spectrum antineoplastic agent introduced into clinical practice. It is active across an enormously broad range of different tumor types. We've studied KEYTRUDA as monotherapy in more than 30 different tumor types and have responses in the vast majority of those tumor types. And in many, many important tumor types, my view is that KEYTRUDA will become foundational. What we demonstrated is that one can add other therapies to KEYTRUDA and achieve even more beneficial responses. Preclinically, the addition of radiotherapy, traditional cytotoxic chemotherapy, targeted chemotherapies as well as other immune-based therapies, including therapies related to infection with oncolytic viruses as well as immunization, all of those things preclinically work in combination with KEYTRUDA to improve the effect of PD-1 antagonism itself. Clinically, we also have evidence for combination -- the activity of combinations. And I think what will happen in the future is that those combinations will become more and more diverse. So the choice of combination will be very much focused on the individual patient, precision medicine, if you will, based on a range of different issues, the patient's performance status and age, a variety of indices related to the tumor and increasing knowledge about responsiveness. That's a long, long winded way of saying, of course, we're interested in having other agents that are active other targets to the extent that they can add real benefit in the meaningful segment of the KEYTRUDA-responsive cancer population.

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**Teri Loxam** - Merck & Co., Inc. - SVP Investor Relations and Global Communications

Thanks, Roger.



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**Operator**

It's from the line of Jason Gerberry with Bank of America.

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

Just 2 for me. Just first, Roger, KEYNOTE-042, can you talk just a little bit about what drives your confidence for this -- into the study readout, particularly given, I guess, some mixed data with monotherapy and sub 50% expressers? And if that study is positive, how are you guys viewing the commercial opportunity relative to the recent positive KEYNOTE-189 outcome? And then my second question, the outlook for JANUVIA, I think, has long been for stable performance into the out years. Just kind of curious if that includes incremental contribution from SGLT2 fixed-dose combinations. Or do you think that the JANUVIA/JANUMET franchise without that contribution can be stable next year?

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

Right. I'll start, and then Adam can take the commercial aspect. I mean, for KEYNOTE-042, which is an expanded version of KEYNOTE-024 that looks at individuals whose tumors express lower levels of PD-L1, we do believe that PD-L1 expression is one measure of likely responsiveness to KEYTRUDA, and we've demonstrated that in a whole variety of settings. But it's not the case that the only individuals who respond to KEYTRUDA are those whose tumors express PD-L1 in greater than 50% of cells. Indeed, we have had good results in lower-expressing populations and in a whole variety of different settings. So I'm optimistic about KEYNOTE-042 in a broader population, but, of course, we have to wait for the data. We do expect the data will be available in the first half of this year. The study is under the supervision of a Data Monitoring Committee and is event-driven. So once those events are complete, then we'll have the answer. And again, before I pass on to Adam, I would just say that when -- my expectation is that when oncologists think about how they're treating lung cancer patients, one of the issues will be: Is this individual somebody who will likely respond to monotherapy which has a more favorable profile with respect to toxicity than does combination therapy? Where an individual is younger, more robust, a combination therapy would -- might be more attractive. And in older population with many comorbidities, combination therapy might be less attractive, irrespective of what, for example, PD-L1 expression said. But -- so that's just an example of the way in which I think therapy will be personalized going forward. But Adam can give more details.

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

Yes. So with regard to commercial opportunity, in metastatic lung cancer, KEYTRUDA is the leading option today across I-O and non-I-O therapies. So we are in a very strong position, and we believe that we will continue to be able to build upon that strong position moving forward. With regard to the diabetes franchise, I would continue to look at it as a franchise, and we believe it will be a relatively stable franchise. We believe that the growth outside the U.S. will be increasingly important as we move forward. So for example in China, we have NRDL approval for JANUVIA now, and we're launching that in China as we speak. I believe that the SGLT2 and the SGLT2 combo with JANUVIA will continue to be important, but altogether, we look at the diabetes franchise as a relatively stable portfolio moving forward.

**Teri Loxam** - Merck & Co., Inc. - SVP Investor Relations and Global Communications

Thanks.

**Operator**

It's from the line of Steve Scala with Cowen.



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

First, for Roger, on KEYNOTE-189, Merck, of course, announced that PFS and OS were achieved, but small trials suggest KEYNOTE-021G may have created an unrealistic expectation for the outcome of larger chemo combo trials. So do you think if the degree of PFS and OS benefit in KEYNOTE-189 was substantially less than KEYNOTE-21G that it would still be well received? Second question is for either Ken or Roger, how would you characterize Merck's pipeline today versus that in the past? Today, Merck has a pipeline that has the fewest disclosed products in big cap pharma. Of course, that could just be a function of disclosure policy. But any thoughts on the pipeline today would be appreciated.

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

Right, Steve. Well, with respect to KEYNOTE-189, I can't really respond to a hypothetical about what the market would do if -- and what physicians might believe if the results were X, Y or Z. I have to retreat back to what I said before, which is we're encouraged by the strength of the KEYNOTE-189 data. And we're going to present those data just as soon as possible in an appropriate scientific venue, and then everyone will have a chance to look at them and decide how they feel about those data, but we're certainly encouraged by the strength of them. And the second question is, how do we feel about the pipeline? Well, of course, in general terms, you always want more things in your pipeline. That's always the way. On the other hand, I guess I would point to the pillars of growth that Rob mentioned. First of all, we have a lot of exciting opportunities in the oncology space, not just KEYTRUDA and Lynparza, which are important; and selumetinib, which also became part of our collaboration with AstraZeneca. But beyond that, we have a series of molecules in the immuno-oncology and related space that look really pretty exciting. We haven't had a chance to say much about those, but they include molecules like our STING agonist for intratumoral injection, like our LAG-3 antibody, like anti-GOT antibody, a number of others that have gone forward and a bunch of other interesting programs. And of course, we acquired a small company with a Phase I asset in Rigontec just late last year. So we have a lot of things going on there. And some of that data that we're seeing there are really quite intriguing and quite promising. So as we look in the oncology space, we see more opportunities for growth. We also have an opportunity for growth in the vaccine space. As Adam detailed, we have an enormously strong vaccine profile, particularly as we continue to expand the activity in GARDASIL space with GARDASIL-4 and GARDASIL 9. So we are -- that program is -- well, it is a remarkable vaccine that offers the promise of dramatically reducing the incidence of papilloma virus-related disease and particularly cervical cancer. But beyond that, we are going into Phase III with an extended pneumococcal conjugate vaccine with 15 serotypes. We have still other vaccines coming forward. We have extremely interesting cytomegalovirus vaccine, which looks quite exciting. We have a dengue vaccine, which looks quite interesting. And so there's a lot of work going on in the vaccine program that is really very exciting. Broadly speaking, we have activity in many other areas, including neuroscience and cardiovascular disease, and many of those look quite interesting as well. So I would say that it's very difficult to compare pipelines across companies and across time. But I'm enthusiastic about the opportunities we have and believe that we can dramatically grow our business based on the programs that we're currently pursuing.

**Teri Loxam** - Merck & Co., Inc. - SVP Investor Relations and Global Communications

Thanks, Roger.

**Operator**

It's from the line of Seamus Fernandez with Leerink.

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

So just a quick one. Roger, can you just give us a general sense of the other evidence that suggests that a combination of KEYTRUDA with chemotherapy, particularly the ALIMTA chemotherapy, has benefits not just on PFS but perhaps on overall survival? Is there any evidence to suggest that? Or is the definitive evidence going to be provided in the presentation of the KEYNOTE-189 results? As we've talked to physicians, they've really emphasized that, that would be something that they view as incrementally exciting about the KEYNOTE-189 data set because they've already started to evolve their practice in that direction. And then the second question is really around the opportunity to see leverage in the Merck story



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and in the portfolio. I was hoping Rob and Adam could really talk about the opportunities and the points of leverage that you see in 2019-plus, as we've now clearly defined the story for 2018.

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

Okay. Seamus, with the -- with respect to the KEYTRUDA plus chemotherapy story, I would say, first of all, we agree that overall survival is the gold standard in terms of treatment of malignant disease, and our goal is certainly, where possible, to demonstrate that improvements in overall survival actually take place. As -- the 021G data, which is again quite a small dataset, just 60 patients per arm in a 2-arm study, was surprising in that as the data emerged and despite crossover, as we looked over time, overall survival became more and more meaningful. The study was not powered for an overall survival result, but as we saw those data become stronger and stronger, it led me to decide that we really wanted to change the statistical analysis plan for the KEYNOTE-189 study to emphasize overall survival as an endpoint. We did it just for that reason. And because of that, KEYNOTE-189 study, which had over 600 patients enrolled in a 2-to-1 randomization, was powered for overall survival, and as we announced, the overall survival result was positive. So on its first interim analysis, it met both the PFS and overall survival endpoint, and we will be presenting those data. And I think that will be very important to oncologists engaged in treating cancer patients.

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

And then with regard to -- as we look out, we're obviously not giving guidance beyond 2018 today. But as I broadly look into the future, I think we have some real pillars of strength. Oncology is going to continue to be a real pillar of growth for us, new indications, additional data with KEYTRUDA. We believe Lynparza will continue to be a real growth opportunity for us. And vaccines, in particular GARDASIL, we believe has a lot of growth potential moving forward. And then we have several products in the Hospital and Specialty areas that should provide us continued growth such as BRIDION. So as we look to the out years, we still think we have some pretty good pillars of growth.

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

I would also add that our Animal Health business, which is a global business with a great, strong portfolio, both in production and companion, also, I think, will provide us with strong growth outpacing the industry comparisons they have.

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

And then finally, I guess, to tier you down from sales to how we think about earnings, clearly, as we've consistently said, we continue to have a goal of delivering a leveraged P&L over time. As you see in 2018 and as I think we had guided previously, we are in a period of investment behind the many opportunities we see in the pipeline that Roger has outlined. We will continue to drive that investment going forward. But tiering down the growth in revenues, the real tailwinds that Adam and Ken laid out, those pillars of growth, down through the P&L, we do actually expect long term we will return to a leveraged P&L over time as we go forward.

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**Teri Loxam** - Merck & Co., Inc. - SVP Investor Relations and Global Communications

Thanks, Rob.

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**Operator**

It's from the line of Chris Schott with JPMorgan.

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

The first one here is just can you give a little bit more color on your tax rate dynamics for 2018 and beyond? You're obviously, clearly seeing a benefit, but your rate is coming in what seems to be a couple of hundred basis points above many of your peers. So help me understand a little bit the dynamics there. And how much room is there for an improvement relative to this 19% to 20% rate that you're talking about? The second question I had was just latest on the EU filing for that broader first-line lung indication based on 189. Just latest thoughts on timing there. And is there anything you can do to accelerate that process at all?

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

Yes. Chris, thanks for the question. So with regards to the tax rate in 2018, it is slightly higher than what we had in 2017. But I think it's important to point out that 2017 actually benefited from some onetime tax items primarily related to benefits related to foreign tax credits. That's important -- the tax credit plan that we were able to do that drove the rate down in 2017 by a few points. So in reality, probably a better run rate to look at is 2016, which was at around 22%. So if you look at that going forward, we actually see tax reform benefiting us by a few points. We'll still though be in that range, a little bit over 19%. The guidance we gave, 18% to 19% for -- or 19% to 20%, sorry, for 2018. And as we look at that, part of what's going on is we have a higher mix of income in the United States relative to some of the other companies. That does cause us to have a little bit higher of a structural rate. That's actually been the case over time. That continues. But as we look beyond 2018, we actually do think we will see the rate come down. If I was putting something out there, I'd say probably another percentage down from where we were going to be in 2018 as we move forward in '19 and beyond.

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

And Chris, with respect to the regulatory strategy, we have had discussions with regulatory agencies in light of the 189 data, and we'll certainly be following their advice with respect to filing strategies and how one can review this data. Obviously, we're eager to see this data incorporated into practice as regulators see fit.

**Teri Loxam** - Merck & Co., Inc. - SVP Investor Relations and Global Communications

Thanks, Roger.

**Operator**

It's from the line of Alex Arfaei with BMO Capital Markets.

**Alex Arfaei** - BMO Capital Markets U.S. - Pharmaceuticals Analyst

First of all, Roger, congratulations on Keynote-189. Your team's foresight to include overall survival certainly appears to have paid off. Will 189 be able to provide insights by subgroup, either PD-L1 tumor mutation burden or other factors to help physicians determine what type of patients are most likely to benefit from the combo as opposed to monotherapy? And then, Adam, how should we think about the growth opportunity of GARDASIL longer term? You mentioned China. I think you folks keep emphasizing the global opportunity. Just help us understand whether that's a near-term thing or if it's sustainable. And similarly, your HIV assets don't get a lot of attention. Just wondering if you could help us understand the commercial opportunity there.

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

Right. Well, with respect to the KEYNOTE-189 data, we are going to -- we're expecting to present these data in the appropriate scientific forums as soon as possible. And as I've said, I'm -- we're certainly encouraged by the strength of the data. This data, when they are presented, will include a



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lot of different evaluations across a broad range of different stratification, subgroups and -- as one would expect in those analysis. So there'll be an opportunity for people to look at a broad range of different determinants that may or may not have some effect. Obviously, I can't comment on what those data might look like. We should have the opportunity to present them relatively soon.

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

And with regard to, first, HPV, I think that's going to be an important contributor to our business and growth aspects not only in 2018 but beyond that. And we believe we can continue to drive underlying demand for both GARDASIL and GARDASIL 9. We're seeing greater coverage of the younger cohorts over time and in a more gender-neutral manner. We believe that about 50% to 70% of males and females in the U.S. have received at least the first dose, so there's room even there for continued growth. And outside the U.S., we still believe there is significant opportunity. I mentioned China. We're in the early stages of launch, but I think it could be a very significant growth opportunity for us there over time. So I think we have very strong growth prospects for GARDASIL and GARDASIL 9 in the foreseeable future. With regards to our HIV franchise, we've been in the HIV field for many, many years. And if you look at where we are right now, we are launching doravirine. And I think that, that is really a bridge, to a large degree. And when I say launching, we're preparing for the launch of doravirine. It's under review. But I look at that as a bridge to the future products that Roger has in the pipeline, which will enable us someday in the future to be a leader again in the HIV field. So it's a place that we know well. It's a therapeutic category where I think there's still significant medical unmet need, and I think there are ways in the future with longer-acting agents or agents with potentially less side effects that could make a significant impact.

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**Teri Loxam** - Merck & Co., Inc. - SVP Investor Relations and Global Communications

Great. Thanks, Adam.

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**Operator**

It's from the line of Umer Raffat with Evercore ISI.

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

Perhaps first one for Ken. Ken, there's a meaningful part of your business that's been hitting on all major clinical and commercial milestones, KEYTRUDA-driven obviously. Do you think that business trades at a material discount to its intrinsic value? And if so, how do you envision unlocking that value? And maybe one for Roger. Roger, one of your competitors on the European side is really emphasizing that their emerging Phase III data in I-O, chemo will basically span each possible chemo combination there is out there in a separate dedicated Phase III. Do you think that impacts your positioning in first-line lung, which is primarily centered around an ALIMTA-based I-O, chemo?

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

So let me just comment on the first question as it relates to the commercial execution and clinical execution we've seen with respect to KEYTRUDA. So first of all, I do think it is unprecedented to see how quickly this company has moved forward in that whole area of oncology. We've seen very strong growth that Adam talked about, 150% in the U.S., 175% or so outside the U.S. I believe as more data emerges, people will be able to see this opportunity the way we see it internally. And I think that they will see why we are so excited about that one particular opportunity. And then, as we've said several times, KEYTRUDA, which we think, again, is a pipeline within a product, is also accompanied by very strong additional assets, including Lynparza and a number of other internal opportunities that we have. So from our perspective, I think it's really important for us to continue to execute on that. And as the world begins to see that more clearly, I think our oncology franchise will be more well received. It's also been said here also that things where we have a legacy or leadership. We have great opportunities in front of us with GARDASIL. Roger talked about our pneumococcal vaccine opportunity. We have CMV and the RSV and dengue behind that. We've talked about our Hospital and Specialty business, HIV, BRIDION, neuroscience, et cetera. And again, I really want to -- I want to underscore that our Animal Health business really is a global business





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leader in its segment. So I think -- to try to get to your questions, I think as execution continues, I think the evidence will emerge, and I think people will see why we are so comfortable and excited about what we have in our portfolio and our pipeline.

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

And with regard to I-O, chemo combinations and sort of the breadth of such combinations, if I could just elevate for a minute. I would say we should pause and reflect what a remarkable time this is, that the combination of KEYTRUDA with chemotherapy based on the 021G data and then, of course, our recent announcement with respect to KEYNOTE-189 is providing meaningful results in patients with metastatic lung cancer who previously had really very limited opportunities. And I guess I would make 3 points. The first point is that, as we discussed with 021G, and KEYNOTE-189 only makes that stronger, the combination with chemotherapy that we demonstrated with ALIMTA and platinum therapy kind of sets a floor on what one should expect in terms of treatment of lung cancer. You need to do at least that well, and that's very important going forward in the future. So that's the first thing. The second thing I would say is that there will be a lot of studies of different chemotherapeutic agents in a variety of different settings. I would point out, for example, that this is all with reference to the non-squamous, non-small cell lung cancer population. But squamous carcinoma of the lung is an important contributor to morbidity and mortality and, in certain regions, a quite large contributor. And we do have the KEYNOTE-407 study, which will be coming out some time in the first half of this year and also promises to provide important information about how to treat such individuals with different chemotherapy regimens obviously, but with KEYTRUDA as a background. So I think that's an important thing to recognize. And the third thing to recognize is that, again, with time, I think we will see that a broadening of the set of options that exist for cancer patients such that one will select appropriate therapy based on the individual characteristics of patients, for example, with lung cancer, in that selection, I believe that KEYTRUDA will still prove to be foundational across a very broad range of treatment options.

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**Operator**

It's from the line of Jami Rubin with Goldman Sachs.

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

Ken, I have a question for you. I would say that you've kind of gone out of your way the last couple of years in downplaying your interest in a transformational deal. And I'm just wondering if you're rethinking that now that we are starting to see talk again of industry consolidation, Pfizer said so on their earnings call. And it's just interesting, when you take a step back, Merck's shares have been flat the last 2 years despite phenomenal good news for KEYTRUDA, and it seems that the bolt-on strategy hasn't really changed the story. I'm just wondering what your reluctance is to be more aggressive with the strategic direction of the company.

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

Well, Jami, thanks for the question. I would say, first of all, as I've suggested before, we are actively engaged in looking for the best opportunities to enhance our pipeline. And I said before that we look at deals with all types of structures, including acquisitions and partnerships, collaborations and licensing. We also don't restrict ourselves as we do our scan across things based on size and structure and stage of development. We are looking for the best opportunity to create the strongest longer-term portfolio for Merck. So I would just say that we continue to look for the best opportunities that we can find. I have expressed in the past my reluctance to do what you call large transformational deal. I think if you look at the history of this so-called large transformational deals, they haven't necessarily provided the ability to those companies when they finish their synergies to drive their pipelines going forward. So I'm very much focused on what will allow this company to be a strong innovator 5, 10 years from now. And if that kind of deal would help us do that, then I would look at it differently.

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**Operator**

Your final question comes from Vamil Divan with Crédit Suisse.





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

So 2 questions, if I could. So one on the KEYTRUDA, Lynparza. Just wondering if you can highlight what the next data points are that we'll see for that combination. And then given the importance that we feel just around you're a single company owning the different components of the combination, can you discuss how pricing negotiations may play out over time? Given the products of separate companies, is there a way for you guys to work together? Or the products just could be priced the way they are? Would you have had more flexibility, for example, if you had acquired a PARP outright? And my second question, following up on an earlier one on Echo 301. I feel like many investors are expecting that data to be definitive one way or the other, either very good or very bad data. I'm just curious, Roger, if that's how you're looking at this trial. It is the first Phase III. We're still in obviously the very early days of immuno-oncology. So I'm thinking it might provide good information, but be more informative and definitive. And wondering if you agree with that or if you think the results really will be definitive and give us a clearer sense of what the combination provides over PD-1 monotherapy.

**Teri Loxam** - *Merck & Co., Inc. - SVP Investor Relations and Global Communications*

Great. Roger, maybe you can start with the KEYTRUDA and Lynparza, the next data point set we're looking at coming up.

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

Right. I mean -- so with respect to KEYTRUDA, Vamil, we've talked about some of those data points, namely the 042 data, which looks at responses in the first-line setting to KEYTRUDA monotherapy in lung cancer -- non-squamous, non-small cell lung cancer in a broader range of patients defined by PD-L1 expressed in the tumor and the KEYNOTE-407 data, which are in squamous non-small cell lung cancer. There's also the KEYNOTE-048 studies in the first-line head and neck cancer settings, which should be quite interesting. And so there's a lot of data that will be coming through. Again, as I make the point, we have over 700 studies, over 400 combinations. There's just an enormous amount of data coming forward. And with Lynparza, there's a quite a detailed plan for expanding the Lynparza indication, not only in the sort of traditional, hormonally responsive tumors, that is to say in ovarian and breast cancer settings, but also in broader settings, including in pancreatic cancer. All of those things are really quite interesting, and it's quite a robust program. So a lot going on in Lynparza as well.

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

And if you look at combination pricing, I mean, in general, it's just too premature to discuss the pricing of combos until we see the data, the incremental improvements of combinations, how they compare with monotherapies. And I believe the market will reward innovation, particularly innovation at least to improve outcomes over the current monotherapies. But we have to see the data to really get a sense of what that would look like. And I don't believe you necessarily will have to own everything. I think that the partnerships will be successful, but we need to see data.

**Teri Loxam** - *Merck & Co., Inc. - SVP Investor Relations and Global Communications*

Great. Thanks, Adam. We're out of time, so I'm just going to turn it back over to Ken for closing.

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

So again, thank you all for participating in today's call. I just want to reiterate that we're closing out 2017 with very strong operating momentum, which is a great foundation for 2018 and beyond.

Thank you. Have a good day, and we look forward to speaking to you in the future.



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### Operator

This concludes the Merck Fourth Quarter 2017 Sales and Earnings Call. You may now disconnect.

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