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PRESENTATION

Operator

Good morning. My name is Darla, and I will be your conference operator today. At this time, I would like to welcome everyone to Merck's First Quarter 2018 Sales and Earnings Conference Call. (Operator Instructions) Thank you. I would now like to turn the call over to Teri Loxam. Please go ahead.

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

Thank you, Darla, and good morning. Welcome to Merck's First 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 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.

I would like to remind you that some of the statements that we make during today's call may be considered forward-looking statements within the meaning of the safe harbor provision of the U.S. Private Securities Litigation Reform Act of 1995. Such statements are made based on the current beliefs of Merck's management and are subject to significant risks and uncertainties. If our underlying assumptions prove inaccurate or uncertainties

materialize, actual results may differ materially from those set forth in the forward-looking statements. Our SEC filings, including Item 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.

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

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

Thank you, Teri. Hello, everyone, and thank you for joining the call today.

With our first quarter performance, we're off to a strong start for 2018, including the KEYNOTE-189 results that were presented at the recent American Association for Cancer Research meeting. These compelling data showed longer survival in nonsquamous first-line lung cancer patients when KEYTRUDA was combined with chemotherapy as compared with chemotherapy alone. This should help establish KEYTRUDA as a new standard of care in this patient setting.

This is a significant advance especially given that lung cancer kills more patients than any other form of malignant disease. KEYTRUDA offers new hope for these patients, and KEYNOTE-189 sets a new bar against which future trials in first-line lung cancer treatment should be measured.

Delivering therapeutics and vaccines for unmet medical needs is what Merck is all about. And doing it in a way that provides long-term value to shareholders in addition to patients is our top priority. Our solid first quarter performance provides good momentum for the rest of the year and into the long term.

We firmly believe that our prospects for revenue growth through 2021 and then beyond to 2025 are under appreciated. We have always believed in KEYTRUDA, but we think our data from KEYNOTE-189, along with what we anticipate to be a strong program going forward, firmly establishes KEYTRUDA as a foundation for cancer treatment and a substantial driver for this company.

We also believe we have tremendous near- and long-term opportunities with our partner products, Lynparza and Lenvima, along with a robust early-stage oncology pipeline. We believe our vaccines portfolio, including GARDASIL and complemented by our next generation pneumococcal asset, V114, can drive significant value.

Our early-stage pipeline, including vaccines, HIV, neuroscience and other areas, should also be significant contributors.

The continued strength we expect from Animal Health further adds to our confidence. Business development remains a top priority, and we will continue to look for opportunities to further augment our outlook. We must continue to execute, but I am very optimistic about our near- and long-term trajectory, driven by these key pillars.

And with that, I will now turn the call over to our Chief Financial Officer, Rob Davis, to go through our results in more detail. Rob?

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

Thanks, Ken, and good morning, everyone.

Our first quarter results reflects continued strength in our key pillars and good operational discipline resulting in top and bottom line growth. Our underlying business continues to perform well, setting the company up for a strong start to the year. I will note that our first quarter results included a onetime nonoperational benefit of just over $0.03 related to the Apotex litigation settlement originally expected to occur in the second quarter as well as a more favorable-than-expected FX benefit.

Total company revenues were $10 billion, an increase of 6% year-over-year, driven by both the Human Health and Animal Health businesses. Excluding the impact of exchange, first quarter revenues grew 3%.

Our Human Health business grew 4% excluding exchange. Adam will provide more color on those results in a moment.

As we noted in our press release this morning, given the size of our Animal Health business, it became a reportable segment this quarter resulting in additional disclosure requirements, including segment profits. Animal Health sales totaled $1.1 billion in Q1, an increase of 13% compared with the first quarter of 2017, including a 6 percentage point positive impact from foreign currency.

Excluding the impact of exchange, livestock sales grew 6%, while companion animal sales grew 9%.

Animal Health segment profits were $413 million in the first quarter of 2018, representing a roughly 39% operating margin. Note that these profits exclude certain expenses and other overhead costs not directly incurred by the business. When compared to a year ago, the quarterly segment profits decreased 1% compared to $417 million in the first quarter of 2017, primarily driven by exchange, seasonality and onetime charges. We anticipate for the full year the Animal Health business will deliver a leveraged P&L, excluding the impact of exchange.

As you can see, our Animal Health business is profitable, has strong growth, provides the company with significant diversification from the Human Health business and benefits from synergies with our human health R&D capabilities. As such, Animal Health represents an important pillar of growth for Merck in 2018 and beyond.

Turning back to the total company P&L, non-GAAP gross margin was 75.7% in the quarter, a decrease of 170 basis points versus the first quarter of 2017, largely due to unfavorable foreign exchange as well as amortization of unfavorable manufacturing variances partly resulting from last year's cyber incident.

Non-GAAP operating expenses of $4.3 billion increased 1% year-over-year, including a negative 3 percentage point impact from foreign exchange.

Excluding FX, both M&A and R&D declined in the quarter with the decrease in R&D reflecting the timing of licensing costs, which more than offset the increased clinical development spending and investment in early drug development. Taken together, we earned $1.05 per share on a non-GAAP basis, up 18% excluding exchange.

Turning to the outlook for the year, we are narrowing and raising both our revenue and non-GAAP EPS guidance ranges for 2018. We continue to believe that several of our growth pillars, including oncology, vaccines and Animal Health, will drive both top and bottom line growth for the year. We also expect a more favorable exchange environment.

For the full year, we now expect revenues to be between $41.8 billion and $43 billion, including an approximately 2 percentage point impact from foreign currency at mid-April rates.

This top line increase flows to the bottom line, and we now expect non-GAAP EPS to be between $4.16 and $4.28, including a roughly 1 percentage point positive impact from foreign currency at mid-April rates. All other elements of our non-GAAP guidance provided during the fourth quarter earnings call remain unchanged.

In summary, we expect our momentum to continue through 2018. We will remain disciplined in our allocation of resources while we fully fund our near-term opportunities and invest in our pipeline to drive long-term growth. This approach positions us well to maximize our ability to grow both revenues and earnings and to deliver shareholder value.

Now I'd like to turn the call over to Adam.

Adam H. Schechter - *Merck & Co., Inc. - Executive VP & 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 first quarter of 2018. My comments will be on a constant-currency basis.

Merck's Global Human Health business achieved solid growth in the first quarter. Sales of $8.9 billion grew 4% driven by several important franchises which more than offset competitive pressures and loss of exclusivity for select products.

Merck's sales outside of the U.S. grew 8%., representing now almost 60% of total Global Human Health sales.

I'll now highlight a few of our key franchises and I'll start with oncology. Our Oncology business continues to expand rapidly, led by KEYTRUDA, which is now a foundational cancer treatment across multiple tumor types. Global sales of KEYTRUDA more than doubled to nearly $1.5 billion versus prior year. In the United States, there are more new patient starts on KEYTRUDA than any other immunotherapy, and KEYTRUDA remains the leader in patients with metastatic lung cancer. We have received overwhelmingly positive feedback from key opinion leaders and physicians based upon the recently presented KEYNOTE-189 data. They were very impressed by the overall survival benefit across all PD-L1 subgroups. And given that OS is the gold standard, we expect the use of this chemo combo to substantially increase moving forward.

Beyond lung, KEYTRUDA remains the leading immunotherapy in head and neck and bladder cancers and it continues to be used extensively in metastatic melanoma. In addition, we are gaining traction in MSI high where testing rates continue to increase across many different tumor types.

Outside of the U.S., KEYTRUDA sales nearly tripled from a year ago as access continues to increase and lung cancer is now representing the majority of sales in major European markets.

In summary, KEYTRUDA has become foundational in cancer care and the potential growth for KEYTRUDA in 2018 and beyond remains very strong.

We are also very pleased by the performance of Lynparza in both ovarian cancer and more recently in metastatic breast cancer with the launches progressing well from the January U.S. approval. Lynparza leads the PARP inhibitor class in both new and total prescriptions.

In addition, Lenvima will be an important product for our oncology portfolio through our recently announced collaboration with Eisai. We are accelerating the development and the commercialization of Lenvima, which has already established itself in several approved indications, including renal, thyroid and more recently hepatocellular cancers.

We are very optimistic about the long-term potential of both Lynparza and Lenvima, and we believe they represent important additions to our growing Oncology portfolio.

Now moving to our vaccine business. Global sales exceeded $1.5 billion in the first quarter, driven by continued strong demand for GARDASIL, which grew 20% despite pressure in the U.S. from the transition to the 2-dose regimen. Ex U.S., sales nearly doubled, driven by a strong launch in China following its approval last year and continued strong demand in other markets.

We view GARDASIL and our vaccines portfolio as a key pillar of Merck's future growth.

Turning to diabetes franchise. Global diabetes sales grew to $1.4 billion for the quarter. U.S. sales declined as TRx and pricing trends remain consistent with past quarters. Ex U.S, growth was strong, driven by increased demand in most markets around the world. We continue to view the diabetes franchise as a relatively stable franchise moving forward.

Moving to the hospital specialty portfolio, where BRIDION stands out as a fast-growing product driven by strong formula acceptance and favorable customer experiences. In the U.S., BRIDION is used in a wide range of procedures and has gained significant share of the neuromuscular blockade reversal market since its launch just 2 years ago. BRIDION continues to grow strongly ex U.S. as well, where it is launched in 60 countries.

In closing, it is a remarkable time at Merck to be launching so many important new oncology products and indications. With our broad portfolio and our global footprint, we were able to overcome several competitive pressures and patent expiries and deliver a 4% growth in the quarter. We remain optimistic by what we see in front of us for the rest of this year and beyond.

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

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

Thanks, Adam.

The first quarter was an important one for Merck Research Laboratories with progress on many fronts. Much of the activity this quarter was focused in the oncology therapeutic area, where we had the opportunity to present meaningful new data and to advance regulatory review across several important programs.

For example, yesterday, we announced that the FDA has granted priority review with a PDUFA date of September 23 to our supplementary Biologics Licensing Application seeking full approval for the use of KEYTRUDA in combination with pemetrexed and platinum-based chemotherapy for the first-line treatment of metastatic nonsquamous non-small cell lung cancer in patients whose tumors lack EGF receptor or alpha gene mutations. Data supporting the filing were derived from our KEYNOTE-189 study in which patients receiving this KEYTRUDA-plus-chemotherapy combination showed a greater than 50% improvement in overall survival as compared with those receiving chemotherapy alone.

These results were presented at the American Association for Cancer Research, or AACR, annual meeting in early April, and published simultaneously in the New England Journal of Medicine. Dr. Roy Herbst, the discussant selected by AACR to comment on the KEYNOTE-189 data, described our KEYTRUDA-chemotherapy regimen as a new standard of care for patients receiving initial therapy for metastatic nonsquamous non-small cell lung cancer. The KEYNOTE-189 data are also under review at the European Medicines Agency and by the Pharmaceuticals and Medical Devices Agency, or PMDA, in Japan.

During the AACR meeting last month, we were also able to present data from our KEYNOTE-054 study performed in collaboration with the European Organization for Research and Treatment of Cancer, which demonstrated that adjuvant therapy with KEYTRUDA reduced the risk of death or tumor recurrence by 43% as compared to placebo in patients undergoing definitive surgery for high-risk stage III melanoma. These results were also published in the New England Journal of Medicine.

During the first quarter, we also obtained important new results from our KEYNOTE-042 study showing improved overall survival in patients with EGFR and alpha mutation negative metastatic or advanced non-small cell lung cancer receiving first-line treatment with KEYTRUDA as a single agent as opposed to traditional platinum-based chemotherapy, when the tumor cells of these patients showed PD-L1 tumor proportion scores of at least 1%. Because this was a monotherapy study, patients with both non-squamous and squamous tumor histologies were included in the study, details of which will be presented at the upcoming American Society for Clinical Oncology, or ASCO, annual meeting next month.

These data extend those from our KEYNOTE-024 study for which we received regulatory approval from the FDA in 2016, which demonstrated improved overall survival in the smaller cohort of patients whose tumors expressed the PD-L1 biomarker on greater than 50% of cells. The new results, therefore, offer the promise of extending the benefit of KEYTRUDA monotherapy to the majority of patients with non-small cell lung cancer.

KEYTRUDA has already received approval from the FDA for use in 10 different settings involving 7 different tumor types: melanoma, non-small cell lung cancer, squamous cell carcinoma of the head and neck, gastric cancer, classical Hodgkin lymphoma, urothelial cancer and in solid tumors with evidence of DNA mismatch repair deficiency or microsatellite instability.

During the first quarter, the FDA also granted priority review with a PDUFA date of June 28 to our supplementary filing for the treatment of advanced cervical cancer following progression on or off chemotherapy.

KEYTRUDA is also under review for the third line treatment of patients with primary mediastinal B-cell lymphoma and especially aggressive malignancy. The PDUFA date was extended until July 3 to permit analysis of additional data that we have provided.

Another filing based on our Phase III KEYNOTE-040 trial and supporting the use of KEYTRUDA in the second-line treatment of recurrent or metastatic squamous cell carcinoma of the head and neck has also been accepted for review by the FDA with a PDUFA date of December 28.

In all, there are now more than 750 studies of KEYTRUDA listed on ClinicalTrials.gov, including more than 400 combination studies. Not all of these studies will succeed, of course. During the first quarter, for example, we announced that a Phase III study exploring the utility of Incyte Corporation's epacadostat used in combination with KEYTRUDA failed to meet its primary endpoint of progression-free survival and overall survival in patients with metastatic malignant melanoma as compared with KEYTRUDA therapy alone.

However, numerous other combination programs employing other agents appear quite promising. Beyond KEYTRUDA, the first quarter saw important progress in the development of Lynparza, our PARP inhibitor that we are developing with our colleagues at AstraZeneca. Already approved in the United States for use as maintenance therapy for patients with platinum-sensitive ovarian, fallopian tube or primary peritoneal cancer without a complete or partial response to chemotherapy, the European Medicines Agency adopted a positive opinion for a similar indication that will become applicable in all participating European markets following ratification by the European Community.

Lynparza is also under review by the EMA for use in patients with BRCA-mutated HER2-negative metastatic breast cancer following treatment with traditional chemotherapy in the neoadjuvant, adjuvant or metastatic setting, an indication that was approved in the United States during the first quarter.

Progress has also continued in our infectious disease research. During the first quarter, we announced that the combination of imipenem/cilastatin and relebactam, our new beta-lactamase inhibitor, demonstrated a favorable overall response in patients with independent, insensitive bacterial infection, which was the primary endpoint of our first Phase III study. The addition of relebactam promises to expand the utility of imipenem, an important broad-spectrum antibiotic. These data will form the basis of a new drug application which we intend to submit in the very near future.

Separately, we announced the initiation of 2 Phase III studies of V114, our novel polyvalent pneumococcal conjugate vaccine. Based on favorable serology data from our earlier studies, some of which we presented at the 2018 International Society on Pneumococci and Pneumococcal Diseases in Melbourne, we are optimistic that this new vaccine will demonstrate improved immunogenicity, along with satisfactory safety and tolerability findings in healthy adult subjects and in adults receiving therapy for human immunodeficiency virus infection.

As has already been mentioned, the first quarter was also an important one for business development, with the announcement of our collaboration with Eisai Corporation on the development of Lenvima, an orally available protein tyrosine kinase inhibitor already approved in the United States as monotherapy for the treatment of differentiated thyroid cancer that is no longer responsive to radio iodine; and for the second-line treatment of renal cell carcinoma in combination with everolimus. Initial studies combining Lenvima and KEYTRUDA treatment defined the dose and schedule for the combination and yielded intriguing results regarding efficacy in multiple tumor types. Indeed, a Phase III program for the first-line treatment of advanced renal cell carcinoma, testing the Lenvima/KEYTRUDA combination versus Lenvima plus everolimus or monotherapy sunitinib, began in October of 2016. So we've been engaged in studying Lenvima in combination with KEYTRUDA for some time.

Lenvima has broad activity as a monotherapy and was recently approved for the first-line treatment of unresectable hepatocellular carcinoma in Japan, the first new systemic therapy for this disease approved in Japan in more than a decade.

During the first quarter, we also announced the acquisition of Viralytics Incorporated, providing us with a coxsackie A21-derived oncolytic virus called Cavatak, that has been studied as both monotherapy and in combination with KEYTRUDA. Details of these clinical programs involving Cavatak will be presented at upcoming scientific meetings.

Speaking of which, during the first quarter, we submitted more than 100 abstracts for presentation at the ASCO meeting next month. Included in these presentations are examples of many combination studies, including those involving traditional chemotherapy, targeted agents like Lenvima and exploratory immunological manipulations. Data to be presented at ASCO also include the previously mentioned KEYNOTE-042 monotherapy

study in the first-line treatment of non-small cell lung cancer. Our KEYNOTE-407 study of KEYTRUDA plus traditional chemotherapy in the treatment of squamous cell carcinoma and our KEYNOTE-427 monotherapy study in the first-line treatment of renal cell carcinoma.

We look forward to sharing these data with the broad international community of oncologists at ASCO in 2018.

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

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

Thanks, Roger.

Darla, we're ready to move on to our Q&A phase. (Operator Instructions) So with that, Darla, let's turn it over.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Your first question is from David Risinger with Morgan Stanley.

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

I wanted to ask 2 questions. First, could you just update us on the potential approval timing for 189 ex U.S. in major markets? And then second, with respect to the company's operating leverage potential, it appears that some of the negative pressures on key franchises will subside after 2018 and there should be operating leverage in coming years. But I just wanted to ask you to characterize how you're thinking about the opportunity to drive potentially faster operating profit growth than revenue growth in coming years.

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

David, it's Roger. With regard to the approval timing for 189 ex U.S., the files are moving forward in a variety of jurisdictions. We expect them to move in the usual sort of way. There are no special accelerations that we see in Europe or in other jurisdictions, but the files will move forward. And as we learn more, we'll update you on their progress.

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

Thanks, David. This is Rob. I'll address your question on operating leverage. The answer is we do expect, as we've been signaling for quite some time, that we do expect long-term operating margin expansion and improvement due to the fact -- of really several things. One, obviously, as we continue to see growth in our sales line and the shift in our mix of our products, that should drive operating margin improvement. And as we have been talking about over the last several quarters, we've been in the period of heavy investment, particularly into the clinical studies behind KEYTRUDA and just the vast oncology portfolio we have in total moving through the clinics. So that, obviously, has been putting some pressure on our ability to drive leverage in the near term and will continue to make leverage more challenging over the near term. But long term, we are focused on driving operating margin improvements, so you should see that.

Operator

It's from the line of Greg Gilbert with Deutsche Bank.

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

Ken and Rob, I know you like the Animal Health business for the reasons you've articulated many times, so I don't need you to repeat those, but how do you balance those attributes with the fact that the business could be much more highly valued outside of the company? And my second question is on the Eisai collaboration. Roger, what are the important points of differentiation you see for Lenvima versus other TKIs?

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

Well, so thanks, Greg, for the question. Let me start by saying what we've stated in the past, which is that we think this is a key growth driver for the company with healthy margins and a strong market outlook. Our goal over the longer term is to drive long-term growth, and we think Animal Health, a business that generates really good cash flows, that actually helps fund the human health R&D we intend to do as a way of generating long-term shareholder value within Merck. In addition, I guess ironically, I might add that from time to time, we're told that a concern is the concentration risk around KEYTRUDA, and this provides diversification from KEYTRUDA as well as the rest of our Human Health portfolio. So I guess I would say we view this business as an important future pillar of growth for Merck.

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

Great. And Greg, the Lenvima, just as you point out, is one of a large number of tyrosine kinase inhibitors that are active across a broad range of malignancies. It's pretty difficult to compare them because the different protein tyrosine kinase inhibitors have related but not identical spectra of activity with respect to the VEGF receptor family, PDGF receptor and others. As a result, one just has to look at the clinical data. I'd say the Lenvima data, first of all, as a monotherapy in renal cell carcinoma and in differentiated thyroid, are strong and the hepatocellular data are really very good; that provided approval in Japan. But this -- our knowledge of this led us to begin the initial combination studies. We found we were able to combine Lenvima with KEYTRUDA effectively. And the results, which we've presented in part for the combination of the 2 in renal cell carcinoma are really very, very encouraging. Additional data on the combination of Lenvima plus KEYTRUDA will be presented at ASCO, and they're really quite interesting results. The Phase III program, of course, is still ongoing and won't be available until next year, but it is a formidable combination.

Operator

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

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

The first one was on KEYTRUDA and just your thoughts on the role of monotherapy KEYTRUDA relative to combo in light of KEYNOTE-189, the data from KEYNOTE-024 as well as the data from the upcoming 042 study. When we think about the high expressers, well, that 1 through 49 population, just trying to understand how you're thinking about how people will be using monotherapy versus combo in those 2 settings specifically. My second question was a broader question just for Ken. I guess my question is just the success you've had with KEYTRUDA and the visibility that provides to the longer-term business, does that change at all how you think about either investing in the portfolio today, your business development priorities or just how you think about core versus noncore assets at all?

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

Roger, you want to start on KEYTRUDA?

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

Yes. So Chris, the decision as to whether to use monotherapy versus combination therapy, I think, will be a very personal one that results from discussions that go on between physician and patient. In a general sort of way, as you can imagine, for patients who have substantial comorbidities and where there is concern about the adverse effect profile of adding chemotherapy, monotherapy is a sensible alternative for patients who are younger; and where comorbidities are not a concern, combination therapy might be the right answer. But it will be a very personalized decision. I guess the important thing to emphasize is that in either case, KEYTRUDA provides the foundation for therapy either with or without chemotherapy. And the data on that becomes stronger and stronger over time.

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

And Chris, with respect to your broader question, so first of all, let me just say that we're pleased that due to the strong execution we've had, KEYTRUDA has the potential to be the largest product Merck has ever had, which is a good thing for Merck but also for the patients that we can help. But we are, and aspire to be, much more than just a KEYTRUDA story. And so as it relates to business development, as I've always said, it's an important priority for the company. Everything is in scope. In terms of acquisitions, we look at our portfolio to decide what's better in our portfolio, what's better outside our portfolio. But as we move forward, and we're going to continue to look for those opportunities to drive and enhance our pipeline, like the deals we've done with Eisai and AZ. The challenge is obviously, recently, as we've looked at a number of acquisitions over the past couple of years, the competition for assets has been such that often the prices became unreasonable based on the assumptions that we're able to make. But I just want to say again we have a strong balance sheet. We have the power and the flexibility to do deals at any size and stage and we're going to continue to look for things that can drive long-term value and growth for our company.

Operator

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

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

Just a couple of questions. Mostly for you, Ken, congrats again on winning the I-O war with KEYTRUDA, which has been phenomenal news for patients, but that has not translated into shareholder value creation as Merck's shares have been sort of a chronic underperformer for the past 1, 3, 5 years. So just as you sort of wind down your period as CEO, and I also want you to touch upon succession plans, what are your priorities to unlock shareholder value? You just said you're not going to spin out Animal Health. I believe that would be one very easy way to unlock value. But in the absence of doing that, what are the other plans to unlock value? Investors have been frustrated that there has been less aggressive BD activity. Can you talk more about that? And then, Rob, you touched upon margin leverage, but will this be primarily just coming from mix or is there an opportunity for absolute cost cuts? And then Ken again, if you could comment on succession plans.

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

Thank you, Jami, for your questions. So first of all, of course, we would like to see our stock perform better than it has in recent years, particularly given the fact, as I said, we have executed, I think, exceptionally well in the I-O space. And we also think we've positioned the company for long-term growth and value creation. As I said in my opening comments, we actually believe that our revenue growth opportunities are somewhat underappreciated. But moving to, I think, the thrust of your question, we continue to look for opportunities to augment our growth and our pipeline through business development. I won't repeat what I've said before. There are challenges. I think as you know, across this industry, there are challenges as it relates to finding the right kind of assets to drive our long-term growth. But that is what we expect to do and that's what we intend to do. As it relates to succession, all I can say is that, that's obviously an issue that our board is very, very focused on. And that's something that's totally in their viewpoint, it's something that they intend to proceed with. And when we have something to announce, we'll let people know. But I'd just assure you that is something that's primary in the board's concerns right now.

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

And good morning, Jami, on your question on what's driving operating margin, obviously, given the strong revenue growth we expect between now and 2021 as well as more broadly through 2025, along with our product mix shifting to a more specialty focus, we do anticipate operating margin expansion as we move forward. I would point out that if you look back over the last few years, we've actually done aggressive reductions, mainly in our SG&A spend. If you recall, we went to a 2 -- over $2.5 billion cost-cutting exercise from 2013 to 2015. That allowed us to drive EPS growth during that period while we were seeing the revenue decline and importantly build out an oncology franchise from scratch and invest in R&D. So as we look forward, we really are more focused on how do we drive leverage by being productive and seeing our expenses grow at a rate slower than sales. With the focus in SG&A, we've continued to show discipline in allocation to our areas of growth, I do think there's opportunity to see SG&A as a percentage of sales continue to improve. I'd point out at 24.9%, we're already pretty much near the best-in-class within our space, and that's what allowed us to fund R&D. So there is some opportunity there, but this is much more about how do you manage the growth of spend in a disciplined way at a rate slower than sales long term to take advantage of product mix through revenue growth to drive operating margin, not cost-cutting initiatives.

Operator

It's from Vamil Divan with Crédit Suisse.

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

So one, I know there's been a lot of focus on lung cancer market and obviously the data you've presented there. Just -- maybe, I guess, this is for Adam, just some thoughts on the commercial impact you think that might have on these KEYTRUDA and other indications? And could there be this sort of halo effect that some have been talking about in terms of just driving KEYTRUDA (inaudible) sort of preferred P1 across a whole range of indications? And then my second question is more for Roger, I guess, with the IDO news that you mentioned. I'm just wondering how you -- how that changes, how you think about advancing mechanisms? As you think about combinations, do you -- does it make more of an emphasis on finding monotherapy activity from agents before you move them into combinations? Or just any sort of thoughts. You have so many different combinations that you're working on, how do you think about prioritizing one that may be more likely to succeed than others?

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

Yes, Vamil, this is Adam. Thanks for the question. And I'll start with the U.S. In the U.S., we're already seeing growth across all indications. We're seeing a particularly strong uptake in first-line lung, but we're also encouraged by the recent launches. So there's a strong launch in bladder where we're already #1. Head and neck is continuing to perform very, very well. We see good traction in MSI high with increased testing. And when you look at the critical program that Roger talked about, I think we will be a leader in many indications as we move forward. And I do think that there becomes a halo impact, as you see the efficacy data across multiple indications where KEYTRUDA really does become foundational in cancer care. We also -- international markets are seeing not only increase in melanoma but lung is now driving significant revenue, particularly in the larger European markets. And I also believe that there would be a halo over time as we continue to get more and more data moving forward. The last thing I'd say is that the key opinion leader and the physician feedback on 189 coming out of the meeting is just remarkable. And we're hearing it in all markets around the world, we're hearing it in community-based physicians as well as in the key opinion leader landscape. And I do think that there is a very positive mindset coming out the AACR meeting.

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

Right. And Vamil, with respect to other, I think what you meant is immunological mechanisms for combinations. First of all, I think we should say that with respect to IDO1, the thing that was most attractive about it was its safety and tolerability profile. And in the single-arm studies, it looked as if responses were broader and deeper. With that favorable tolerability profile, there was reason to want to advance it. Sure, we would -- we'd love to see combinations with agents that have profound single-agent efficacy. There are some that one can employ in that regard. I think that we do need to look much more carefully at the data from the epacadostat study and understand in more detail exactly what we're seeing there. We

have, as has been announced by our colleagues at Incyte, scaled-back the epacadostat combination program but are continuing some Phase II studies now in lung cancer. And we'll look at these data from an immunologic perspective and try and understand exactly what happened there. There are many other programs involving, for example, toll-like receptor agonists, our STING program, our RIG-I program, oncolytic viruses. Some of those, for example, in the combination with TVEC, have already demonstrated combined responses. So there's reason for optimism that we will find the right combinations, but it's clearly going to require quite a lot of clinical experimentation.

Operator

It's from Tim Anderson with Bernstein.

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

I'd like to press you again on M&A because I'm -- I've kind of been confused what the message is. Merck has talked about not doing transformative deals, which I think really speaks to big pharma tie-ups and how that doesn't create value. At AACR, Roger talked about deals not really -- deals [I guess] not really being revenue based. Yet today, you mentioned your balance sheet is strong, you kind of suggest you're looking at everything. You claim that asset prices are high. I don't think that's really true when you look at big biopharma names. And so my question is this: can you really rule out that it's not realistic that Merck is looking at a big biopharma name? It would be great if you could just narrow down what it is you're willing to consider versus not. I understand nothing transformative, but that still leaves open a very broad bandwidth of target companies potentially. Second question is on KEYNOTE-042. I know results haven't been released. Can you say, at least directionally, whether you saw a meaningful benefit on efficacy in low expressers, such as the 1% to 20% segment? I think that was one of your cutoffs. Or could the benefit in the ITT group really have been driven by primarily the high expressers?

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

Okay, thanks, Tim. Let me just start by saying what I said earlier, which is that when we look at the possibilities, we try not to restrict our scope in terms of what we look at. What I've said before, and I will say again, is that a large, what some people would call transformational, deal is not our preference. It is not consistent with our strategy. What we are trying to do is to enhance our pipeline with those kinds of deals, collaborations, acquisitions, whatever they may be, that actually enhances the pipeline long term. I also would say that we are not looking to do deals solely for revenue. At the same time, if we are able to do deals that enhance our pipeline -- and again, we're looking at all kinds of deals in terms of size and scope, if we're able to enhance our pipeline and at the same time increase revenue, that would be something that we would be very interested in doing. And indeed, I think that characterizes the Eisai and the AstraZeneca deals because in both those cases, we have immediate revenues as well as access to what we think are good scientific opportunities. So I'll just say again, we continue to look for good opportunities across all acquisitions, partnerships, collaborations and licensing. And on your point about pricing in the marketplace, what I was referring to is, in the past, we have looked at assets that based on the competition got too expensive for our assumptions. I was not making a general comment about the valuations in today's marketplace.

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

Right. And Tim, on KEYNOTE-042, what we announced -- remember, this study was designed to look at a population of cancer patients who had PD-L1 scores at baseline of 1% or greater. For reasons having to do with appropriate statistical analysis, the analysis looked first at the population that had greater than 50% and then stepped down ultimately to the total population. And we announced that it met the endpoint of overall survival in those analyses. Really not going to be able to give you a lot more detail on that study, more color, (inaudible) because we will be presenting that study at ASCO in June, so very soon. And you'll have a chance to see the totality of the data there.

Operator

It's from Steve Scala with Cowen.

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

A couple of questions. First, Ken, you mentioned with more intensity than in the past that Merck revenue prospects are under appreciated. Consensus looks for 3% compound revenue growth through 2022. Are you saying that revenue growth will be more like mid-single-digit, if not higher, through 2022 and beyond? I mean, if that's the case, then you probably don't need to do M&A. And then one for Adam on GARDASIL. Can you give us a sense of GARDASIL's potential in China? For instance, can China double the current GARDASIL sales base from $2.5 billion to $5 billion alone?

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

Okay, Steve. With respect to your first question, I'm not going to be specific about numbers and I'm not giving long-term guidance. What I can say is that we look at our portfolio. We look at the growth that's possible, for example, in oncology and we're very confident about our ability to grow the company in the near to long-term based on our key pillars, as I've said before, oncology, vaccines, animal health and hospital specialty. So we're very confident in our ability to drive that growth, and I can't be more specific in terms of specific guidance.

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

And then -- hi Steve, this is Adam. GARDASIL continues to perform very well in many markets around the world, and we see it as a continuing growth driver for us as we move forward. I mentioned in my script that outside the U.S., we saw significant growth in this quarter and that was partially driven by the performance in China. There's no doubt that China represents a strong opportunity for GARDASIL moving forward. We're just in the initial launches in China. We're off to a very strong start. But we're going to have to really wait to see a period of time to understand if that demand will continue over time. So I believe that represents a very good opportunity for us, but the magnitude of which we're not going to talk about today. We have to give it more time.

Operator

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

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

A couple of questions, please. First, for you Ken and Adam, the FDA and the HSS has made clear that they want to see commercial success for biosimilars. I note on the PBM side, many PBMs, including Express today, have -- voluntarily has opted to adopt pass-through of rebates to patients. The question on the biosimilar side is do you think insurers will voluntarily adopt the biosimilars-first strategy before anything gets mandated by CMS through the legislative or regulatory pathway? And then second, Merck has been a pioneer of tissue-agnostic approvals for the KEYTRUDA in MSI. Given the reimbursement of next-generation sequencing on the Medicare as of the beginning of this year, I'm somewhat surprised Merck isn't exploring a trial of KEYTRUDA in patients with germline DNA damage repair given the (inaudible). Do you have a trial ongoing? Do you have one planned? Given the size of the market, isn't that an obvious area of interest for you?

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

Yes, so hi, Andrew, this is Adam. I'll start with biosimilars and I'll be focused on the U.S. market. I think that there will continue to be a significant potential market for biosimilars in the U.S., and I do think that there's a lot of energy to ensure that cost savings can occur by the appropriate utilization of biosimilars. Whether it's through regulatory environment or payers that are volunteering to try to use biosimilars first, I do believe that there will continue to be an increase in their utilization. At the same time, I think that you'll continue to see price pressure and you'll see the free market work the way in which it's supposed to work. So the parent compounds or the originators might come down in price in order to compete with the biosimilars. And I think at the end of the day, what payers are looking to do is to reduce costs by the appropriate utilization of the biologic products. So I do believe you'll see continued pressure for increased use of biosimilars.

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

And Andrew, it's Roger. We are very interested in the question of what exactly is driving appropriate antitumor responses in KEYTRUDA-treated patients, and have done a lot of work on DNA sequence substitutions as part of that. The story is more complex than, of course, all of us would like it to be. They have a quite large study in press describing the relationships among these things. The answer, of course, is that we believe that DNA damage repair does contribute to responsiveness to KEYTRUDA. And that's one of the reasons, of course, that we've been especially interested in the combination with Lynparza. Our colleagues at AstraZeneca have done quite a lot of work on DNA damage repair, and the combination of the 2 is a likely mechanism for exploiting further the ability of KEYTRUDA to elicit profound antitumor responses and improve overall survival. So we're deeply involved in this. We're looking at it from a number of perspectives. It's a complicated story, and we'll have a lot more to say about it in the next few months.

Operator

It's from the line of Geoff Meacham with Barclays.

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

Adam or Roger, on first-line lung in the U.S., you touched on this, but I want to get a better sense from you as to who the incremental prescriber is or what overall share you think could now be in play based on the full 189 data set. I'm assuming that low expressers could be the biggest opportunity. And then on -- Ken, another strategic question for you. You mentioned Animal Health diversifying the model and concentration risk. Investors have long been worried about the LOE from diabetes. How much of a strategic priority is filling this gap over the long term?

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

Yes, hi, Geoff, this is Adam. As I mentioned before, the key opinion leader and even in the community base there's an excitement on the 189 data is very strong. As I mentioned in the past, I think we did a very good job with penetrating the greater than 50 PD-L1 marketplace previously, and a lot of that was the monotherapy use. Where we weren't as successful, it was in the patients with 1 to 49 or the patients below 1. And what we're hearing is now that we've shown the overall survival data in all of those segments that there will be increased utilization of the combination therapy for those segments. And I think that there's a lot of runway to go into those 2 segments.

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

And Geoff, this is Rob, I'll answer the question about filling the gap related to JANUVIA/JANUMET. As Ken mentioned in his prepared comments, we are feeling very confident in the growth potential we have. And if you look at some of the recent deals we've done, we are focused on filling that gap. and I believe doing deals like the Lenvima deal with Eisai, doing the deal with AstraZeneca for Lynparza as well as you look at assets we have in our pipeline like our (inaudible) V114 assets for pneumococcal pneumonia, all of these are starting to fill that gap. So we are focused on it and we think we're making progress. There's more to do and that's why business development continues to be a focus. But I think if you look at where we are today on revenue going forward, given these new assets and the increasing confidence we have in them, we're making progress. And Animal Health is also an important part of that. It continues to perform extremely well. It is a diversification. I think people don't give credit for the Animal Health business for what it is. It's an annuity stream and it carries a risk profile very different than the pharma business. And as a result, it gives us both diversification and good growth at rates above both Merck and the animal health industry. So in that sense, it also should help to fill that gap. So we're focused on that. We're making progress. More to come.

Operator

It's from Jason Gerberry, Bank of America Merrill Lynch.

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

Just first question, just want a clarification. I thought I heard you say, KEYNOTE-407 would be presented at ASCO but we didn't see them in the titles or (inaudible) top line. So Roger, could you just provide some clarification there? And then on your 15 vaccine that you initiated Phase III studies on, I'm just wondering if you guys can comment a little bit on how you see the product competitively positioned relative to Prevnar? Is it basically roughly about 15% to zero-type coverage with no additional kind of negative trade-offs? Is that sort of the ultimate value proposition if that study's successful?

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

Yes, Jason, it's Roger. 407, it was actually -- the title was in the abstract publication, and it will be presented at ASCO. So those data will -- people will have a chance to see them. It wasn't specifically named, but the title was there with respect to squamous lung cancer. Regarding V114, the serology data which we had a chance to present in Melbourne just recently, are really very, very strong for the (inaudible) vaccine, and it provides the opportunity to both strengthen the response to serotypes covered by other pneumococcal conjugate vaccines but also to add additional serotypes, which will be important in terms of preventing invasive pneumococcal disease. So we see opportunities there in both areas, and we anticipate that assuming that we can get those same kinds of results in the Phase III studies, that it will have a very attractive profile.

Operator

It's from Alex Arfaei with BMO.

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

A few quick ones, if I may. Rob, on your tax rate, we're seeing notably lower tax rate from some of your peers, I'm just wondering if there's a further opportunity for lowering your rate as well. Roger, you're obviously showing a very strong execution, R&D execution with KEYTRUDA, but there seems to be a notable difference in your R&D productivity with KEYTRUDA and the rest of the pipeline. I mean, just wondering if you can comment on that, please, and if there's any additional steps being taken to close that apparent gap? And then finally, Adam, not sure if I missed it, but could you please provide us estimated KEYTRUDA sales by different indications.

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

Yes, this is Rob. I'll answer your question about the tax rate. So if you look at where we are, we are guiding for 19% to 20% for this year. As we indicated on our fourth quarter call, we do expect, as we move into 2019, there is the opportunity for us to see a further reduction in our tax rate of up to 1 percentage point. So you will see our tax rate improve as we move forward from '18 into '19.

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

And Alex, I guess you and I might have to agree to disagree on the issue of the rest of the pipeline. I thought you were going to say our pipeline execution outside KEYTRUDA is even stronger. If you look at things like the registration for PREVYMIS, which is an extraordinary drug in CMV, it is already being adopted as the standard in (inaudible) transplant and (inaudible) organ transplant work is going along -- look at the work that was done in the development of BRIDION, look at the work that's being done on the totality of infectious disease programs. I guess I would say I feel really good about the way in which the clinical development organization is prosecuting these the way in which our regulatory affairs organization is gaining registration for these molecules. And with the balance of new molecules that are coming out of the pipeline, including 20 in the immuno-oncology area alone. So I'm actually feeling pretty good about it, and let's talk.

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

And then with regard to utilization of KEYTRUDA by indication, I'll start with the U.S. Based on the latest data we have, and these are rough estimates, we think about 60% is in lung, 15% in melanoma, about 5% in head and neck, about 5% in bladder and about 15% in other indications. Outside the U.S., metastatic melanoma and lung is where the majority of utilization is, but we're already seeing in some of the large European markets that lung is becoming the largest indication.

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

Okay. So thank you all for participating in today's call. I want to reiterate again that we're starting 2018 with strong momentum. And as I mentioned at the beginning, I am confident about our near- and long-term trajectory. That confidence doesn't provide any basis for us not to continue to look to BD to augment our pipeline, but we are confident in the near- and long-term trajectory of the business. And I thank you for being on the call today, and I hope you have a good day.

Operator

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