Q1 2020 Earnings Call

Company Participants

- Frank Clyburn, Executive Vice President, Chief Commercial Officer
- Kenneth C. Frazier, Chairman of the Board and Chief Executive Officer
- Peter Dannenbaum, Investor Relations
- Robert M. Davis, Executive Vice President, Global Services, and Chief Financial Officer
- Roger M. Perlmutter, Executive Vice President and President, Merck Research Laboratories

Other Participants

- Andrew Baum, Analyst, Citi
- Chris Schott, Analyst, J.P. Morgan
- David Risinger, Analyst, Morgan Stanley
- Louise Chen, Analyst, Cantor Fitzgerald
- Mara Goldstein, Analyst, Mizuho Securities
- Navin Jacob, Analyst, UBS
- Seamus Fernandez, Analyst, Guggenheim
- Steve Scala, Analyst, Cowen and Company
- Terence Flynn, Analyst, Goldman Sachs
- Tim Anderson, Analyst, Wolfe Research

Presentation

Operator

Good morning, my name is Jerome, and I will be your conference operator today. At this time, I would like to welcome everyone to the Merck & Co. First Quarter Sales and Earnings Conference Call. All lines have been placed on mute to prevent any background noise. After the speakers' remarks, there will be a question-and-answer session. (Operator Instructions)

Thank you. I would now like to turn the call over to Peter Dannenbaum, Vice President of Investor Relations. Please go ahead.

Peter Dannenbaum {BIO 20569031 <GO>}

Thank you, Jerome, good morning, welcome to Merck's first quarter 2020 conference call. Today, I'm joined by Ken Frazier, our Chairman and Chief Executive

Officer; Rob Davis, our Chief Financial Officer; Dr. Roger Perlmutter, President of Merck Research Labs; Frank Clyburn, our Chief Commercial Officer; and Mike Nally, our Chief Marketing Officer.

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 is 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 in our press release. We've 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 we make during today's call may be considered forward-looking statements within the meaning of the Safe Harbor provision of the US Private Securities Litigation Reform Act of 1995. Such statements are made based on the current beliefs of Merck's management and are subject to significant risks and uncertainties. If our underlying assumptions prove inaccurate or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Our SEC filings, including Item 1A and the 2019 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. Our SEC filings, today's earnings release and an investor presentation with some highlights of our results are all posted on merck.com.

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

Kenneth C. Frazier {BIO 1391636 <GO>}

Thank you, Peter. Good morning and thank you all for joining today's call. In this challenging and unprecedented time, our first quarter performance reflects strong demand for our portfolio of innovative products, continued commercial and clinical execution and the dedication and resilience of our employees around the world. The fundamentals of our business remain strong. The COVID-19 global pandemic posses extraordinary challenges to all of us including serious threat to the health of people, businesses and economies around the world. Without question our industry and our company have a unique ability and responsibility to help the world respond to this global pandemic by working collaboratively to deliver solutions to coronavirus infection, while also maintaining the supply of medically important product to those who need them.

Amidst this crisis we at Merck are focused on protecting the health and safety of our employees and their families while also ensuring that our essential medicines and vaccines continue to reach the patients we serve. Importantly, the majority of Merck's manufacturing plants and clinical supply sites remain fully operational. We have seen little impact to the production, supply or distribution of our medicines, vaccines and animal health products. In many markets around the world, including the US, while

our offices and laboratories remain open, our colleagues are primarily working from home. And for patients currently enrolled in our clinical trials, we are making every effort to ensure that patients in affected areas are able to continue their treatment and receive appropriate care and monitoring. Conditions are fluid and evolving, but as conditions allow, we are enrolling patients in ongoing studies and we are starting new studies.

Of course, there is great interest in what we're doing to address COVID-19 from a scientific perspective. Roger Perlmutter will speak to the totality of our efforts in more detail, but I will mention that we have deep scientific experience and expertise in both antivirals and vaccines. And our research colleagues are actively engaged in efforts to combat COVID-19. We have teams of scientists researching COVID-19 itself and assessing antiviral and vaccine candidates with their potential to impact the disease. In addition, we've been working extensively with the broader scientific community to assess different assets and have been engaging with a range of research organizations on collaborative effort. We know from our experience with viral epidemics like HIV and Ebola that scientific collaborations are essential to develop medicines and vaccines in a global public health emergency like the one we are facing now. We also know that the path to a new medicine or vaccine is rarely short nor is it easy, but we are optimistic that our industry's efforts will create new tools to combat this coronavirus. And Merck is committed to playing its part in response to this global pandemic for the patients that depend on our medicines and vaccines, the global community and those directly impacted by COVID-19.

The underlying demand for our innovative portfolio of products remain strong and our business remains fundamentally sound. However, the pandemic is impacting patients' ability to access hospitals and physician offices particularly for many of our products, which require physician administration. And social distancing measures are also impacting customer access and demand for our animal health products. Rob and Frank will speak to the near-term impact to our business in a minute, but on a longer-term basis, we remain confident in our outlook for strong growth once people adjust and find ways to address the needs of health and health care beyond COVID-19.

Importantly, our financial strength and strong balance sheet allow us to continue with our capital allocation priorities including investing in R&D and in our growth drivers, investing in manufacturing capacity expansion, paying our dividend and continuing our search for value enhancing business development, which remains a top priority. We also remain fully committed to our spin off transaction and we believe we are on track for completion in the first half of 2021. We completed several important milestones in the quarter including the naming of the new company Organon & Co Inc a name which has strong brand equity and generates trust among healthcare professionals for its dedication and innovation in women's health. We've also named several members of the Organon leadership team. We continue to believe that two more focused companies will allow us to reach more patients, drive stronger growth and unlock longer-term value for shareholders.

To conclude, we recognize now more than ever the importance of our investment in R&D and the value of our science-based approach. We remain dedicated to our mission to save and improve lives through the discovery of innovative new medicines and vaccines to treat and protect patients in the midst of the pandemic, and in the future.

With that, I'll now pass it over to Rob Davis to review the details of our performance and outlook.

Robert M. Davis {BIO 6955931 <GO>}

Thanks, Ken and good morning everyone. As Ken stated while we are operating in a challenging time our first quarter results demonstrate the strong underlying fundamentals of our business as well as successful planning and execution that is allowing us to maintain to continuous supply of our medicines and vaccines to the patients we serve. We remain confident in our long-term growth prospects, driven by the strong underlying demand for our products. So we are now seeing the COVID-19 will impact our near term results due mostly to patient access challenges. In this environment, our strong financial position and conservatively positioned balance sheet is allowing us to maintain strong liquidity and very healthy access to the capital markets and our capital allocation priorities remain largely uninterrupted.

Now turning to our first quarter results. Total company revenues were $12.1 billion, an increase of 11% year-over-year or 13% excluding the negative impact from foreign currency. Both our human health and animal health businesses contributed to the growth this quarter. COVID-19 had an immaterial impact on our business in the first quarter with both pushes and pulls across our divisions and regions. The remainder of my comments pertaining to sales will be on an ex-exchange basis. Our human health revenues grew 12% led by key products in our oncology, vaccines and hospital businesses. In oncology, KEYTRUDA sales increased 46% year-over-year, reaching $3.3 billion. In the United States growth was driven by all key tumor types and we continue to strengthen our overall leadership position in the IO market including across indications for lung, bladder and head and neck cancers. Our launches in renal cell carcinoma and endometrial and first-line head and neck cancers continue to fuel momentum and we are excited about the prospects for our application for a 6-week dosing regimen across all indications, which is currently under review by the FDA.

Outside the United States, lung cancer indications continue to drive KEYTRUDA growth. In the EU growth continues to be driven by the uptake of KEYNOTE-189 with secured reimbursement across all major markets and we are encouraged by early uptake in the adjuvant melanoma head and neck and renal cell carcinoma launches. In Japan KEYTRUDA showed growth driven by new launches and continued strength in lung despite the implementation of the huge seller price adjustment in February. Our oncology portfolio continues to benefit from both our products in Lynparza and Lenvima, with Lenvima continuing to lead the PARP class in the United States with over 60% share. While Lenvima maintains market leadership in first-line hepatocellular carcinoma, and benefits from the launch in combination with KEYTRUDA and endometrial carcinoma.

Turning now to vaccines. GARDASIL growth reflects continued positive underlying demand globally as well as the timing of shipments in China, which contributed roughly $120 million in growth to the quarter and the timing of public sector purchases in the US, which benefited revenue by approximately $70 million. PNEUMOVAX also contributed to growth this quarter, in part due to increased demand related to heightened interest in pneumococcal vaccination given the COVID-19 pandemic in the United States and Europe. Our hospital business benefited from growth in BRIDION reflecting strong performance across all major regions and in PREVYMIS reflecting demand and the benefit of launches globally. Animal health revenue increased 21% this quarter to $1.2 billion. Livestock grew 24% largely due to the contribution of the Antelliq acquisition and COVID-19 related buy-in. Companion animal grew 17% driven by demand for BRAVECTO as well as the COVID-19 related buy-in.

Turning to the rest of our P&L, my comments will be on a non-GAAP basis. Gross margin was 75.5% in the quarter, a decrease of 40 basis points year-over-year. Operating expenses of $4.4 billion were roughly flat year-over-year. SG&A spend decreased 7% driven by lower promotion and selling costs, due in part to COVID-19 while R&D spend increased 10% reflecting higher clinical development and research costs as well as higher licensing costs. In total, our operating expenses were favorably impacted by $100 million in reduced spending due to COVID-19 largely driven by lower promotional and selling costs and delayed spending on our clinical trials. The year-over-year increase in other expense was driven by higher net interest expense due to reduced cash balances, partially offset by net gains on our security holdings predominantly reflecting our investment in Moderna. Our effective tax rate for the quarter was 17%. Taken together, we earned $1.50 per share, an increase of 26% excluding exchange.

In summary, the underlying demand for our products in the first quarter even after adjusting for timing in COVID-19 impacts, delivered very strong growth and demonstrates the continued underlying strength and operational momentum in our business. As we move through the year and eventually put the impact of COVID-19 behind us, this demand will be the foundation upon which we expect to deliver strong and sustained growth into the future.

Now turning to our outlook for the remainder of the year. As we head into the second quarter, we are seeing decreased patient visits due to reduced access to hospitals and other healthcare providers as well as social distancing recommendations. I'd like to pass the call to Frank to provide additional color on the dynamics we are seeing.

Frank Clyburn {BIO 20654315 <GO>}

Thanks, Rob and good morning everyone. As you've heard from Ken and Rob, the impact to our business from the ongoing pandemic is largely driven by a reduction in healthcare provider and patient interactions as hospitals redirect resources toward COVID-19 and patients avoid healthcare facility visits and postpone preventive care. To better understand the impact to Merck, it is important to highlight that our portfolio is heavily weighted towards products administered by a physician. In fact,

roughly two-thirds of our global human health revenue is comprised of physician administered products.

Taking this a level deeper, we've seen updated guidelines and recommendations from the CDC and various professional associations further enforce social distancing measures via delays in wellness visits and the postponement of treatment. For example, based on recommendations from the American Academy of Pediatrics and CDC most pediatricians have pushed out the routine immunization of all children except for those under 24 months in the United States. And in the United States physician office visits across various areas of medicine are currently running down in the neighborhood of 70% versus pre-COVID-19 levels. As a result of these measures, we are seeing impacts to our vaccine portfolio including the GARDASIL, PNEUMOVAX and our pediatric vaccines and to our women's health products in both our fertility medicines as well as IMPLANON/NEXPLANON of physician administered implantable.

Non-urgent elective procedures have also been postponed or canceled in most major markets in order to slow the spread of disease and enable hospital prioritization of COVID-19 patients. Many sources are reporting current declines in elective procedures of over 70% with urgent procedure volumes also being affected though to a much lesser degree. These declines impact the product like BRIDION, which is used across many surgery settings. And even oncologists are delaying appointments and procedures as they prioritize patients based on severity and the immediate needs of different tumor types, resulting in extended dosing schedules for existing patients as well as delays in the start of therapy for newly diagnosed patients.

As Rob will outline in a minute, however based on our overall assumption with respect to the timeline for a return to a more normal environment as well as our experience in China, a market which was impacted earlier by the pandemic, but which is now recovering, we expect to be most heavily impacted in the second quarter. Most importantly, we believe the underlying demand for our portfolio of products remained strong based on the substantial medical benefits they bring to patients. As the peak of the pandemic passes, we believe providers and patients will move quickly to find ways to safely provide and seek treatment. And as a more normal environment for patient access is reestablished, we believe our portfolio will again be well-positioned to achieve strong long-term growth.

With that, I will turn it back to Rob.

Robert M. Davis {BIO 6955931 <GO>}

Thanks, Ken. Now turning to guidance. We expect decreased volumes due to the reduced access and social distancing impacts that Frank described, particularly in the second quarter, which we assume is the peak of the virus in the United States and Europe. We expect to begin to see this dynamic subside as hospitals begin to normalize through the third quarter, and as social distancing measures begin to lift across geographies, at which point we would expect a phased return to more normal

levels of volumes unencumbered by access concerns. While we do expect to progress to normal, pre COVID-19 volumes by the beginning of the fourth quarter, a large portion of the impact from Q2 will carry to the full year.

In animal health, we expect to experience a more protracted recovery timeline given decreased demand for milk and protein due to the shutdown of restaurants and schools, reduced visits to veterinarians and the impact of reduced employment and incomes. Of course our actual results could vary based on how the disease progresses and how various countries respond. We now expect revenues of $46.1 billion to $48.1 billion, which reflects a decrease of $2.5 billion from our previous midpoint. This difference is comprised of approximately $2.1 billion of negative impact due to COVID-19 on an ex-exchange basis, made up of approximately $1.7 billion from human health and $400 million in animal health. We also now assume a negative impact from foreign exchange of roughly $750 million or 2.5 percentage points using mid-April rates. Finally human health operational strength of roughly $300 million partially offsets the negative COVID-19 and foreign exchange impacts.

We now expect gross margin to be roughly 75%. Operating expenses are expected to decline at a low single digit rate, driven by lower SG&A. Our updated assumption anticipates lower promotion in selling expenses and clinical trial costs. We now expect our full year tax rate to be in the range of 17% to 18%. We continue to expect other expense of roughly $200 million. We continue to anticipate 2.54 billion shares outstanding. Given the current environment and at an abundance of caution, we have temporarily paused our share repurchase activity which will help ensure that we preserve our strong financial position to pursue our capital allocation priorities of investment in the business and ongoing business development. Taken together, we now expect our non-GAAP EPS to be between $5.17 to $5.37, which reflects a decrease of $0.43 from our previous midpoint. This range includes a roughly 3.5 percentage point negative impact from foreign currency equating to an approximately $0.11 FX headwind versus our prior assumptions.

Importantly, the company's financial strength and conservatively positioned balance sheet is allowing us to execute our capital allocation priorities, which remain unchanged despite the currently challenging environment. As of the end of the quarter, we held $8 billion in cash and (Technical Difficulty) securities and retain good access to the commercial paper markets. In addition, our cash collections continue as expected with no significant disruption from the COVID-19 pandemic impact to-date. As a reminder, our first priority is to invest in our existing R&D programs as well as to support new programs aimed at COVID-19. This pandemic underscores our commitment to R&D now more than ever. We will continue to invest in manufacturing capacity expansion and we remain firmly committed to the payment of our dividend.

In addition as Ken noted, business development remains a priority and we will continue to look for the best external sources of science to augment our pipeline. We will assess the environment on an ongoing basis and consider reactivating the repurchase programs as warranted. In summary, our first quarter results demonstrate the strong demand we see for our innovative portfolio and the underlying

fundamental strength in our business. While the pandemic will impact us in the short term, we are well-positioned financially to weather the storm and continue the investments we are making across our business to drive growth and importantly to bring additional innovations to the patients we serve. We also remain confident in the underlying demand for products based on their competitive positioning and the benefit that they provide and fully expect to see our growth return once patient access normalizes. As a result, our expectations are unchanged regarding our ability to deliver sustainable long-term growth. We believe all of this continues to be a source of significant and sustainable long-term value for both our patients and our shareholders.

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

Roger M. Perlmutter {BIO 3077183 <GO>}

Thanks, Rob. I will divide my commentary on our first quarter results into three parts. First, I will describe the current operational status of Merck Research Laboratories focusing in particular on clinical research and on our interactions with regulatory agencies. Second, I will highlight some of the important results that we achieved during the first quarter and will outline some of what we hope to achieve as the year progresses. Finally, I will comment specifically on the actions that we hope and what we have taken to address the COVID-19 pandemic.

So let me begin with our operational status. At an early point our global clinical operations team recognize the importance of the SARS-CoV-2 infections that were reported in Wuhan, China and made advanced preparations to manage what became the COVID-19 pandemic. These preparations included pre-positioning clinical supplies, strengthening our clinical supplies network, putting in place processes to enable virtual monitoring and over time developing processes for home deliveries investigational agents, including in some cases developing alternative infusion sites.

Operating virtually the clinical operations team including data management and our quality organization has been able to maintain our overall clinical trial schedule. We have in some cases reduced enrollment in certain jurisdictions, but we have not halted enrollment and are continuing to launch new clinical trials across most jurisdictions. As examples our team processed 36 database logs in the month of March and enrolled more than 700 new patients across our Europe, Middle East Africa sites. These numbers provide substantial reassurance that our clinical programs are moving forward, indeed although I cannot predict what the course of the pandemic will be in the future, for now our 2020 MRL objectives are not in jeopardy. This progress is owed entirely to the extraordinary work of teams across our organization spanning five continents and a very broad set of government regulatory agencies with whom we interact.

Turning now to important research accomplishments, as noted previously, the first quarter began with FDA approval of KEYTRUDA as monotherapy for the treatment of certain patients with high risk non-muscle invasive bladder cancer, our 23rd

KEYTRUDA indication. And we continued to generate important data related to the ability of KEYTRUDA to improve cancer therapy. An interim analysis of the pivotal Phase 3 KEYNOTE-355 study demonstrated that KEYTRUDA in combination with standard chemotherapy improved progression-free survival versus chemotherapy alone in the first-line treatment of patients with metastatic triple-negative breast cancer whose tumors expressed PD-L1 with a combined proportion score greater than or equal to 10. This results complements the data from our KEYNOTE-522 study in which a combination of KEYTRUDA plus chemotherapy provided as neoadjuvant treatment versus chemotherapy alone improved the pathologic complete response rate in patients undergoing surgery for triple-negative breast cancer. We expect to describe these results in detail at an upcoming medical meeting.

We also announced the results of our KEYNOTE-204 study, which demonstrated that KEYTRUDA monotherapy improved progression-free survival in adult patients with relapsed or refractory classical Hodgkin lymphoma as compared with brentuximab vedotin. These data strongly support our current indication in classical Hodgkin lymphoma and the study will continue to permit evaluation of the dual primary overall survival endpoint. Also during the quarter, we announced the results of our KEYNOTE-177 trial, a Phase 3 study in which monotherapy with KEYTRUDA improved progression-free survival as compared with standard chemotherapy in the first-line treatment of patients with unresectable or metastatic colorectal cancer whose tumors had demonstrated deficiency in mismatch DNA repair or evidence of DNA microsatellite instability, the so-called MSI-high phenotype. The study will continue as is customary to permit evaluation of an overall survival endpoint once the data are mature.

Most will recall that in 2017 we gained the very first approval of a tumor agnostic PD-1 directed therapy indication with the identification completed in collaboration with colleagues at Johns Hopkins University of MSI-high status as a biomarker for tumor responsiveness. At the end of the first quarter, we also received priority review from the FDA for what we regard as a second potential tumor agnostic indication. The use of KEYTRUDA in certain patients whose tumors have a high mutational burden that is greater than equal to 10 mutations per megabase of DNA irrespective of tumor type.

We look forward to presenting all of these data at upcoming scientific meetings and in peer-reviewed journals. As I've indicated, we are also engaged in discussions with regulatory agencies regarding these data. Finally, we announced last week that, based on discussions with the FDA we have responded to their prior complete response letter and have resubmitted our application for approval of the use of KEYTRUDA in a 400 milligram every 6 weeks dosage form across all indications in adults based both upon modeling information and new data that have emerged from our KEYNOTE-555 study, which will be discussed in part of the American Association for Cancer Research meeting later today.

We've also seen important progress in our partnership with AstraZeneca on Lynparza our leading PARP inhibitor. Just last week we announced new results from a key secondary endpoint of our PROfound trial, which showed statistically significant improvement in overall survival in men with metastatic castration-resistant prostate

cancer, whose tumors have mutations in the BRCA1, BRCA2 genes or in the 80-mg [ph], all of which are important for homologous recombination related DNA repair following treatment with Lynparza as compared with abiraterone or enzalutamide therapy. The result provides yet another example of the benefit of Lynparza therapy in patients whose tumors have defined DNA repair mutations.

I'll remind you that we presented primary data from the PROfound study at the European Society for Medical Oncology Meeting in October of 2019. We expect the details of the PROfound study, though not those just announced will be published in the top tier medical journal in the very near future, perhaps this week. I should also note, with respect to Lynparza that our PAOLA-1 study a Phase 3 trial examining the combination of Lynparza plus bevacizumab versus bevacizumab alone in the first-line maintenance treatment of women with advanced overall -- ovarian cancer is under review by the FDA with a PDUFA date in this second quarter. I cannot complete our survey of important results in tumor therapy without mentioning the approval two weeks ago of Koselugo known generically is selumetinib, which is the first selective therapy approved for patients with neurofibromatosis type 1 who are suffering from symptomatic inoperable plexiform neurofibromas. The approval of Koselugo is part of our now long standing collaboration with colleagues at AstraZeneca who first identified this important next signal transduction inhibitor.

Beyond oncology we also advanced important programs in other therapeutic areas. Earlier in the quarter, we had the opportunity to present the results of our Phase 3 VICTORIA study performed in collaboration with colleagues at Bayer, which demonstrated that vericiguat, an investigational soluble guanylate cyclase agonist provided benefit as judged by a composite endpoint including heart failure hospitalization or cardiovascular death as compared with placebo when given as add-on therapy to well-treated patients with established heart failure, with reduced ejection fraction who had suffered a worsening event. This represents the first study of its kind in the population of very high risk for further cardiac complication. The data were published in the New England Journal of Medicine and presented virtually at the American College of Cardiology meetings just last month.

Also during the quarter we announced that in our Phase 3 program gefapixant our investigational P2X3 antagonist reduced the 24-hour call frequency in patients with longstanding chronic cough, details of these results will also be published and presented in the not too distant future. Finally, in the metabolic disease area, we have just announced results for the Phase 3 VERTIS CV cardiovascular outcomes trial. In this study conducted jointly by Merck and Pfizer compared administration of STEGLATRO oral sodium-glucose cotransporter 2 or SGLT2 inhibitor versus placebo in the treatment of patients with type 2 diabetes and established atherosclerotic vascular disease. And achieved its primary endpoint of non-inferiority for major adverse cardiovascular events. These events were defined as time to the first event of CV death, non-fatal myocardial infarction or non-fatal stroke.

The key secondary endpoints of superiority for STEGLATRO versus placebo were time to the composite of CV death or hospitalization for heart failure. CV death alone and the composite of renal death, dialysis transplant or doubling of serum creatinine

from baseline were not met. While not a pre-specified hypothesis for statistical testing, a reduction in hospitalization for heart failure was observed, with STEGLATRO. The safety profile of STEGLATRO was consistent with that reported in previous studies. Detailed results of VERTIS CV are scheduled to be presented on June 16th at the Virtual American Diabetes Association's 80th Scientific Sessions.

I will now describe activities during the past quarter directed at developing treatments that could have an impact on the course of the COVID-19 pandemic. As a leading vaccine manufacturer for more than 100 years, it is no surprise that we have embarked upon a broad-based development program for SARS-CoV-2 vaccine. Let me put these results in the proper context. Vaccine development is extraordinarily difficult and customarily requires many years of investigation. As others have noted during the past quarter century despite enormous effort, there have been only seven vaccines directed against previously unaddressed human pathogen that earned registration. Four of these seven were developed by Merck Research Laboratories. So we have relevant experience in this area.

ERVEBO, our most recent vaccine, which has been demonstrated to provide protection from -- with the Zaire strain of Ebola virus was developed rapidly and under emergency use authorization to help address outbreaks in West Africa. Nevertheless still required a multi-year development program and involved building a factory that we are proud to say can produce one million doses of vaccine per year. The development and registration of ERVEBO required the efforts of hundreds of our employees as well as an extraordinary commitment from the World Health Organization and from health-care workers in Guinea, Sierra Leone, Democratic Republic of the Congo and in many other jurisdictions. With the COVID-19 pandemic however, we are tasked with creating a completely new vaccine in one-tenth the time that we devoted to ERVEBO, and we must plan to manufacture this vaccine at one thousand times the scale.

We approached this challenge with enthusiasm, but also with humility. We know from long experience that creating safe and effective vaccines typically requires decades of effort and investment. We are mindful of the imperative to act with speed, indeed with urgency. Based on the progress that we have made, I will say that I'm optimistic that a vaccine capable of inducing a potent neutralizing immune response to SARS-CoV-2 can be invented, but it is also critical to develop a comprehensive understanding of this particular coronavirus, which will allow us to design, develop, and ultimately to manufacture vaccine that can be deployed globally.

With this in mind, we have first supported efforts to characterize effective immune responses to SARS-CoV-2 infection. As we announced yesterday, we have partnered with scientists at the Institute for Systems Biology, Swedish hospital and the Providence Health System all in Seattle with Stanford University and numerous others to collect cells in sera over multiple time points from patients diagnosed with COVID-19. Data derived from these analysis will be made available to researchers worldwide and will position us to decipher correlates of immunity to this coronavirus.

With respect to the vaccines themselves we've been thoughtful in selecting proven platform that we have used to generate vaccines with desirable qualities in the past.

Of course, in light of my prior comments regarding the difficulty of developing successful vaccine, I cannot guarantee to you that any of these approaches will prove effective in the near term. However, you should have no doubt that scientists in our own laboratories and those of our collaborators are committed to this process. We have also worked to identify internal resources that can support the manufacture of these potential new vaccines at an appropriate scale and we are in discussions with contract manufacturers who could assist in what would surely rank as the most challenging vaccine production initiative ever undertaken. Beyond our search for vaccines, we are also engaged in studying potential antiviral drugs that could be deployed more rapidly. Here too we have evaluated compounds in our own laboratories and have identified programs in other laboratories that could prove beneficial. Time does not permit me to describe these programs in detail. Instead I would like to mention that the global community of biopharmaceutical companies have been very open to collaboration to address this challenge. Within MRL we are trying to help as many of our colleagues as we possibly can both through the active consortium led by the National Institutes of Health and also through interactions with many companies large and small that have contacted us for advice and assistance with their own programs.

I will close by emphasizing that at Merck, our mission is to translate breakthrough research into medicines and vaccines that improve and extend life. This mission has never seemed more vital than it does today. I wish to express my gratitude to all of my colleagues here at Merck who are working tirelessly in pursuit of a means to ameliorate the COVID-19 pandemic. I'll now return the call back to Peter.

Peter Dannenbaum {BIO 20569031 <GO>}

Thank you, Roger. Jerome while you line up the queue, I just want to remind everybody, our upfront comments went a bit longer than normal today, we're prepared to go past 9 o'clock. But we do ask that you limit yourselves to one or two questions, so we can get as many questioners in as possible. So, thank you. Jerome if you could line up the queue please?

Questions And Answers

Operator

(Operator Instructions) Your first question comes from the line of Terence Flynn with Goldman Sachs. You may now ask your question.

Q - Terence Flynn {BIO 15030404 <GO>}

Great, thanks for taking the questions. Maybe two from me, just wondering, I know you commented a little bit on this. But in terms of the environment and your approach to capital allocation, I know you called out no further share repurchases. So can you just give us any more detail, the main driver there is that, you see an

increasing number of M&A, your BD opportunities now in this environment. And the second was just wondering with respect to the pharma guidance, specifically the new guidance, can you give us any more detail on the pacing of the impact, I am assuming the majority of that's going to occur in the second quarter and then can you break that down by product, meaning, how much is KEYTRUDA versus GARDASIL versus other? Thank you.

A - Robert M. Davis {BIO 6955931 <GO>}

All right. Good morning and thanks for the questions. With regard to maybe the second question first, the pharma guidance is the majority of that will hit in the second quarter and the majority of it is in the United States. And maybe I'll turn it over to Frank to give you some of the more specifics on product detail before coming back to the first question.

A - Frank Clyburn {BIO 20654315 <GO>}

Yeah, so in the second quarter, we do anticipate vaccines in particular, it's important to note that we have a very broad vaccine portfolio that ranges from infants all the way to older adults. And we do anticipate that, based on well visits being down approximately 70%, that will impact our vaccine portfolio. Also in the hospital specialty area, BRIDION as I mentioned elective surgeries are down approximately 70%. So we do see an impact there. It's important to note, we're having of significant product IMPLANON/NEXPLANON which requires physician administration. We think there'll be an impact there in the second quarter.

And then as far as oncology goes, overall, we believe that oncology is pretty resilient. We are seeing new patient visits decline by approximately 10% to 20% depending on the indication and we think that will have a slight impact in the quarter from a new patient perspective, but feel very confident as we move into the third and fourth quarter for not only oncology, but for the rest of our portfolio. Rob?

A - Robert M. Davis {BIO 6955931 <GO>}

Thank you, Frank. And then on your question about share repurchase program, just to be clear, and I had it in the prepared remarks, but it's worth reinforcing, we really decided to temporarily stop the share repurchase program predominantly out of an abundance of caution. Our financial position continues to be strong. And as we said, it really was to make sure that we can continue to do all of the investments we want to do in R&D and CapEx to support our future growth and in business development as you asked. So it's really across all those areas that we want to make sure we can prioritize investment and we will continue to look at it and very well could reinstate the share repurchase as we see the situation evolve in the marketplace.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Thank you. Next question.

Operator

Our next question comes from the line of Chris Schott with J.P. Morgan. You may now ask your question.

Q - Chris Schott {BIO 6299911 <GO>}

Great, thanks very much. Just a follow-up on the vaccine commentary. Can you just talk a little bit more about how you see that business normalizing. It sounds like clearly the 2Q trends are going to be depressed, but should we think about a catch-up in 3Q and 4Q as wellness visits return or is it just more like normalized volumes and we shouldn't expect as much of a catch-up I guess specifically on that line.

The second question which is a bigger picture question about, we're clearly seeing high unemployment rates and what it more broadly does that mean for Merck's business. Should we be thinking about lower price and adverse payer mix as representing a headwind to your business as we look beyond some of these near term COVID disruptions or is that a manageable kind of dynamic as we think about the longer-term business? Thank you very much.

A - Frank Clyburn {BIO 20654315 <GO>}

Hi, Chris, it's Frank. Thanks for the question. I'll take your second question first on payer mix and impact and I'll give some color into our mix in the US. It breaks out approximately, Chris, the commercial business represents about a third of our business from a mix perspective. We have about 17% of our mix is important to note is in vaccine private pay, because of the significant size of our vaccine portfolio as we've been discussing. Government represents about half of our overall payer mix, but also important to note, half of that or approximately 26%,27% is KEYTRUDA related because of Medicare Part B.

So we've talked about as KEYTRUDA continues to grow, we anticipate that will grow over time. Medicaid Part or Medicare, I should say Part D is a small percent, approximately 7% and then we have very small percentages of our business in Medicaid. And then the rest is pretty much other with regards to federal and some other parts of our payer mix. But if you look at our portfolio, Medicaid is very small, we're clearly looking at unemployment rates and we'll have to monitor that as it goes forward. I think it's too early to assume anything at this point in time. However, we have taken into our guidance different scenarios as we possibly will see increased unemployment, but for us in particular Medicaid is a small portion of our business.

Shifting to vaccines. Just to give you a little bit more insight, we expect as you come into or towards the end of the second quarter into the third quarter, we expect that the infants and young children who have missed their vaccines during COVID-19 will be prioritized first. We then expect that we'll see the adult pneumococcal vaccines come back strongly as we head into the flu season. And then we expect adolescents and young adults will probably come back a little bit slower, Chris, as patients are able to engage with the healthcare systems.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Right. Next question please.

Operator

Your next question comes from the line of Tim Anderson with Wolfe Research. You may now ask your question.

Q - Tim Anderson {BIO 3271630 <GO>}

Yeah. Thank you. So I'm sure it does not go unnoticed by you, that Merck so far is the only company to lower guidance, but we're may be only halfway through at least our company's reporting and I'm just really trying to tease out, what else beyond product mix could be driving that? Is it you guys run your supply chain narrower or you're less able to kind of manage business from a work from home environment. Could it be that you're possibly more conservative? For example, you're pausing share buybacks and Merck, I think, is in a pretty strong cash position. You have slowed down in brands, but I would think also you have slowed down in spending that you could find as an offset kind of again mirroring what other companies are seeming to be able to pull off in their guidance. So I don't know if there's anything else that you can add beyond what you've said, but it just strikes me as odd.

Second question is on KEYTRUDA and a big investor overhang is TIGIT data from Roche. A good oncology company, it's randomized Phase 2, first-line lung, it's coming up here at ASCO most likely, and we know they're pushing into Phase 3. And so, I'm wondering how is this not going to be a continual worry both for Merck and investors, as part of that if you can just update us on your own TIGIT program, which I know is earlier Thank you.

A - Kenneth C. Frazier {BIO 1391636 <GO>}

I think we'll start with Rob and then turn it over to Roger for TIGIT.

A - Robert M. Davis {BIO 6955931 <GO>}

All right, great. And thanks Tim for your question. So, if you look at why we lowered guidance and understand again the profile of our business and I think it's really important that we just really hit this home. It is the fact that we are seeing reduced access is what's driving the reduction in guidance because of the fact, as Frank said, two-thirds of our products are physician administered and that is, probably somewhat unique and is causing the impact. And as we said, while we expect to get back to normal by the time we get to the fourth quarter, because we're going to see a large impact, mainly in the second quarter, a little bit in the third, that second quarter impact largely carries to the year and is really what's driving it.

The other thing to point out is our human health reduction is only a little over half of what's driving the reduction in our guidance. It's actually, it's almost half of it is coming from foreign currency and the fact that we have the impact in animal health. And if you look at it, the impact in animal health is actually more significant than it is in the human health business. So that is also a little bit of a differentiation relative to some of our peers. And if you look then at, how does that translate down to the bottom line, what you see is, actually for the full year, we're actually bringing down OpEx more than what is the impact of just COVID-19 reductions in spend. Some of

that is also due to the way currency is flowing through our operating expense line, but then there is a little bit of incremental savings we also were assuming.

I would say we didn't go harder at OpEx primarily because we don't see this as a demand-driven issue and we want to be in a position that, as the market normalizes, we can come back fully with our products. So we're expecting to continue to invest in research and development, R&D will continue to grow and we will continue to make selective investments to be prepared to come back strong as we see the market normalize and that's why we have not pulled down OpEx further. But you shouldn't read anything more into this, than the mix of our business and the fact that the access is impacting our ability to deliver what we originally expected for the year. Roger on TIGIT.

A - Roger M. Perlmutter {BIO 3077183 <GO>}

Right. Let me speak more generally to the combinations with KEYTRUDA. And it is the case that really since we began or since I began working with the KEYTRUDA program back in 2013, we have been exploring a whole variety of different combinations with various agents and that's what led us of course to partner with AstraZeneca and Lynparza and partner with Eisai, with Lenvima and has led us to develop a whole set of programs internally that we are using in combination with KEYTRUDA in various clinic clinical studies, including TIGIT and numerous other biologicals that are well advanced in our program.

I've indicated before that we have really quite impressive data in some of these combinations. Most importantly, of course, in our Lenvima combination where we have registration in endometrial cancer and have already presented data for the combination in renal cell carcinoma. But beyond that, with the biologicals as well, we are looking for effects that are really meaningful and that will make a big difference from an efficacy standpoint while preserving the very favorable profile that KEYTRUDA has already demonstrated. So we are making good progress. We're looking forward to developing some of these agents, assuming that these play-out. And of course, we'll be watching what others do, I think we're in a very good place.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Great. Next question please.

Operator

Your next question comes from the line of Mara Goldstein from Mizuho Securities. You may now ask your question.

Q - Mara Goldstein {BIO 2458369 <GO>}

Great, thank you. Just a little bit more on currency if you don't mind. And I'm just curious as you speak to how you've made these adjustments for currency, can you possibly get us some more granularity on what is a contracted issue versus what is actually a country by country swing in currency. And then secondarily, can you just

confirm the timing of the split-off given everything that's going on from a COVID perspective?

A - Robert M. Davis {BIO 6955931 <GO>}

Yeah, good morning, thanks for the question. So on a currency basis, if you look at what is driving the reduction, it is entirely just due to change in where we see rates as of mid-April. So basically we took the mid April exchange rates and assumed those held for the full year. And as of the result of the fact that what you've seen is that, really versus almost every currency the dollar has strengthened as there has been a flight back to the dollar as soon as a quality currency and as a defensive measure, that is impacting us. It's hitting us across all of our currencies, but importantly what's happening as well and we're not able to hedge as much as we normally would is because we are also seeing a material impact in the emerging market currencies as well where we don't hedge today. So it's really that is what's driving entirely the $750 million reduction that we talked about in our guidance.

And then on your second question on the timing of the spin-out, as Ken noted in his prepared remarks, we continue to expect to have the spin-out completed in the first half of 2021, that is consistent with where we guided last quarter.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Great. Next question please.

Operator

Your next question comes from the line of Navin Jacob with UBS. You may now ask your question.

Q - Navin Jacob {BIO 20931208 <GO>}

Hi, thanks. Thanks for taking my question. Navin from UBS. Roger, a question for you on your COVID-19 vaccine program. It's just -- it was interesting that you mentioned or highlighted that you have chosen to go with proven platforms. Wondering your thoughts on some of the more novel platforms such as mRNA, why perhaps you may not be looking at some of those more novel platforms. Sort of associated with that also would love your thoughts on neutralizing antibodies as a method for either treatment or prophylactic treatment. And then separate to that, but along the same lines, wondering how you're thinking about whether mutations around the spike protein could create selective pressure and how you think about items such as that or whether it's antibody dependent enhancement that may be putting some -- maybe affecting how you're thinking about proven platforms versus more novel platforms. Thank you very much.

A - Roger M. Perlmutter {BIO 3077183 <GO>}

Right. Well, thanks very much for the question. So first of all, we are interested in any and all approaches that could be helpful in reducing the impact of the COVID-19 pandemic. And we've been in discussion with most all of the organizations that are trying to do this in various different ways, whether that's using passive immunization

with antibodies or trying to use alternative methods of active immunization that can more rapidly be brought into the clinic like nucleic acids, mRNA in particular. And of course we have a long history of collaboration with people who have done that kind of work.

Our sense though is that, the task before us is one that requires a vaccine that will be quite stimulatory and that will yield neutralizing antibodies ideally with a single immunization. Of course, it must first be safe because you're talking about a vaccine that would in principle be given to much of the world's population in order to protect the world's population. And since we believe that virtually everyone is susceptible, these are all high bars and that makes us want to return to proven platforms that have these kinds of characteristics and that's where we have put our focus. My expectation is that over time, we will need more than one vaccine in order to actually protect the human population from SARS-CoV-2. So that's sort of thing that we've looked at.

Specifically with respect to the neutralizing antibodies being administered as passive vaccination, we've looked at a number of those, in the near term that may turn out to be a useful approach for individuals who perhaps in the treatment context and also for individuals who are at extraordinarily high risk and have a great susceptibility because of age and comorbidities, but as a broadly based method to protect the human population, I think probably less likely to be used just for logistical reasons. That doesn't mean that we wouldn't be willing to work with others to help develop that if that prove to be the near term, the most important thing that I could do. And finally, I would say that, just to put the cart back behind the horse, I mean, the issue of selective pressure on mutation, we should recognize that while right now we're not seeing an enormous amount of variation in the SARS-CoV-2 virus, when we put selective pressure on the virus either with an anti-viral drug and some of those do indeed look fairly promising early on, or with a vaccine, it is possible that we will see variance emerge and those variance could prove to be important. And that's something else that we're paying quite a bit of attention to.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Thank you. Next question please.

Operator

Your next question comes from the line of David Risinger with Morgan Stanley. You may now ask your question.

Q - David Risinger {BIO 1504228 <GO>}

Yes, thanks very much. I have two questions for Roger please. To follow on to your remarks regarding COVID, could you please comment on the potential to one, inject disinfectants and two, to use UV rays inside the body to cure COVID. No, I'm just kidding, I'm sorry. So on a more serious note, could you discuss Merck's novel IO agent readouts to watch in 2020. And second, could you discuss your conviction in the profile of Merck's 15-valent pneumococcal conjugate vaccine and your disclosure and adult filing plans. Thank you.

A - Roger M. Perlmutter {BIO 3077183 <GO>}

Yeah, David, so with respect to novel immuno-oncology agents, I mean, I've mentioned some of this before in response to a prior question, but we have a stable of them, we are of course looking at our own CTLA-4 molecule have been for some time in combination with KEYTRUDA. We are also looking at LAG-3 TIGIT and a whole variety of others we have 20 or so agents that we have tested in the clinic and all of these are being tested, first is monotherapy. And thereafter as combination with KEYTRUDA, but I should emphasize that KEYTRUDA really is quite special, we've not seen anything of course that has characteristics that are like KEYTRUDA, if we did, that would be a very different story.

And, you know, it's no surprise because we, and many other investigators, university-based investigators myself included looked for these kinds of things for decades and never found anything that looked like KEYTRUDA, it's unlikely we're just going to kick one over now when we didn't have those in the past. That doesn't mean though that those things in combination with KEYTRUDA couldn't be beneficial and we're seeing some early signs that suggest that's possible and we'll have quite a lot more to say about that during the coming year.

And the second question had to do with our conviction with respect to our 15-valent molecule V114 for invasive pneumococcal disease. We have a lot of conviction behind it. I think we've already reported our Phase II data that everyone has had a chance to see, the Phase 3 data will be available to us very, very soon. And as soon as those data become available, assuming the data Phase 3 recapitulate what we saw in Phase 2, which is certainly our hope and expectation those, the top line of those data will be announced of course and we at that point provide more clarity with respect to our filing plans, but our expectation would be that, filing could occur not long thereafter. So we're really very enthusiastic about this vaccine because of the important new serotypes in it. And also the balance with respect to the immune response that we saw in our V114 studies in Phase 2.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Thank you. Next question please.

Operator

Your next question comes from the line of Steve Scala with Cowen. You may now ask your question.

Q - Steve Scala {BIO 1505201 <GO>}

Thank you. I have two questions. As has been stated clearly, Q1 beat, but full-year guidance was lowered. We are now about a third of the way through Q2, in the month of April, which could be the peak of the pandemic, you must be seeing a major impact on oncology vaccines, hospital and animal health. Is that a reasonable conjecture? And secondly, Roger, many investors were underwhelmed by the data on vericiguat and gefapixant, what in your view are investors missing? Thank you.

A - Kenneth C. Frazier {BIO 1391636 <GO>}

Great. Start with Frank.

A - Frank Clyburn {BIO 20654315 <GO>}

Steve, I'll start. So to answer your question, yes, Steve, as I mentioned in my prepared remarks, with regards to vaccines, we are seeing an impact due to the reduction in patients in well visits, we are seeing a reduction in our hospital specialty area, in particular BRIDION with the reduction in elective surgeries, as well as women's health. So we are seeing that in Q2, which is why we've updated our guidance. And we also want to reiterate though, we do see as we are seeing in China, as we get through this period, we believe things will come back gradually in Q3. And then as we get into Q4, we'll return to normal operations. And I just want to continue to echo that, we're very confident in the overall portfolio and in the demand trends that we see.

A - Robert M. Davis {BIO 6955931 <GO>}

I would just add on the animal health front. It's a similar situation to human health, we are seeing the impact now in the quarter and we do expect that the second quarter will be the vast majority of the impact driving what is the full-year reduction. So it definitely will be most acute in the second quarter, but it will continue a little bit into the third and fourth and be a little bit more prolongated than what we expect from the human health business driving a larger downside impact to our animal health business than it's having to our human health business.

A - Kenneth C. Frazier {BIO 1391636 <GO>}

Great. Roger?

A - Roger M. Perlmutter {BIO 3077183 <GO>}

Yeah, Steve. Thanks for the question. So first of all on, vericiguat, and the VICTORIA study. So the VICTORIA study address the patient population that typically is excluded from most studies, and these are patients who have had a recent decompensation in their status. These are patients with reduced ejection fraction, heart failure, who have typically undergone heart failure hospitalization as a result of some deterioration. And hence, this is a very brittle population, if you looked at the data that were published, but what you saw with it was that these patients were really quite ill and had indices of heart failure of heart stress that were much, much higher than what is typically found in a heart failure population.

So the reason why the paper was published in the New England Journal of Medicine, the reason why it was -- there was a plenary presentation at the American College of Cardiology and these results is precisely because this is a very different population, the therapy is given as add on to existing heart failure therapies and improves outcomes. And so, that's a pretty important result and I think there is a lot of enthusiasm for it within the cardiovascular community amongst those physicians who treat heart failure. So I think that's really important to recognize. This is really

quite a change in terms of how we think about these patients and it's an important patient population to treat.

And then with respect to the gefapixant, well of course, we haven't presented the gefapixant data, we'll have a chance to do that. I think everyone should recognize two things. The first is that, chronic cough is an extremely common complaint in the general population. So physicians are often called upon to try and help people who are interrupted by chronic cough and in our Phase 3 study, we had some individuals who had chronic cough complaints, continuous chronic cough complaints for more -- for decades. So this is a pretty significant interruption in their lives. On the other hand, I don't want to dismiss the difficulty of going into a completely new area, because there are no, there hasn't been no drug registered for chronic coughs, there's been no study of this kind previously. It's a completely novel area. It will take some time for this to develop and for people to understand it.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Great. Next question please.

Operator

Your next question comes from the line of Louise Chen with Cantor. You may now ask your question.

Q - Louise Chen {BIO 6990156 <GO>}

Hi, thanks for taking my questions. So my first question is on the TMB high opportunity here, what is that for Merck and is there any off-label usage of KEYTRUDA in that population already. And if so, how much? And then second question is, if you could provide more color on your Taiho Astex KRAS opportunity and when we can start to see data from that pipeline asset? Thank you.

A - Kenneth C. Frazier {BIO 1391636 <GO>}

First question on TMB high, Roger, would you like to speak to TMB high, please and also the second question.

A - Roger M. Perlmutter {BIO 3077183 <GO>}

Right, okay. For TMB high, so this -- the basis for seeking registration is a study done in a variety of different tumor types, the KEYNOTE-158 study, in which their responses at the moment are currently inadequate. And so, the goal was to look and see, well, was there anything that we could do in these tumor types in which we could demonstrate that KEYTRUDA had an effect in certain patients. And we looked at a variety of different markers so that we could use. It turned out for us that a tumor mutational burden marker greater than 10 mutations per mega base was associated with an improved overall response in certain of these tumors. And that's what we've sought registration for and we are in the midst of having those discussions with the agency. So we'll see what happens. I frankly I am not aware of off-label use and we wouldn't necessarily know anything about that in that population.

And with regard to our KRAS program, it's actually quite a broad program, looking at both GDP and GTP bound forms of KRAS and looking at the mutations beyond the cysteine mutation codon 12 mutation, (inaudible) mutation, which occurs in a fraction of patients, but there of course are many other mutations aspartic acid substitution, vailing substitution et cetera. So we're looking quite broadly, but it will be a while before we have the opportunity to bring the first of those compounds into the clinic.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Great, thank you. We have a number of questioners still in the queue. We're going to stop at 9.15, but we're going to keep going for now. Next question please.

Operator

Your next question comes from the line of Andrew Baum with Citi. You may now ask your question.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Andrew, are you there?

Q - Andrew Baum {BIO 1540495 <GO>}

Yes, I'm here, can you hear me?

A - Peter Dannenbaum {BIO 20569031 <GO>}

Yes.

Q - Andrew Baum {BIO 1540495 <GO>}

Terrific. So question for Roger on TIGIT. You're clearly seeing efficacy signals from your trial activity, as Genentech has noted, is seeing strong efficacy signals in a PD-L1 high. So is the central reason before accelerating any Phase 3 program, whether TIGIT is additive or synergistic to chemo in patients with low PD-L1 expressing tumors or is there some other hurdle, which is holding you back. And on the same note, how do you view the commercial risk reward of taking your further time optimizing the patient population at the expense of potentially disadvantaging yourself by giving Roche more lead time should that Phase 3 program in first-line non-small cell lung in combination with chemo pans out, that's the first question.

And then second question very quickly to Frank, you have discussed the fairly obvious impact of delayed presentation to health care providers for third-party administered pharmaceutical, could you talk to how you think about in the US, the commercial impact associated with rising un-insurance rates associated with unemployment. I realize that you have far less exposure than some of your peers, but I'm interested in your thoughts generally, but obviously it does relate to things such as Diovan as well which tells you have commercial exposure. Thank you.

A - Kenneth C. Frazier {BIO 1391636 <GO>}

Great. Roger, first on TIGIT and then we'll turn it to Frank.

A - Roger M. Perlmutter {BIO 3077183 <GO>}

Well, Andrew. Thank you. Thanks for the question. Again on TIGIT, different companies will have different perspectives on this. Our view really is quite simple and it's not -- I wouldn't over-think this, what we want to see is sufficient evidence of benefit in combination which is -- where you can unambiguously say that, both elements, that is KEYTRUDA in our case and the anti-TIGIT antibody both elements and that same is true from LAG-3 or CTLA 4 any others are at each contributing and so that there is at least additive effect and ideally better than that if one could get it. And so, we want to be absolutely sure of that and we want to be absolutely sure that we're addressing the right patient populations. And of course we want to be sure that there is no deterioration in the favorable adverse experience profile of KEYTRUDA. So it's just a matter of reaching a conclusion about that, we could eventually reach the conclusion that, no, we don't actually think it's good enough. And there could be a whole variety of reasons for that or we could reach the conclusion,yeah, we think this is really important, let's move forward. There are a number of programs in which we are sort of looking at that and we find some data that's intriguing, but we just don't have enough data yet to make us feel comfortable about it. Other people might look at that data and say, we need to go immediately, we are doing what we think is the right thing in that regard.

A - Kenneth C. Frazier {BIO 1391636 <GO>}

Great. Frank?

A - Frank Clyburn {BIO 20654315 <GO>}

And Andrew, I think we're all concerned obviously of what we're seeing in the US with regards to rising unemployment. As I mentioned earlier, for us, we'll have to see the shift potentially (Technical Difficulty) over to higher discounted segments like Medicaid, but just (Technical Difficulty) portion of our business currently and as we look going forward our business in payer mix is more geared towards Medicare and in particular Part B Medicare.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Great. Next question please.

Operator

Your next question comes from the line of Seamus Fernandez with Guggenheim. You may now ask your question.

Q - Seamus Fernandez {BIO 7525186 <GO>}

Great, thanks so much for the question. So just a couple here. Could you guys comment -- I know we've commented on the Medicaid side of things, but 340B expansion could be a meaningful threat to the industry overall. Just trying to get a better understanding of what Merck's 340B exposure is currently, since that's the

hospital-based program that then could shift to Medicare based pricing. So just love to get a better understanding of your thoughts there on exposure.

And then for Roger, can you just help us understand what's unique or special about Lenvima that has Merck pursuing such a broad effort where others with similar type TKIs, now certainly not and I think this is where I'd love for you to comment on the differentiation have not pursued that. And I think this is particularly interesting in the context of the relatively limited patent life for Lenvima. Thanks so much.

A - Kenneth C. Frazier {BIO 1391636 <GO>}

Frank, then Roger.

A - Frank Clyburn {BIO 20654315 <GO>}

Yeah, Seamus. So, just, if you look at 340B the majority of the exposure really is for products like JANUVIA and also KEYTRUDA. For KEYTRUDA, approximately a third is within 340B segment today, it has been growing slightly year-on-year and we'll have to see how as I mentioned, things continue to unfold with regards to what's happening in the environment and it's obviously something that we're closely monitoring.

A - Kenneth C. Frazier {BIO 1391636 <GO>}

Great. Roger on Lenvima.

A - Roger M. Perlmutter {BIO 3077183 <GO>}

Right. So Seamus that the -- we're quite data driven on this. We were enthusiastic about Lenvima initially from the monotherapy data that our colleagues at Eisai had obtained and we thought there was a chance that that could prove to be a good combination with KEYTRUDA we had -- we did some experiments like that with them and then we signed our agreement with them. And when we signed our agreement, we thought, let's do a signal detection study, looking across a broad set of tumors, and as we've done that, we've seen a lot of really quite interesting signals, those of course weren't the only combinations with multi-kinase inhibitors that we tried, but we've seen impressive signals in combination with KEYTRUDA. And as you know every multi-kinase inhibitor is different, each one hits a different range of molecules and their effects are different.

So that's quite hard to describe why that's true and whether that reflects VEGF receptor antagonism in the context of FGF receptor or whatever, but what you can say is that they are all different. And the results that we've obtained with Lenvima have been very promising. So we're quite enthusiastic obviously first of all in endometrial, in other tumors, the data we presented for renal and there are many others besides. So we're moving forward with that program.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Great, thank you all for your questions and apologies to those we didn't get to. I'm going to turn it over to Ken for closing remarks.

A - Kenneth C. Frazier {BIO 1391636 <GO>}

All right, thank you everyone for joining us today. Our mission is save and improve lives. We'll continue to drive the company in the coming days and months in the midst of the coronavirus pandemic. Merck is committed to doing everything in its power to ensure our medicines and vaccines reach patients around the world and we expect to contribute to the global pandemic response efforts today and also to prepare for the next potential crisis.

The underlying demand for our product remained strong and our fundamentals remained very sound. In the near term, I reiterate our portfolio is different. And as a result, our near-term guidance takes into consideration, what's really happening in the outside world in an attempt to be realistic about physicians and their ability to access patients. But in the final analysis we believe that our underlying business fundamentals are very sound going forward and we look forward to providing update on the business as we continue to navigate through these challenging times. And until then, we hope that you and your families all stay safe and healthy. Thank you.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Thank you.

Operator

Thank you presenters and thank you ladies and gentlemen for joining Merck & Co. First Quarter Sales and Earnings Conference Call. That concludes this conference. Thank you all for joining. You may now disconnect.