OVERVIEW:
Company Summary
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PRESENTATION

Operator

Thank you for standing by. Welcome to the Merck & Co. Q1 Sales and Earnings Conference Call. (Operator Instructions) This call is being recorded. If you have any objections, you may disconnect at this time.

I would now like to turn the call over to Mr. Peter Dannenbaum, Senior Vice President, Investor Relations. Sir, you may begin.

Peter Dannenbaum  Merck & Co., Inc. - VP of IR

Thank you, Shirley, and good morning, everyone. Welcome to Merck’s First Quarter 2024 Conference Call. Speaking on today’s call will be Rob Davis, Chairman and Chief Executive Officer; Caroline Litchfield, Chief Financial Officer; and Dr. Dean Li, President of Merck Research Labs.

Before we get started, 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 in our press release.

I would like to remind you that some of the statements that we make today 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 and the 2023 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.

During today’s call, a slide presentation will accompany our speakers’ prepared remarks. These slides, along with our earnings release, today’s prepared remarks and our SEC filings, are all posted to the Investor Relations section of Merck’s website.

With that, I’d like to turn the call over to Rob.

Robert M. Davis - Merck & Co., Inc. - Chairman, President & CEO

Thanks, Peter. Good morning, and thank you for joining today’s call. We’ve begun 2024 with continuing momentum in our business. We’re harnessing the power of innovation to advance our deep pipeline and are maximizing the impact of our broad commercial portfolio for the benefit of patients. We drove strong growth across key therapeutic areas, executed strategic business development and are now launching a significant new product in the cardiometabolic space while also preparing for the potential approval and launch of 2 additional important candidates in vaccines in oncology.

We have significant opportunities ahead of us across all areas of our business, and we’re highly focused on realizing them.

I continue to be inspired by the dedication of our talented global team, which is working tirelessly to bring differentiated medicines and vaccines to patients through seamless scientific, commercial and operational execution. In March, we received FDA approval for WINREVAIR, a first-in-class treatment for adults with pulmonary arterial hypertension, a rare progressive and ultimately life-threatening disease. This marks the achievement of a significant milestone for our company. It exemplifies the value of our strategic priorities and demonstrates how our enduring commitment to our purpose is resulting in tangible benefits for patients.

Just over 2 years since adding WINREVAIR to our pipeline, our attention now turns to the execution of a strong commercial launch where we have already seen prescriptions being written. We see a tremendous opportunity to positively impact the lives of people living with PAH. And further, the importance of this therapy to patients provides us with increased confidence in our ability to deliver sustainable long-term value for our shareholders. Strategic business development focused on the best external science remains an important priority for our company. We’ve demonstrated that we can leverage our deep discovery prowess to identify important acquisition targets and then add significant value through our powerful clinical research engine, our regulatory expertise and our commercial scale, which together can serve to accelerate development and enable broad global access to important medical discoveries for patients in need.

Turning to our first quarter results. We achieved strong growth, reflecting robust demand for our innovative portfolio. We’re pleased to reflect this momentum in our updated full year guidance, which Caroline will speak to in a moment. Turning to our broader research efforts. We’re focused on advancing our expansive and diverse pipeline of leading-edge programs for the benefit of patients. In vaccines, we presented additional compelling data for V116, a vaccine that is specifically designed to help protect against the majority of invasive pneumococcal disease in adults ages 65 and older and look forward to its potential approval in June. Each of these programs are platforms where we can provide meaningful protection to broad populations on a global scale. In HPV, we’re building on the foundation set by GARDASIL to further reduce the global burden of certain HPV-related cancers and disease by potentially providing broader protection with a new multivalent HPV vaccine and by generating data to clearly demonstrate whether or not a single dose of GARDASIL-9 provides comparable long-term protection to the approved 3-dose regimen in males and females ages 16 to 26.

In pneumococcal, we presented compelling data for V116, a vaccine that is specifically designed to help protect against the majority of invasive pneumococcal disease in adults ages 65 and older and look forward to its potential approval in June. Each of these programs are platforms where we can provide meaningful protection to broad populations on a global scale. In HIV, in partnership with Gilead, we shared promising data from our revitalized program for a once-weekly combination of islatravir and lenacapavir in the treatment setting. We’re actively progressing our comprehensive clinical program, which is focused on both treatment and prevention strategies to meet the evolving needs of the HIV community.
And in oncology, we initiated several late-stage programs of novel candidates from our diverse pipeline as we work to expand our impact for patients and reinforce our leadership position over the long term. Finally, across our deep pipeline, we have significant clinical momentum in a range of therapeutic areas. Cutting-edge science is at the core of who we are, and I'm confident that Merck is well positioned to deliver the next wave of important innovations and value to patients, shareholders and to all of our stakeholders.

In summary, our science-led strategy is delivering compelling proof points that we are creating a sustainable innovation engine that with continued clinical success will lead to a more diversified portfolio of growth drivers over the next decade and beyond. I again want to recognize the enormous efforts across our global organization. My confidence is strong and growing, that we are well positioned to build on this momentum and drive patient impact and value creation this year and well into the future. With that, I’ll turn the call over to Caroline.

Caroline Litchfield - Merck & Co., Inc. - Executive VP & CFO

Thank you, Rob. Good morning. As Rob noted, we have had a strong start to the year with robust growth across our business, which reinforces the confidence we have in our outlook. We are also making strategic investments to leverage leading-edge science to save and improve lives around the world, positioning us to continue to deliver long-term value for patients, customers and shareholders. Now turning to our first quarter results.

Total company revenues were $15.8 billion, an increase of 9% or 12% excluding the impact of foreign exchange. The impact from exchange is primarily driven by the devaluation of the Argentine peso, which was largely offset by inflation-related price increases consistent with market practice.

The following revenue comments will be on an ex-exchange basis. Our human health business continued its momentum with double-digit growth of 13%, driven by oncology and vaccines. Sales in our Animal Health business increased 4% across both companion animal and livestock products. Turning to the performance of our key brands. In oncology, sales of KEYTRUDA grew 24% to $6.9 billion, driven by increased uptake from earlier-stage cancers and continued strong demand from metastatic indications. In the U.S., KEYTRUDA grew across a broad range of tumors. In earlier-stage cancers, the increase was largely attributable to non-small cell lung cancer following the launches of KEYNOTE-671 and KEYNOTE-091.

In the metastatic setting, we saw strong uptake from the recent launch of KEYNOTE A39 in first-line advanced urothelial cancer. Outside the U.S., KEYTRUDA growth was driven by continued uptake in earlier stage cancers, including high-risk early-stage triple-negative breast cancer and renal cell carcinoma as well as continued strong demand from patients with metastatic disease. Inflation-related price increases consistent with market practice in Argentina also contributed to growth. Alliance revenue from Lynparza and Lenvima grew 24% to $6.9 billion, driven by increased uptake from earlier-stage cancers and continued strong demand from metastatic indications. In the U.S., KEYTRUDA grew across a broad range of tumors. In earlier-stage cancers, the increase was largely attributable to non-small cell lung cancer following the launches of KEYNOTE-671 and KEYNOTE-091.

Our vaccines portfolio delivered strong growth, led by GARDASIL, which increased 17% to $2.2 billion, driven by global demand. Sales also benefited from the timing of shipments in China and CDC purchasing patterns in the U.S. VAXNEUVANCE sales grew to $219 million, driven by continued uptake of the pediatric indication in the U.S. and ongoing launches in international markets, particularly in Europe. In the U.S., VAXNEUVANCE sales also benefited from CDC purchasing patterns. Sales in our Animal Health business grew 4%. Livestock sales growth was driven by price actions as well as demand for swine and poultry products. Companion animal growth reflects price actions.

I will now walk you through the remainder of our P&L, and my comments will be on a non-GAAP basis. Gross margin was 81.2%, an increase of 4.3 percentage points driven by reduced royalty rates for KEYTRUDA and GARDASIL, which went into effect at the beginning of this year as well as favorable product mix. Operating expenses decreased 4% to $6.4 billion, a charge of $656 million related to the acquisition of Harpoon Therapeutics this quarter was lower than the $1.4 billion of charges a year ago for certain business development transactions. Excluding these charges, operating expenses grew 8%.

We remain committed to investing appropriately to realize the promise of our expensive early and late phase pipeline and support the promotion of our key growth drivers. Other expense was $87 million. Our tax rate was 16.1%, including the impact from the Harpoon transaction for which no tax benefit was recorded. Taken together, earnings per share were $2.07, which includes a $0.26 negative impact from the charge related to Harpoon.
Now turning to our 2024 non-GAAP guidance. The operational strength of our business has enabled us to raise and narrow our full year revenue guidance. We now expect revenue to be between $63.1 million and $64.3 billion, reflecting strong year-over-year revenue growth of 5% to 7%, including the negative impact from foreign exchange. At the midpoint of this range, operational strength in our business of approximately $600 million is partially offset by an incremental headwind from foreign exchange of approximately $400 million using mid-April rates resulting in a full year negative impact from foreign exchange of approximately 3%.

Our gross margin assumption is now expected to be approximately 81%. Our estimated range of operating expenses is between $25.2 million and $26.1 billion, which does not assume additional significant potential business development transactions. Other expense is expected to be approximately $250 million. Our full year tax rate is unchanged between 14.5% and 15.5%. We assume approximately 2.55 billion shares outstanding. Taken together, we are increasing and narrowing our expected EPS range to $8.53 to $8.65. This is a $0.07 increase at the midpoint despite an incremental headwind from foreign exchange of approximately $0.05 using mid-April rates, resulting in a full year negative impact from foreign exchange of more than $0.30.

As you consider your models, there are a few items to keep in mind. The increase in our sales guidance is driven by the strong performance across our current product portfolio, led by KEYTRUDA, which continues to experience growth from additional indications and patient demand. For GARDASIL, second quarter ex U.S. growth will be adversely impacted by shipment timing to China. This year, we expect more evenly distributed quarterly shipments to China. Recall, in 2023, we accelerated shipments from the second half to the first half of the year, which primarily impacted the second quarter. Over the near and long term, we remain confident in our ability to protect many more people from HPV-related cancers and drive growth of GARDASIL.

Sales of LAGEVRIO in the first quarter were driven by an extended wave of COVID-19 in Asia Pacific markets. LAGEVRIO continues to be an important treatment option for certain patients with COVID-19. So we continue to anticipate full year sales to be lower than last year. We are excited to provide a novel treatment option for adult patients with pulmonary arterial hypertension, following the recent FDA approval of WINREVAIR. We are seeing high interest from patient groups and a range of relevant prescribers. We are also making good progress in enabling access.

Several payers have already established coverage policies consistent with the label and STELLAR study criteria, while others are in the process of developing their policies. As we go forward, we intend to provide an appropriate level of transparency to enable insight into the impact we are having on patients, including prescription data and revenues. In summary, we are confident in a successful launch of WINREVAIR, consistent with our prior expectations and look forward to providing updates on our progress.

Now turning to capital allocation, where our strategy remains unchanged. We will prioritize investments in our business to drive near- and long-term growth. We will continue to invest in our innovative pipeline, including the initiation of many new late-stage clinical trials across multiple novel candidates, each of which has the potential to meaningfully address important unmet medical needs. We remain committed to our dividend and plan to increase it over time. Adding compelling science to our pipeline through business development remains a high priority. We maintain ample capacity given our strong investment-grade credit rating and cash flow to pursue additional science-driven value-enhancing transactions. We will continue to execute a modest level of share repurchases.

To conclude, we remain confident in the near- and long-term outlook of our business, driven by the global demand for our innovative medicines and vaccines as well as our exceptional pipeline. Our unwavering commitment to use the power of cutting-edge science to improve the lives of the patients we serve has put us in a position of financial and operational strength. Our excellent execution and continued investments in innovation will enable us to deliver value to patients, customers and shareholders now and well into the future. With that, I’d now like to turn the call over to Dean.

Dean Y. Li - Merck & Co., Inc. - Executive VP & President of Merck Research Laboratories

Thank you, Caroline. In the first quarter, we continued to make progress with a steady cadence of clinical regulatory milestones across our pipeline. Today, I will provide updates from our cardiometabolic disease portfolio, HIV and vaccine programs and close with advances in our oncology pipeline. As Rob and Caroline noted, late last month, we received approval from the FDA for WINREVAIR, our first-in-class active and signaling
inhibitor for the treatment of dose living with pulmonary arterial hypertension to increase exercise capacity, improve WHO functional class and reduce the risk of clinical worsening events.

WINREVAIR is a novel therapeutic option that targets a new PAH treatment pathway and is indicated to treat a broad PAH population. This approval marks a significant step towards our goal of transforming the treatment journey for many patients with PAH. WINREVAIR is currently being reviewed by the European Medicines Agency with a decision anticipated in the second half of this year. The Phase III ZENITH and Hyperion studies evaluating patients with more advanced disease and those earlier on in their disease journey, respectively, are ongoing as well as the Phase II cadence trial evaluating WHO Group II pulmonary hypertension, a type of left heart disease.

Our commitment extends to a broad range of pulmonary hypertension, informed by results from the Phase II cohort of the Phase II/III insignia PAH study evaluating MK-5475, our inhaled soluble guanylate cyclase stimulator and the STELLAR trial results for WINREVAIR, we have made the decision to focus the development of MK-5475 on WHO Group 3.1 pulmonary hypertension associated with COPD, and not further proceed in PAH. PH-COPD is an area of significant need with no specific therapies currently approved. Our HIV pipeline continues to advance. Last month, presentations at the conference on retroviruses and opportunistic infections, reinforce progress in our strategy to develop less frequent dosing regimens for managing and treating HIV.

We believe these programs have the potential to help address adherence, stigma and other challenges faced by some individuals taking daily antiretroviral pills. In collaboration with Gilead, safety and efficacy findings were presented from a Phase II study evaluating a once-weekly oral combination of istaltravir, an investigation on nucleoside reverse transcriptase translocation inhibitor and lenacapavir, a first-in-class capsid inhibitor for the treatment of adults living with HIV. At 24 weeks, the trial met its primary endpoint and in a secondary endpoint maintained a high rate of viral suppression. Additional longer-term data will be presented at a later date.

In addition, safety and tolerability data were presented for MK-8527 a novel oral NRTTI candidates from 2 Phase I trials that evaluated ascending single dose and multiple doses in adults 18 to 55 years old, not infected with HIV. MK-8527 is being investigated as a potential monthly option for HIV pre-exposure prophylaxis. Vaccines remain an important element of our pipeline, and we are making progress across several programs. Findings from multiple Phase III trials of V116, our investigational 21 valent pneumococcal conjugate vaccine were presented at the meeting of the International Society of pneumonia and Pneumococcal Diseases last month. V116 was shown to be immunogenic for all 21 serotypes covered by the vaccine, including a pneumococcal vaccine naive and vaccine experience adults as well as those at increased risk for pneumococcal disease. If approved, V116 would be the first vaccine specifically designed to address the majority of serotypes that cause invasive pneumococcal disease in adults, ages 65 and older.

The target action date is June 17. The meeting of the CDC’s Advisory Committee on immunization practices is scheduled shortly thereafter. Since the initial approval of GARDASIL, a steady flow of clinical and real-world evidence has been generated to support the favorable efficacy, effectiveness, safety and long-term durability of protection against certain human papillomavirus-related cancers and diseases in both males and females. Despite the proven public health benefit of HPV vaccination, the latest global cancer statistics from the International Agency for Research on Cancer indicate there is more to do to help increase vaccination rates.

The latest statistics from 2022 ranked cervical cancer as the fourth most common cancer globally in terms of incidents and mortality in women and the leading cause of cancer death in 37 countries, predominantly in sub-Saharan Africa, South America and Southeast Asia regions. At the Urogen Congress, last month, we disclosed plans to build on the development of GARDASIL with a new clinical program to identify a novel multivalent HPV vaccine candidate with the potential to extend protection against a broader array of HPV types. This includes several types known to disproportionately impact African and Asian populations and individuals of African and Asian descent. First-in-human studies are scheduled to start in the fourth quarter of this year.

In addition, we announced plans to conduct 2 randomized, double-blind multiyear clinical trials in females and males ages 16 to 26 years to examine the short- and long-term efficacy and immunogenicity of a single dose of GARDASIL-9 versus the currently approved 3-dose regimen. The goal of these studies is to generate data that clearly demonstrates whether or not a single dose of GARDASIL-9 provides comparable long-term protection to the approved regimen, while also satisfying the high standards required by regulatory authorities. The clinical trials are anticipated to start enrolling in the fourth quarter.
In oncology, we continue to focus on our 3-pillared strategy comprised of immuno-oncology, precision molecular targeting and tissue targeting agents. In immuno-oncology, September 2024 will mark a decade since the first approval of KEYTRUDA in metastatic melanoma. KEYTRUDA has since amassed approvals for 39 indication and continues to reinforce its reputation as a foundational therapy for certain types of cancer. Building on the recent FDA approval for KEYTRUDA in combination with chemotherapy for the treatment of FIGO 2014, Stage II through IVA cervical cancer, we recently announced that the pivotal KEYNOTE-A18 trial met its primary endpoint of overall survival, potentially providing a new standard of care for these patients. Our commitment to providing better options to prevent and treat cervical cancer remain strong. Also, in women’s cancer, the Phase III KEYNOTE-868 trial, known as NRG-GY018 was granted priority review by the FDA for the first-line treatment of patients with primary advanced or recurrent endometrial carcinoma. This agency has set a target action date of June 21.

Outside of the U.S., the European Commission approved KEYTRUDA in combination with platinum doublet chemotherapy as neoadjuvant therapy followed by adjuvant KEYTRUDA in adult patients with non-small cell lung cancer at high risk of recurrence based on the Phase III KEYNOTE-671 study. This marks the first approval in Europe for an anti-PD-1 PD-L1 therapy as part of a treatment regimen for the neoadjuvant followed by adjuvant treatment of resectable non-small cell lung cancer based on positive overall survival results.

Next to precision targeting. Building on the success of KEYTRUDA for certain patients with non-small cell lung cancer, earlier this month, we announced the initiation of the Phase III clinical trial for MK-1084, an investigational oral selective KRAS G12C inhibitor in combination with KEYTRUDA for the first-line treatment of certain patients with metastatic non-small cell lung cancer. The decision to proceed to Phase III was based upon early promising evidence from a Phase I study showing antitumor activity and a manageable safety profile. KRAS is one of the most prevalent oncogenes in human cancers, and G12C is the most common KRAS mutation in patients with non-small cell lung cancer.

In the tissue targeting space, we are moving with speed and rigor to advance a broad pipeline of antibody drug conjugates with multiple planned and ongoing Phase III trials. In just over 6 months, we have made remarkable progress in our collaboration with Daiichi Sankyo. Recently, we announced that the first patient has been dosed in the Phase II/III REJOICE OVARIAN01 trial evaluating the efficacy and safety of raludotatug deruxtecan, an investigational CDH6 directed DXDADC in patients with platinum-resistant ovarian cancer. We are poised to begin a Phase III study evaluating ifinatamab/deruxtecan, a B7-H3-directed ADC in small cell lung cancer, a notably difficult-to-treat tumor type. New treatment options are desperately needed for these patients where the prognosis remains poor.

We are pleased to have recently completed the acquisition of Harpoon Therapeutics, which provides novel T cell engagers, including MK-6070, an investigational delta-like ligand 3 targeting T cell engager, also being evaluated in certain types of small cell lung cancer as well as neuroendocrine tumors.

Finally, please mark your calendars for the evening of Monday, June 3, where we will host an investor event at ASCO in Chicago and provide an update on our diverse portfolio of immuno-oncology, precision molecular and tissue-targeting agents.

Looking forward, June promises to be a busy month with 3 regulatory action dates, including V116 for prevention of invasive pneumococcal disease and pneumococcal pneumonia in adults. KEYTRUDA for primary advanced or recurrent endometrial carcinoma; and patritumab/deruxtecan for advanced EGFR-mutated non-small cell lung cancer.

We continue to execute on our strategy with a focus on operational excellence and look forward to providing further updates on our progress throughout the year.

And now I will turn the call back to Peter.
OPERATOR
(Operator Instructions) Our first question comes from Terence Flynn with Morgan Stanley.

Terence C. Flynn - Morgan Stanley, Research Division - Equity Analyst

This is probably one for Dean. Obviously, you guys have been focused on building out your cardiometabolic franchise now. You have the sotatercept launch underway. You've got an oral PCSK9 in late-stage development. You have a GLP glucagon also moving forward for NASH, I believe. But I guess I'd just be curious how you think about the opportunity in obesity broadly as, on one hand, it seems like it could align with your current footprint. But on the other hand, it seems like Merck has gone more towards specialty markets and away from kind of primary care. So maybe just would love your thoughts there, Dean, as you think about building out.

Dean Y. Li - Merck & Co., Inc. - Executive VP & President of Merck Research Laboratories

Well, thank you very much. Yes, we are excited about the build-out that we have in cardiovascular metabolic. You pointed out the programs that have the most visibility right now. But let me assure you, there will be other programs that you will have more visibility over the coming years.

In relationship to your question about GLP and obesity, I think there's 2 ways to look at it: you can look at it from a GLP angle, and you can look at it from an obesity angle. If you look at it from a GLP angle, there has been really important work showing its impact in diabetes, weight loss, more recently, in cardiovascular outcomes, most recently in sleep apnea.

And you're right, we're very interested in relationship to MASH. We think that's an also important outcome. And we also think that there will be distinct populations, whether you call it obese or whether you call it NASH or -- within that GLP space. With distinct populations, it will be important to give a benefit of a molecule that really takes care of the primary concern. And that's our play, for example, in NASH, where we think we have a very tolerable drug that has significant reduction in liver fat and also gives a weight loss of 10% to 12%.

When you look at that, I think these different outcomes may need different molecules. More generally, if you're talking about obesity, I do think that there's important work going on right now. But I think that there could be another wave where people start thinking about orals, how tolerable they are, the accessibility they are, combinations, how do you maintain, how you preserve muscle and also additional outcomes. And it may not be that the same molecule is the best molecule that wins out in every one of those sub populations. And so I would just -- I wonder if there will be some fractionation of the patient population when you say the word, for example, generally, obesity. And we wonder if there's opportunity there.

OPERATOR
Our next question comes from Evan Seigerman with BMO Capital Markets.

Evan David Seigerman - BMO Capital Markets Equity Research - MD & Senior BioPharma Research Analyst

I wanted to touch on some of your work in lung cancer, specifically with KRAS G12C, echoing Dean's comment. So this space is becoming increasingly crowded. Maybe walk me through what you believe differentiates your assets today from the currently approved one or from the pan-KRAS assets in development.

Dean Y. Li - Merck & Co., Inc. - Executive VP & President of Merck Research Laboratories

Yes. So this is one of my more favorite projects. So I appreciate that you actually ask a question about it. When you look at KRAS, as you point out, there is -- it's one of the most important driver mutations in multiple cancers. And if you say more broadly, not KRAS but pan-RAS, that is also true.
In relationship to KRAS G12C, that's a small percentage of all the KRAS mutations and all the RAS mutations. But where KRAS G12C is especially prominent is in non-small cell lung cancer. It’s, depending on the percentage, 12% to 15% in that patient population.

And I will also emphasize that we have a lot of data in relationship to that patient population in non-small cell lung cancer. It’s KEYNOTE-189. It’s chemo plus IO. You need a potent compound with a KRAS to move it into first line. That’s the game that we’re trying to play. So it’s crowded. But what you’re looking for is a potent compound that has tremendous monotherapy efficacy. But most importantly, when you combine it with, for example, pembro, you maintain the dose, you maintain the ability to not have dose modifications. And that’s the data that made us excited about this because I think we reported an ORR of 71% in combination. So that’s why we’re advancing that.

The race for us is to get it in first line and then to think about other KRAS indications and IO-sensitive/insensitive and also other molecules that are coming through in the lung cancer space. And some of them are related to antibody drug conjugate. So we are very excited about our KRAS G12C program, 1084, which is moving to Phase III.

Operator

Our next question comes from Chris Shibutani with Goldman Sachs.

Chris Shibutani - Goldman Sachs Group, Inc., Research Division - Research Analyst

Maybe focusing on the pipeline on areas that you do not highlight as often, specifically immunology. And then a lot of the discovery work that you talk about in CNS. With immunology with a TL1A, can you just help us understand where we are on the Crohn’s study there and also the Pandion acquisition, like in just Phase II.

And then CNS, you highlight how many folks you have doing discovery research. How do you feel about the distribution of your efforts in CNS there? So just 2 areas not highlighted in the press release, but I think are important to your overall portfolio.

Dean Y. Li - Merck & Co., Inc. - Executive VP & President of Merck Research Laboratories

Thank you very much. So I’ll first touch immunology and specifically in the TL1A space. So that TL1A, we think that it will be a highly effective -- the higher efficacy, and also not just in terms of efficacy, in terms of tolerability. That ulcerative colitis program Phase III has started already and is recruiting. We are hopeful that we will be announcing the opening of the Phase III and patients coming in for the Crohn’s disease over the next few months. So we are very excited about moving TL1A eagerly and appropriately aggressively move it in Phase III to really sort of outline the really differentiated profile that we have seen for TL1A, and specifically, our compound.

I should also emphasize that we also are looking at TL1A not just within sort of inflammatory bowel disease, but we’re also interested in other diseases. And one of the things that’s really interesting about TL1A, it is blocking inflammation. But there is reasons to believe that it can have profound effects on fibrosis, and that’s our interest in Crohn’s disease.

But there are other diseases, for example, in the lung where fibrosis is a really important component. And we will be interested to see those. We have other assets moving forward both from the Prometheus acquisition that is not the TL1A as well as other internal that are moving forward with alacrity.

In relationship to neuroscience, we hope to be getting the readout with MK-8189. We have other programs that are moving and advancing. And we have made some commitments in the early discovery space in a BD standpoint to accelerate some of our works that have been made public.

I think over the next 1 to 2 years, we’ll see readouts Phase IIb, Phase Is moving to Phase II. But I think at that point, we will be able to speak more fully. But I think the investment in neuroscience, I think, is critically important. From a health care unmet need, you have to list from an economic value to the health care system and population. Especially in the United States, neuro disease continues to be a really important place, and I would
say neuro disease not just in terms of degenerative but -- not just classic neuro disease but in the psychiatry arena as well. And you've seen others advance business development in that space. We're interested in continuing in business development there, but also importantly, moving our own internal program, the lead program being MK-8189.

Operator

Our next question from Daina Graybosch.

Daina Michelle Graybosch - Leerink Partners LLC, Research Division - Senior MD of Immuno-Onco and Senior Research Analyst

I want to ask some on pneumococcal vaccine. You mentioned several times V116 is customized for adults 65 and older. In the ACIP meeting, they discussed a recommendation in adult 50 or older. And I wonder if you could comment on where you think the ACIP recommendation will end up for V116. And on V117, I wonder if you could talk about how the stack scene, which I believe is now in Phase I is customized for pediatric patients.

Robert M. Davis - Merck & Co., Inc. - Chairman, President & CEO

Yes. Maybe I can start, Daina, and then Dean can add. Obviously, I would just start by saying we were very pleased with the overall tone and tenor of the discussion coming out of the ACIP meeting. And as you look at what we have with V116, we continue to believe -- if you look at the strength of the data behind that, and we've talked about -- Dean mentioned some of the clinical readouts that have come. But recall, we cover 83% of the serotypes-causing disease in adults. That's 30% higher than PCV20. So it's significant, and that was how it was specifically designed, targeting those serotypes which are most prevalent in adult disease.

As a result of that, we continue to believe the value proposition of V116 is very compelling. If you look at the cost effectiveness, it's going to be a very cost-effective vaccine. And as a result, I think that's why you started to see the ACIP ask questions about the 50 to 65 age cohort as well as the 65-plus.

So I don't want to get ahead of the ACIP and their recommendation. But I would say our belief and conviction in the value of the data and the value this vaccine will bring for patients in the pneumococcal space is significant. And I would expect overall that we're going to see broad coverage coming out of the ACIP.

Dean Y. Li - Merck & Co., Inc. - Executive VP & President of Merck Research Laboratories

Yes. I would just add, again, we want to be respectful of ACIP and the FDA. But you did point out something that I think is something that clearly we took notice. When Rob talks about that 83% versus 50% and 30% more, and the specific question that you're asking about, 50 to 64, I would remind everyone that dropping that age for universal vaccination have been considered previously for other vaccines. And they could not come to a situation where they thought that it would be a good idea based on cost effectiveness and as such. And by increasing it from 50% to 83%, we believe that we changed the calculus, and that made why there is renewed interest in lowering that age based on the broader coverage given for V116.

Robert M. Davis - Merck & Co., Inc. - Chairman, President & CEO

And I think there was a second question you had, Daina, about V117. I'll just maybe give a general answer, which is, obviously, if you look at the strategy of V116, it's the same strategy with V117: How do we develop an investigational PCV vaccine that is targeted specifically to those serotypes that cause disease in children, in peds, without hopefully causing untoward effects. And so it's a model that follows that. We've not given any details to the additional serotypes or our thinking. But just understand that if you look at the model of V116, V117 is the same thing in peds.
Operator

Our next question comes from James Shin with Deutsche Bank.

James John Shin - Deutsche Bank AG, Research Division - Research Analyst

Firstly, I know Merck does not provide product-level guidance, but given WINREVAIR’s importance and investor focus, can you provide any color on WINREVAIR contribution to guidance? And then second one is for Dean on REJOICE-Ovarian and I suppose precision oncology in general. But does the field know how much overlap there is between (inaudible) FRalpha? And then for patritumab, I know the data for HER3 shows high expression in advanced patients, but there’s a lot of development in advanced space. So how does Merck envision patritumab to be positioned or sequenced?

Robert M. Davis - Merck & Co., Inc. - Chairman, President & CEO

Yes. Maybe, James, I'll start. And thank you for the question. The short answer is, unfortunately, we don't provide product-level guidance. So I don't think we want to get into trying to tell you what we see WINREVAIR as being a contributor in 2024.

But with that said, I think it’s important to make a few points just so you understand how we’re seeing it. First of all, we’re very excited to provide this novel treatment for patients with PAH. As you know, we think this will be a game changer in that space. We were well prepared for the launch. And I can tell you the launch, although very early, is going well so far. We’ve seen an increasing number of prescriptions being written. We’ve seen repeat prescriptions, and that’s coming both from the COE space, from the Centers of Excellence, which is about 150 in the United States, as well as from non-COEs, which is a good development.

We’ve already begun making shipments to patients’ homes. And hopefully, we’ll have patients being dosed very soon, if not already.

And then I think the other thing I’d note is the prescribers as well as the locations are both from the Centers of Excellence and also non-COE. So that’s something to note. And then finally, from a payer perspective, we’re seeing good access. No real limits. In fact, we already have several payers who have established coverage policies. And I think as Caroline pointed out in the prepared comments, very consistent with the label and what we saw in STELLAR. But the fact that we’ve seen policies enacted giving coverage to patients already this quickly after launch, we see as a good sign.

It’s obviously early. But everything so far looks quite good. So our confidence in a successful launch has not changed. We continue to see this consistent with our expectations. And as we move forward, we’ll give you appropriate level of transparency. But I just want to give flavor, even though we can’t give the specific guidance you were asking for.

Dean, I’ll let you take the second part of the question.

Dean Y. Li - Merck & Co., Inc. - Executive VP & President of Merck Research Laboratories

Yes. So I’ll just add a little bit in relationship to WINREVAIR. I think it’s important to emphasize that the indication or the label that we have is a broad indication and is based on STELLAR. And there will be potential data flows that will continue to inform and strengthen the field. We have STELLAR and SOTERIA, which is open label. We have ZENITH, which is advanced, and that will look at mortality and morbidity; and HYPERION, which is in more -- earlier in the journey.

We have the European action that will happen in the second half of 2024. And I would just emphasize that this is something that health care professionals and self-administration is possible. And in relationship to that, there will be a demand for innovation, and we hope to provide that innovation as this becomes even more used in a self-administration standpoint.
You asked a number of questions and many of the questions related, and some of it got blurred out, but some of it related to ovarian, but more broadly speaking, tissue targeting and ADCs. So I’ll just give you an overview. When we look at the field, we look at cancers where there is IO and chemo and that combination. And where will we see that? We ask ourselves, can you combine an IO agent with a chemo agent? And we think about KEYTRUDA, but we also think about next-gen tissue targeting IO agents, such as the recent immune engagers that we have from Harpoon.

And then on the other hand, we think about chemo, we think of precision targeting like RAS, how can it combine? And we also think in terms of ADCs. And the specific case that you’re talking about, you have HER3 patritumab. That’s moving along in EGFR non-small cell lung cancer. In B7-H3, there’s prominent data that’s in small cell lung cancer, maybe in prostate. And for CDH6 itself, that ovarian data is quite interesting, and that’s raludotatug.

At least for us, it’s very interesting because the initial data with our partners in Daiichi Sankyo is striking to us. Because in that patient population, it looked like allcomers did extremely well and that in some situations, you think about a biomarker. But for the CDH6, the impact across sort of biomarker subsets was quite impressive. So I hope that gives you a general structure and we’re happy to -- and thank you very much for that question.

Operator
Our next question comes from Umer Raffat with Evercore.

Umer Raffat - Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research

I’m just trying to think through your next-gen HPV vaccine. And I guess, how should we think about potential penetration rates with a revaccination opportunity with the new broader-spectrum HPV, especially in patients who have already taken GARDASIL 9.

Dean Y. Li - Merck & Co., Inc. - Executive VP & President of Merck Research Laboratories

Revaccination and relationship to HPV, is that what the question is?

Robert M. Davis - Merck & Co., Inc. - Chairman, President & CEO

The new (inaudible).

Dean Y. Li - Merck & Co., Inc. - Executive VP & President of Merck Research Laboratories

With the G9+. I’m struggling to answer your question because I first got to make a G9+ that works really, really well. And when I get that, that will be great because there are patient populations that I think would be extremely well served. But I would also emphasize that we’ve just talked about cancer. We talked about early-stage cancer. This is the time that you can really treat and potentially cure, but we’re in the business of preventing cancers as well.

One of the questions that comes to us is that in certain patient populations, you want a vaccine that -- the data, for example, Scandinavia, it’s 90-plus reduction -- 90% reduction in cancer incidents. And then the recent American Cancer Society. We are wondering whether if you make a G9+ vaccine, whether you can make the argument, if we’re successful with the G9+ and what we hope to aspire for, whether you could fundamentally change how one recommends cancer screening for women in relationship to cervical cancer and also the reduction both in men and women of many other cancers outside of cervical cancer.
This is Caroline. I'll just add that as we sit here today, we all know there are many, many people around the world that have not received a vaccine to prevent them against, to help protect them from HPV-related cancers. With the possibility of improving upon G9 with a multivalent vaccine, we're hopeful that we can provide further protection, especially for different population groups. And we will price the vaccine appropriately based on the benefit that it will provide. So we're looking forward to continuing to see growth in GARDASIL and see how the science evolves with our clinical programs.

Operator

Our next question comes from Tim Anderson with Wolfe Research.

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

I have a few questions on KEYTRUDA subcu. It may not be scientifically sexy, but of course, it could be quite commercially meaningful. So we'll see that data, I believe, later this year. Any risk whatsoever to that readout? Or can we consider it to be a slam dunk?

Second question is when the subcu launches in the U.S., presumably next year, will uptake be fast or slow or somewhere in between? And then eventually, how much can a subcu account for the franchise on a volume or a patient basis?

Dean Y. Li - Merck & Co., Inc. - Executive VP & President of Merck Research Laboratories

So I'll take the first part of that. I remind myself, nothing is slam dunk once you place innovative drugs in patients. So I'll answer that question. But I think you highlighted really the pembrolizumab plus hyaluronidase that we're advancing. I would disagree a little bit. I do kind of think it's sexy in some ways. And that D77, we will be sharing that data by early 2025.

The reason I think it's really an important innovation is to really increase the access. You've seen the number of early-stage cancer readout that are coming through with pembrolizumab and KEYTRUDA especially in the earlier stages when we talk about KEYNOTE-671, when we talk about in renal cell carcinoma, where we have OS benefit. I think this is going to be really, really important for patients. It will also be important in patients for treatment, especially in those who have monotherapy and those especially combos with oral agents because it just makes it so much more accessible. So we think this is an important program and that it could have substantial impact on patients and their access to PD-1, where we know the foundational elements of PD-1. And in terms of financial...

Robert M. Davis - Merck & Co., Inc. - Chairman, President & CEO

Yes. Maybe, Tim, I'll just provide some commentary on your questions on uptake and how much of the patient population this can account for. As we think about uptake of this opportunity, I would first point out that we see really -- it starts with the strength of the clinical data underlying the IO agent itself. So it's more about the confidence they have in KEYTRUDA. And then secondarily, it's about the delivery mechanism, which is important as we think about obviously leveraging the data we have and just the breadth of what KEYTRUDA is.

But I will tell you that as we think about bringing this forward when we do launch, our goal will be the price appropriately with the goal of driving quick adoption. So we do want to see adoption happen, and we do think you will see it. Obviously, if you look at then the size of the patient population where it could be, just to give you a sense, by 2028, if we look at the patients who are on monotherapy with KEYTRUDA who are using combinations with orals and those who are moving into earlier stages of disease through some of our adjuvant and neoadjuvant areas with KEYTRUDA, that represents about 50% of the patient population at that time. So that is really the addressable market for what we see the subcu offering to be.
And potentially, we’re not foreclosing the opportunity to also look into the metastatic setting and people being given care in institutions as well as those moving outside of the institutions. But obviously, the value to the patient is ease of use, ability to use it outside of the hospital setting. The time in chair is obviously less if you’re getting a subcu versus an IV. And then from a cost to the health care system, the ability to not have a patient sitting in the chair for as long allowing for more patients to move through, we think, actually drives access and improves the providing of care as well. So we see it both beneficial from a patient perspective and from the provider perspective, and that’s why we do think you’ll see uptake of this important medicine when we bring it forward.

Operator

Our next question comes from Louise Chen with Cantor.

Louise Alesandra Chen - Cantor Fitzgerald & Co., Research Division - MD & Senior Research Analyst

I just wanted to ask you for ASCO on June 3. Are there any specific readouts updates that you’re very excited about presenting?

Dean Y. Li - Merck & Co., Inc. - Executive VP & President of Merck Research Laboratories

I think there’s just going to be a stream of data. There’s going to be follow-ups and a series of KEYNOTE, whether it be gastric, hepatocellular, biliary, bladder, non-small cell lung cancer. There will be discussions of many of the programs that I think you’re beginning to see coming up in the clinical trial website in relationship to a whole series of Phase III related to molecules that you’re familiar with, but also molecules that are sort of earlier in our Phase III development, ranging from bomedemstat to the KRAS program, to many of the ADCs and the updates that we’ve shown in relationship to not just the Daiichi Sankyo ADCs, but the other ADCs, whether it be TROP2 Claudin or (inaudible). So you’ll have a whole full array of discussions of those compounds, some at the ASCO, but some at the ASCO investor event.

Peter Dannenbaum - Merck & Co., Inc. - VP of IR

Great. Thanks, Louise. I know we have several more people in the queue. We’re going to go an extra 5 or 10 minutes to try to get to as many questions as possible.

Operator

Our next question comes from Trung Huynh with UBS.

Trung Chuong Huynh - UBS Investment Bank, Research Division - Analyst

Trung Huynh from UBS. On the WINREVAIR launch, thanks for the comments today on access and coverage. On approval, you noted that 2/3 of your PAH patients would likely Part D and third commercial. Perhaps can you expand on the free assistance program that you’re hoping to initiate? And what proportion of those Part D patients do you think could be receiving free product this year?

Robert M. Davis - Merck & Co., Inc. - Chairman, President & CEO

Yes, I appreciate the question. So as you point out, we are very focused on ensuring that patients get access to the medicine. We’re very much committed to it. And that’s why we do have – in addition to our normal programs we would run, we do have the access program we run. That program is actually independent of our commercial operations. We don’t really report data coming out of that because it’s run through a separate foundation and with the goal, frankly, of making sure that patients get medicines there. So that is available. It can be accessed on our website, and we’re committed to making sure patients get the medicine. But specifics on that, we’re not going to go into.
Operator

Our next question comes from Carter Gould with Barclays.

Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

Maybe on your personalized cancer vaccine with Moderna, as the Phase III sort of nears completion of enrollment, it of course begs the question around the potential to sort of file based on the existing data you have. Can you maybe just update us on your thoughts there and whether you think you still need Phase III data or manufacturing would preclude an early filing? Any help there would be appreciated.

Dean Y. Li - Merck & Co., Inc. - Executive VP & President of Merck Research Laboratories

Yes, I'll take that. I mean I don't want to speak about whether the FDA will take what action or not. But I'll just reemphasize to everyone what is exciting about our INT program and our excitement working with Moderna. So here, we're inducing and coaxing sort of immunity. And we're mixing it with a drug that's well known that unleashes pre-existing immunity, which is KEYTRUDA.

What we have in our hands is a randomized, early-stage IO sensitive trial, where it is very clear of the contribution of components of the INT, not in immunogenicity, but in clinical benefit. So I just want to highlight that about our data as one looks at the data of others.

We also have begun to show that we are moving it in Phase III in adjuvant melanoma and adjuvant non-small cell lung cancer and our ability to move that with speed and rigor but get patients recruited, which is going well, I think will be very important because you're going to need a Phase III regardless of what the FDA decides on an accelerated approval or not. And so that's what we're focused on.

We're also focused on looking at other IO-sensitive tumors such as renal cell carcinoma. And I would just emphasize the strength of the data in relationship to durability is being answered. The ability for us to open these trials and successfully advance it is being answered. And we clearly have work to do with our colleagues who we respect deeply for what they've done in relationship to manufacturing.

Any -- all mRNA vaccine, I mean, they've really pushed the envelope here. Our ability to do that will be important to make this an important treatment. As far as the FDA's decision, the FDA will need to make their decision as to how they consider the opportunity.

Operator

Our next question comes from Chris Schott with JPMorgan.

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

Just a couple of GARDASIL questions. You're pointing to a more evenly distributed China sales this year, and it seems like a tougher 2Q comp. But can you just directionally talk about growth for GARDASIL more broadly for the year? I guess the heart of it is still a healthy growth asset for you this year. And the second one on GARDASIL is if we were to move to a single dose of GARDASIL-9, what does that mean commercially and from a sales perspective for the franchise?

Caroline Litchfield - Merck & Co., Inc. - Executive VP & CFO

Chris, it's Caroline. So in terms of the phasing of GARDASIL, as you pointed out, during 2023, we saw in China an acceleration of the shipment from the second half of the year to the first half of the year, specifically to the second quarter. What that's done is it's provided an actual tailwind to
revenue growth in the first quarter for China, but it will provide a headwind more significant in the second quarter. And that's what we've called out.

As we look at overall growth for GARDASIL, given where we are with the level of vaccinations across the world, given the manufacturing that we have been scaling up, we're confident in our ability to continue to drive growth during 2024. And in 2025, we will see our manufacturing capacity unconstrained so enabling us to further supply and support the market.

As we've talked in the past, our opportunities for growth are significant as we look to continue to improve on adolescent vaccination rates, as we look to improve upon gender-neutral vaccinations, as we look to really activate the mid-adult segment, but increasingly get to the lower-income and middle-income markets, which will come at a different price point.

As we sit here today, continue to be confident in the outlook for GARDASIL over both the near and the long term. As we look at the possibility of a single dose of GARDASIL, the study that we are conducting will be a comprehensive study and will take some time to unfold. What we're seeing in the marketplace currently is where certain low-income markets are implementing a single-dose regimen, they are also increasing the numbers of people they are vaccinating by broadening the age cohort or also opting to vaccinate males at this stage. We'll have to see long term how the data plays out with regards to a single dose to ensure that we will price our vaccine based on the benefit that we're bringing and we vaccinate as many people in the world that we can.

Operator

Your next question comes from Luisa Hector with Berenberg.

Luisa Caroline Hector - Joh. Berenberg, Gossler & Co. KG, Research Division - Co-Head of Global Pharmaceutical Team & Global Pharma Analyst

I also have questions on the WINREVAIR launch. I just wanted to check how straightforward the subcutaneous administration is and when you might expect to launch an auto-injector. Also, should we actually expect the Part D access to come online at a similar pace as commercial? I'm just not sure whether that's something that's maybe sitting more into next year.

And if I can, just another question on that with Part D is that you price for the Part D restructure next year. How do you expect payers to behave when this happens. I can see that the payer will take on a greater burden for higher-priced oral therapies. Do you expect some pushback within the actual drug that you would have higher rebates at that point? Or do you think that incremental burden for the payers might be spread more broadly across all products? It's a kind of bigger-picture question that WINREVAIR brings it into focus.

Dean Y. Li - Merck & Co., Inc. - Executive VP & President of Merck Research Laboratories

So this is Dean. I'll answer your questions in terms of delivery of WINREVAIR. We have it in a vial, and we have it in a situation where both a health care provider or self-administration is both feasible, possible and will be used. We believe that the vast majority with time that people will use it as self-administration. This is a patient population that's quite used to doing injection. So we think that, that will be able to navigate and that the patients will get access.

But as you point out, further innovation will be demanded for, and an auto-injector will be critically important. We are doing the studies right now to evaluate how do we provide such an option, and we hope to have those options and those plans more public in the near future. But we agree with you totally in the fact that a future auto-injector will be important.
Caroline Litchfield - Merck & Co., Inc. - Executive VP & CFO

And Luisa, this is Caroline. At this stage, we are seeing a real acceptance of the value proposition of WINREVAIR in the United States. We’re seeing policy for coverage equally across both the Medicare and Medicaid patient population as well as the commercial segment. So as we move forward, we’ll look forward to just helping as many patients as we can across all of those segments, irrelevant of their coverage.

Operator

Our next question comes from Seamus Fernandez with Guggenheim.

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

Wanted to ask actually about your RSV-targeted antibody, how you’re thinking about that, the optionality for it and the market size and Merck’s potential participation in this market as it relates to the competitors’ global supply constraints at this point in time. It seems like coming to market more aggressively or as aggressively as possible could actually make for a meaningful market opportunity for Merck.

And then just a follow-up, Rob, I wanted to just get your sort of qualitative view 3 years, 4 years in thinking about the evolution of the business. 2028-2029 still represents a meaningful challenge with KEYTRUDA. But as you look forward to the rest of this year and heading into 2025, how important is business development to Merck from here in terms of the size and type of acquisitions I think investors have certainly applauded what Merck has executed on in the last year for sort of mid- to later-stage assets.

Dean Y. Li - Merck & Co., Inc. - Executive VP & President of Merck Research Laboratories

Yes. So I’ll take the RSV question. So clesrovimab, we’re excited about it. As many of the people know, it’s a monoclonal antibody and it’s a way to get passive immunity to infants. We think it’s really important as we have seen recently. And ours is a single fixed dose and has the durability in terms of covering a whole RSV season, I think, is critically important. And the ability to give this to an infant any time and -- versus, for example, alternative strategies, which is maternal vaccination.

And then also, we believe that this will be a distinguished monoclonal antibody and it’s high barrier to resistance. So we’re excited about moving and -- seeing that data and moving with both speed and rigor to get this to the market because we think it will be an important contributor, especially given what we’ve seen in the RSV season just this past season.

I do want to just take this one moment to just say it’s not just the RSV vaccine that we’re very excited. We’re also very excited because it’s very much in the lay press in our dengue V181, which is a live attenuated tetravalent vaccine. And we’re moving with equal eagerness to move that forward into Phase III, as we’ve already seen data from our colleagues in Institute Butantan about the effectiveness and efficacy of this vaccine.

But I’ll turn it back to Rob.

Robert M. Davis - Merck & Co., Inc. - Chairman, President & CEO

Yes. No. Thanks for the question. And so if I would just kind of, I guess, think a little bit about where we’ve been in over the last 3 years, a few points I would want to raise. One, I think we’ve made tremendous progress in a relatively short period of time, and I give all credit to Dean, to our R&D colleagues for what they’ve been able to do, how they have been able to really move just flawlessly products through our pipeline. It’s amazing you think of it now 3 years in, we haven’t had really any major failures. The one maybe hiccup with islatravir, but that’s coming back. And so I feel very proud of what our colleagues in R&D have been able to do.

And then I think about from a commercial perspective, from a manufacturing perspective, we’re pulling the products through, we’re showing value. The fact that we’re ready for the launch with WINREVAIR shows how we can build capability very quickly. We did it in KEYTRUDA, we did it in
JANUVIA and now we're doing it in WINREVAIR, and we'll do it in new spaces coming forward. So we feel very good about that. So across all elements, R&D, commercial, manufacturing, the business is delivering.

And so as we sit here today, if our clinical success continues, I think you're going to see us with a more diversified set of growth drivers over time than, frankly, we've had in many years, if ever. And that's very important. And it all is really what leads to the confidence you've heard me express in other settings, that I'm increasingly less focused on 2028. And I would remind you, by the way, it's a staggered LOE. So it's 2028 in the U.S.; in China, it's 2031; in Europe, in 2032 and in Japan. So it's not a one-moment event. It actually happens over time.

But that being said, as you've heard me say, I see it is more of a hill than a cliff. And my confidence that we're going to come back with fast growth after that is very high. And we're very focused on the sustainable engine from 2030 to 2040 at this point. So I feel good about where we are, but I just want to reinforce it's a team effort, and I've been blessed with a great team.

Peter Dannenbaum - Merck & Co., Inc. - VP of IR

Great. Thank you, Seamus, and thank you all for your time and your interest today. I'm hoping to see many of you at our ASCO event on June 3 or at a few of the conferences that we'll be attending this quarter. So thank you all very much.

Operator

Thank you. And that does conclude today's conference. We thank you for your participation. At this time, you may disconnect your lines.