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OVERVIEW:

Company Summary

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PRESENTATION

Operator

Thank you for standing by. Welcome to the Merck & Co. Q4 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, Vice President, Investor Relations. Sir, you may begin.

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

Thank you, Ivy, and good morning, everyone. Welcome to Merck's Fourth Quarter 2023 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 2022 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 the 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. 2023 was another very strong year for Merck. I'm extremely pleased by the progress we've made to develop and deliver transformative therapies and vaccines that will help save and improve lives around the world. We reached more than 500 million people with our medicines last year alone, over half of which were through donations.

We also made substantial investments in research and development in our ongoing effort to discover and bring forward to patients the next generation of impactful innovations, over $30 billion in total, including the cost of certain acquisitions and collaborations.

As we move forward, I'm confident that our strong momentum will continue, underpinned by the unwavering dedication of our talented global team.

We're realizing the benefits of our sustained focus on key strategic priorities. The excellence of our commercial and operational execution enables us to deliver tangible value in the short term, while we invest in new innovations and strengthen our pipeline for the long term.

In 2023, we advanced important clinical programs and augmented our pipeline with promising business development, such as the acquisition of Prometheus and our collaboration with Daiichi Sankyo. Guided by our science-led strategy, I'm confident that the focused and disciplined business decisions we make and the actions we take will lead to sustainable benefits for the patients we serve and long-term growth and value for our shareholders.

Turning to our results and initial outlook for 2024. We delivered excellent underlying growth in 2023, reflecting robust demand for our innovative portfolio. I'm pleased to share that we expect continued strong growth in 2024, driven by demand for our products, which Caroline will speak to momentarily.

Turning to the progress we're making in research. We're currently pursuing programs across a more diverse set of therapeutic areas with high unmet need and across more modalities than at any time in recent memory. This year, we will remain keenly focused on advancing our broad and diverse pipeline, which includes 2 launches that will address critical health needs and have blockbuster commercial opportunity.

In cardiometabolic, we're very excited by the anticipated FDA action on our application for sotatercept in the United States, which we believe has the potential to transform the treatment journey for many patients suffering from pulmonary arterial hypertension. Our commercial and manufacturing teams are fully prepared for the strong uptake we expect. Sotatercept is an important component of our growing cardiometabolic pipeline, which we believe has significant long-term potential.

In vaccines, the FDA accepted for priority review our filing for V116. If approved, V116 would be the first vaccine, specifically designed to address the majority of invasive pneumococcal disease in adults ages 65 and older. Based on its compelling profile, V116 has the potential to become an

important new preventative option for adults, and we believe it can achieve majority market share in this setting. We look forward to a potential approval in June.

And in oncology, we continue to expand into additional tumor types in earlier stages of certain cancers as well as progress our increasingly broad pipeline of novel candidates. We have achieved substantial diversification with a dramatically expanded set of late-stage programs, which Dean will speak to. I'm confident that Merck is well positioned to provide important innovation to patients and sustain its leadership in oncology, well into the future. I know Dean and his team are energized by our progress and are prepared to build on the success we've had in 2023 to further advance Merck's pipeline and bring transformative innovation to patients this year and beyond.

In summary, our science-led strategy, which keeps the patient at the center of everything we do, is delivering important advancements and helping us build a sustainable growth engine for our company. We've made considerable progress over the past year in advancing and expanding our pipeline, which has resulted in substantially increased long-term commercial opportunities.

We've taken meaningful steps to diversify and position ourselves for sustained leadership in oncology, while also building one of our deepest and broadest pipelines across discovery and development in our recent history outside of oncology and notably in cardiometabolic and immunology.

Further, we also expect to benefit from promising late-stage programs across our vaccines, neurosciences, HIV and animal health pipelines, a robust set of early-phase programs and the potential to add exciting innovation through future science-led business development. As a result, we are increasingly confident that we're well positioned to drive patient impact and value creation this year and well into the next decade.

I would again like to thank our global teams for their commitment to strong research, commercial and operational execution. With a concerted focus on achieving continued excellence, I'm very confident in our ability to deliver short- and long-term stakeholder value. I look forward to providing future updates on our progress and impact.

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

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

Thank you, Rob. Good morning. 2023 was another impactful year for our company. We delivered strong revenue growth of 12%, excluding LAGEVRIO and foreign exchange. Growth was driven by robust performance across Oncology, Vaccines and Animal Health. We remain confident in our ability to continue to deliver strong results in the near term while making disciplined investments in innovative science, which will drive long-term value for patients and shareholders.

Now turning to our fourth quarter results. Total company revenues were $14.6 billion. Excluding the impact from LAGEVRIO and foreign exchange, the business delivered strong growth of 13%. The following revenue comments will be on an ex-exchange basis.

Our Human Health business sustained its momentum. Excluding LAGEVRIO, growth was 14% driven by Oncology and Vaccines. Sales in our Animal Health business increased 4%, driven by companion animal products.

Turning to the performance of our key brands. In Oncology, sales of KEYTRUDA grew 22% to $6.6 billion. Global growth was driven by increased uptake in earlier-stage cancers, including triple-negative breast cancer and renal cell carcinoma, with particularly strong growth in international markets due to the more recent launches of these important indications. Growth was also driven by the strong global need of patients with metastatic disease.

We continue to be encouraged by the positive impact our recent approvals are having on certain patients with earlier-stage non-small cell lung cancer. In the U.S., we have made considerable progress in helping to improve drug treatment rates and have further increased our leadership position in the adjuvant setting.

We also received positive feedback from health care providers following the recent launch of KEYNOTE-A39 in advanced urothelial cancer. With this approval, KEYTRUDA in combination with PADCEV is now indicated for first-line advanced urothelial cancer patients, regardless of cisplatin eligibility. Based on the outstanding clinical data, we believe this regimen has the potential to transform the standard of care for these patients.

Alliance revenue from Lynparza and Lenvima grew 8% and 5%, respectively. WELIREG sales grew 78% to $72 million driven by increased uptake in VHL-associated tumors. We are excited by the opportunity to provide a new treatment option for certain patients with previously treated advanced renal cell carcinoma, following the recent approval based on the LITESPARK-005 study.

Our Vaccines portfolio delivered excellent growth led by GARDASIL, which increased 27% to $1.9 billion, driven by global demand, particularly in China. In the U.S., GARDASIL sales benefited from CDC purchasing patterns.

VAXNEUVANCE sales grew to $176 million driven by ongoing launches in Europe and continued uptake of the pediatric indication in the U.S. As a reminder, fourth quarter 2022 sales in the U.S. benefited from inventory stocking in preparation for the pediatric launch.

In our hospital acute care portfolio, BRIDION sales declined 3%. Increased market share among neuromuscular blockade reversal agents in the U.S. was more than offset by the impact of generic entrants in international markets, particularly in Europe.

Our Animal Health business delivered another solid quarter with sales increasing 4%. Companion animal sales grew 12% driven by the BRAVECTO line of product due to strong underlying demand and timing of purchases. Livestock sales were flat, reflecting favorable price actions, offset by the timing of ruminant product purchases.

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 77.2%, an increase of 1.5 percentage points, largely due to favorable product mix, including a benefit from lower sales of LAGEVRIO. Operating expenses increased to $11.6 billion, including a $5.5 billion onetime charge related to our collaboration with Daiichi Sankyo. Excluding this charge, operating expenses grew 8%, reflecting disciplined investment in support of our expansive early- and late-phase pipeline and key growth drivers. Other expense was $174 million.

Our tax rate was approximately 114%, which reflects the impact of the charge related to Daiichi Sankyo. Excluding this charge, the underlying tax rate was 13.1%. Taken together, earnings per share were $0.03, which includes a $1.69 negative impact from the charge related to Daiichi Sankyo.

Now turning to our 2024 non-GAAP guidance. We expect another year of strong growth driven by key marketed products, and we'll begin to benefit from the anticipated launches of impactful new products, such as sotatercept and V116. We project revenue to be between $62.7 billion and $64.2 billion, representing growth of 4% to 7%. This growth includes a negative impact from foreign exchange of approximately 2% using mid-January rates. The headwind is primarily due to the devaluation of the Argentine peso, which we expect will largely be offset by inflation-related price increases, consistent with market practice.

Our gross margin assumption is approximately 80.5%, which includes the benefit from reduced royalties paid on KEYTRUDA and GARDASIL. Operating expenses are assumed to be between $25.1 billion and $26.1 billion, which includes an approximate $650 million onetime charge related to the announced acquisition of Harpoon Therapeutics. As a reminder, our guidance does not assume additional significant potential business development transactions.

Other expense is expected to be approximately $200 million. We assume a full-year tax rate between 14.5% and 15.5%. We assume approximately 2.54 billion shares outstanding. Taken together, we expect EPS of $8.44 to $8.59. This range includes an approximate $0.26 per share charge related to the planned acquisition of Harpoon Therapeutics, which is not tax-deductible, and the negative impact from foreign exchange of approximately $0.25 using mid-January rates, including the impact from Argentina.

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 are excited by the significant progress our team has made to advance and augment our innovative pipeline in 2023. In 2024, we will

increase this investment, including the initiation of more late-stage clinical trials across multiple novel candidates, each of which has significant potential to address important unmet medical needs.

We remain committed to our dividend and plan to increase it over time. 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 going forward. We will continue to execute a modest level of share repurchases.

To conclude, we enter 2024 with confidence in the outlook for our business in the near and long term. Global demand for our innovative medicines and vaccines remain strong, and we are excited about our expansive pipeline. We are in a position of financial and operational strength as a direct result of our long-standing commitment to science in order to improve the lives of the patients we serve. Our continued investments in innovation and excellent execution will enable us to deliver value to patients, customers and shareholders 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. Good morning. Today, I will provide notable R&D updates since our last earnings call and a brief summary of 2023 accomplishments. Momentum in the pipeline remains strong. Progress is spanning both early- and late-phase programs across multiple therapeutic areas.

Starting with oncology. We are diversifying our portfolio and executing on our strategy, which is broadly based on 3 strategic pillars: immuno-oncology; precision molecular targeting; and tissue targeting. In immuno-oncology, we remain committed to the development of KEYTRUDA and further transforming cancer care to address the needs of certain patients. In the fourth quarter, we received approvals from both the FDA and the European Commission in 2 gastrointestinal indications: one in combination with chemotherapy for the first-line treatment of adults with locally-advanced unresectable or metastatic HER2-negative gastric or gastroesaphageal junction adenocarcinoma based on KEYNOTE-859; and another in combination with gemcitabine and cisplatin for the treatment of patients with locally-advanced unresectable or metastatic biliary tract cancer based on KEYNOTE-966.

As we continue to harness the potential of KEYTRUDA, we have an increased focus on earlier stages of disease, where we believe timely, effective intervention may significantly improve patient outcomes. Last month, we announced FDA approval for KEYTRUDA in combination with chemo radiotherapy for the treatment of FIGO Stage III through IVa cervical cancer based on the Phase III KEYNOTE-A18 trial. This is an important advancement and provides a new option that has potential to become the standard of care.

To date, with all the research conducted with checkpoint inhibitors, the only studies to have demonstrated statistically significant overall survival benefit in earlier-stage cancers are KEYTRUDA-based regimens: KEYNOTE-671 as part of a neoadjuvant followed by post-surgery adjuvant treatment regimen for certain patients with resectable non-small cell lung cancer and KEYNOTE-564 as a post-surgery adjuvant treatment regimen for certain patients with renal cell carcinoma.

Since the approval of a KEYNOTE-671 in October, it is notable that the American Cancer Society released guidance recommending that certain individuals with significant smoking history undergo an annual low-dose CT scan. The guidance also expands the age range for lung cancer screening. We look forward to the opportunity to help impact patients and support the identification of more patients at risk.

Additional data from KEYNOTE-564 demonstrating an overall survival benefit were presented at the ASCO GU conference last week. Detailed findings from KEYNOTE-123 evaluating KEYTRUDA for the adjuvant treatment of patients with localized, muscle-invasive and locally-advanced resectable urothelial carcinoma demonstrating a disease-free survival benefit versus observation were also presented at ASCO GU.

Also in the earlier-stage setting, along with our partner, Moderna, we announced 3-year recurrent-free survival and distant metastasis-free survival data for our individualized neoantigen therapy, V940, in combination with KEYTRUDA for the adjuvant treatment of Stage III and IV melanoma following complete resection. We are encouraged by the durability of the responses observed and the potential for this regimen to impact patients

earlier in their diagnosis. The Phase III trials in the adjuvant setting for certain patients with melanoma and non-small cell lung cancer are actively enrolling.

Progress continues in precision oncology. The FDA approval for WELIREG, our HIF2 alpha inhibitor for the treatment of adults with advanced RCC following a PD-1 or PD-L1 inhibitor and a VEGF-TKI, marks the first drug approved in a new therapeutic class for eligible patients with advanced renal cell carcinoma in nearly a decade and builds on the 2021 approval for the treatment of adults with certain von Hippel-Lindau disease-associated tumors. Additional Phase III studies for WELIREG, in combination with KEYTRUDA and/or lenvatinib for the treatment of certain types of renal cell carcinoma in the advanced and adjuvant settings, are ongoing.

Finally, moving to the tissue targeting space. Together with Astellas and Seagen, now Pfizer, we announced the FDA approval for KEYTRUDA in combination with PADCEV, a Nectin-4-targeting ADC for the first-line treatment to patients with locally advanced or metastatic urothelial cancer based on results from KEYNOTE-A39. These results demonstrated a superior overall survival benefit versus gemcitabine plus cisplatin or carboplatin and extend our pioneering work in combining KEYTRUDA with chemotherapy as well as reinforcing the value of an ADC to enable targeted delivery of chemotherapy to the tumor tissue.

Following the announcement of our collaboration with Daiichi Sankyo in October, we are pleased to receive priority review from the FDA for MK-1022, or patritumab deruxtecan, our investigation of a fully humanized anti-HER3 ADC for patients with advanced EGFR-mutated non-small cell lung cancer previously treated with 2 or more systemic therapies. The agency has set a target action date of June 26.

Through our agreements with Kelun and Daiichi Sankyo as well as our own discovery programs, we have established a robust pipeline of tissue-targeting ADCs. And the recently announced acquisition of Harpoon Therapeutics provides the opportunity to help complement and strengthen our approach by providing a portfolio of novel T cell engagers, the most significant of which is HPN-328, an investigational delta-like ligand 3 targeting T cell engager being evaluated in small cell lung cancer and neuroendocrine tumors.

Our strong diverse portfolio of immuno-oncology precision molecular and tissue-targeting agents positions us well to have a profound impact on even more patients long into the future.

Next to our Vaccine pipeline. We are making notable advancements with our population-specific vaccine program for pneumococcal disease. The FDA has accepted for priority review the new biologics license application for V116, our 21-valent pneumococcal conjugate vaccine, specifically designed for adults supported by results from multiple Phase III clinical trials evaluating V116 in both pneumococcal vaccine-naive and vaccine-experienced adult patient population.

Results from STRIDE-3 trial were presented at the World Vaccine Congress West Coast in November and additional data from STRIDE-3 as well as STRIDE studies 4, 5 and 6 will be presented at the International Society of Pneumonia and Pneumococcal Disease Congress in March.

If approved, as Rob noted, V116 would be the first new pneumococcal-conjugate vaccine specifically designed to address the serotypes responsible for approximately 83% of invasive pneumococcal disease in adults 65 years of age and older, according to CDC data from 2018 to 2021. Importantly, V116 includes 8 unique serotypes, which account for 30% of disease according to the same CDC data. These serotypes are not covered by currently licensed pneumococcal vaccine options. The FDA has set a target action date of June 17.

Turning to programs in the cardiometabolic disease pipeline. We are eager to bring sotatercept to patients as an important treatment option for pulmonary arterial hypertension. The FDA has set a target action date of March 26.

Beyond data from the STELLAR trial, we have the Phase III ZENITH and HYPERION studies, which are evaluating sotatercept in patients with more advanced disease and those earlier on their disease journey. In addition, the Phase II CADENCE trial will evaluate WHO Group II pulmonary hypertension focused on a type of left heart disease.

As we close out 2023, it is important to highlight our significant progress and execution across therapeutic areas and modalities as well as multiple business development transactions. In the year, we have more than 25 regulatory approvals in major markets. We also initiated over 20 Phase III

studies across multiple new classes of assets, including in oncology with bomedemstat, our LSD1 inhibitor in essential thrombocythemia; nemtabrutinib, our BTK inhibitor in first-line chronic lymphocytic leukemia or small lymphocytic lymphoma; MK-2870, our TROP2 ADC in collaboration with Kelun in non-small cell lung cancer and endometrial carcinoma; MK-5284, our CYP11A1 inhibitor in collaboration with Orion in metastatic castrate-resistant prostate cancer; and V940 in collaboration with Moderna for the adjuvant treatment of certain types of melanoma and non-small cell lung cancer.

Also in immunology, with tulisokibart in ulcerative colitis. Finally, in cardiometabolic disease with multiple trials for MK-0616 in hypercholesterolemia.

As a result of the increasing depth and breadth of our pipeline, we are planning to initiate an even greater number of Phase III trials in 2024. Considerable credit goes to my colleagues across the organization for their hard work and unwavering dedication. We are executing on our science-led strategy and look forward to providing further updates on our progress throughout the year.

And now I will turn the call back to Peter.

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

Thank you, Dean. Ivy, we're now ready to take questions. (Operator Instructions) Thank you.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Our first question will come from the line of Umer Raffat from Evercore ISI.

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

I know there's a trial due for you guys later this year, KEYFORM-007 trial. That's the LAG-3 with pembrolizumab in colorectal cancer. Just curious how you're thinking about the risk profile and the odds of success heading into that and if there's been any interim OS analysis.

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

I'll take this. Umer, thank you very much for that question. I mean just to recognize that in MSI high, we have a strong presence with pembro there. The larger group in CRC or colorectal cancer is in the MSS population. At this point, there's not really been any checkpoint inhibitor that's shown dramatic impact in MSS CRC. So our interest in driving pembro plus LAG-3 in that is to demonstrate that a checkpoint inhibitor could have a meaningful impact in MSS CRC.

If we should get a positive signal in that, clearly, we would use that as a beachhead to expand and extend the role of checkpoint inhibitors in MSS CRC, which is a place that requires a lot of more innovation. In terms of specific interim analysis on this, we generally try to keep that when there's data that's worth sharing, that's when we share it.

Operator

Next, we'll go to the line of Trung Huynh from UBS.

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

So for sotatercept, we noticed the HYPERION study primary completion date has now moved to August 26. It was November 29 on clinicaltrials.gov. That's 3 years earlier. Just -- could you just let us know the reason for that change? And if I could sneak one in. Just is there a place to transition sotatercept from inpatient clinic administration to self-administration?

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

So let me take the first question. So there's a series of trials in relationships with sotatercept. So the March date that we talk about is for a potential decision by the FDA for approval based on the STELLAR trial. And we think in the second half of 2024, we may be in a position in relationship to the EU.

We have other trials, as you point out, especially Phase III trials, and they are ZENITH and they are HYPERION. Those 2 are based on events. So it's a tracking of events that sort of define when those happen. So the ZENITH, I think, is now like September 2025 and HYPERION is August 2026. So that's just been event-driven.

In relationship to how best to treat patients, well we're in conversations with the FDA in relationship to where is the best place for patients to be treated. But I'll just highlight that we have an image of an auto injector moving very fast through our pipeline. So that might give you a sense of where we think this may end up.

Operator

Next, we'll go to the line of Daina Graybosch from Leerink Partners.

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

One on Oncology for one of the new assets going into Phase III, the ORION MK-5684. I wonder if you could talk more about that asset. And what gives you confidence that it will demonstrate broad benefit in prostate cancer, in addition to the patients with the ARLBD mutations? And can you confirm the stat design of the 2 Omaha studies will prioritize a hierarchy to statistically look at the mutation segment first?

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

Yes. So just so that everyone is looking at this asset in the same way, there have been critical medicines that ablate androgen field growth in prostate cancer. And the interest in the CYP11A1 is it's very high upstream, and we think that it could be an important contribution.

Clearly, we're in -- as you point out, we're interested both broadly, but especially in the specific mutation patients. And so we will be advancing those trials to look at that subpopulation as well as more broad populations. In terms of the statistical sort of analysis in that, that's something that I think probably would be best sort of discussed with our clinical teams at a different time.

Operator

Next, we'll go to Carter Gould from Barclays.

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

Maybe following up on the commentary on V116. You talked about a potential to reach a majority market share. What does that sort of imply around the potential ACIP recommendation or the potential for a catch-up opportunity in the adult segment?

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

Yes. So I'll just -- so again, we're talking about V116. We're talking about FDA potential action in June 2024, followed by ACIP, followed by MMWR. I think it's in March that we're going to be presenting STRIDE-3 and 6, and I think the data will be out there. And as you'll see in that, between STRIDE-3 and throughout STRIDE-3 all the way to 6, you'll see data in relationship to vaccination of those who are naive versus previously vaccinated. And you will see data in the patient population, or the population that 65, but also in the 50-plus as well. As that data is digested, both by the FDA, but probably very importantly, by the ACIP, I think those data will guide how the ACIP makes their decision.

Operator

Next, we'll go to the line of Evan Seigerman from BMO Capital Markets.

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

I was wondering if you could expand on some of the nuances of your guidance. Specifically, do you include meaningful revenues from sotatercept or V116? I'm assuming they're due for approval at some point this year.

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

Thank you for the question, Evan. This is Caroline. As we've guided for 2024, we're very confident in the underlying momentum in our business across Oncology, across Vaccines, across Animal Health. We also are very excited about the potential launches for sotatercept and V116.

For sotatercept, given the significant clinical data we have and the understanding that there are many patients that have already been identified who can benefit for sotatercept on top of the treatments they have, we are expecting a strong launch. For V116, as Dean just outlined, we'll wait for the FDA approval, the ACIP recommendation. We'll then expect MMWR to publish, and therefore, expect to have impact with V116 coming towards the end of this year.

Operator

Next, we'll go to the line of Terence Flynn from Morgan Stanley.

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

A competitor recently reported some disappointing data with their TROP2 ADC and later line lung. I recognize these TROP2s are all different given the technology, the linkers. But does this impact at all your development strategy for your TROP2 in lung or perhaps increase the need for a biomarker strategy here?

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

Yes. This is Dean. Thanks for that question. So I'll just step back, and I think I've said this previously, especially in lung, it's very important to understand what the standard of care is and that one would have to beat it in a significant way. And the standard of care, in our minds, in the late stage, is roughly KEYNOTE-189. And now in the earlier stage, it's clearly in KEYNOTE-671 both with clear OS data.

What we have said previously is that we are unclear that any one ADC can have as broad of an impact as KEYNOTE-189 or 671 and that in order for ADC to have a substantial advantage in those patient populations, one may need to focus on a biomarker-selected patient population. And so the data that we saw does not change our way of thinking. It's the way of thinking that we've discussed previously.

And I would just add that it's really important, there's also data out there where people are doing retrospective biomarker data in this. For us to demonstrate true efficacy in any patient population, we need a biomarker strategy that is prospective and one that can be easily actionable throughout the world.

Operator

Next, we'll go to the line of Tim Anderson from Wolfe Research.

Adam Jolly - *Wolfe Research, LLC - Research Analyst*

This is Adam on for Tim. On GARDASIL, a 2-dose regimen was recently approved in China. We're wondering if that poses a revenue problem. Potentially, it doesn't, if it just means that more supply gets spread out across more people, and Merck ends up selling just as many doses in total. Can Merck share its perspective here?

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

No, Adam, thanks for the question. So there's actually been Chinese competitors with an offering for some time actually in the Chinese market. And that market is large. We continue to believe in the eligible cohorts in just the urban females, which is the [Tier 1 to Tier 5] (corrected by company after the call) cities, is about 200 million -- a little over 200 million women. And so of that, we think probably about 30% have actually received vaccination. So you're still looking at 120 million, 130 million eligible population.

As we look at this and as we've seen over time, we continue to be very competitive. We're maintaining a vast majority of share in the private market. And really, you're seeing most of the local competitors go to the lower-tier cities and to a different population than we've been targeting. So that does not change our view of the growth potential in China long term. Obviously, we will continue to face competition there, and we are positioning ourselves to continue to succeed there. But the approval you're talking about is not changing our view.

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

The only thing I add, if I may, is we have significant opportunity to protect further females in China. At the end of 2023, we also submitted to the regulatory authorities our data on GARDASIL for males. So we're hopeful to introduce that in the Chinese market in the future.

Operator

Next, we'll go to the line of Mohit Bansal from Wells Fargo.

Mohit Bansal - *Wells Fargo Securities, LLC, Research Division - Senior Equity Analyst*

Congrats on the progress. Maybe one question on V116 as well. So Pfizer has recently made comments around adult market shrinking at this point. So could you comment on how do you see the peak opportunity for V116 in the context of adult market shrinking and then you're taking share from a shrinking market?

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

Yes. I'll start and then Caroline can jump in as well. But I think as you look at the market size and the comments, I don't want to speak to comments that others have made. I think it's also important to understand that as we bring a vaccine which brings significant incremental coverage, at 83% versus, if you look at PCV20, just as an example, it's closer to, I think, about 50%. So you're looking at significant incremental coverage, which I think can have an impact on how you think both about catch-up to cover the disease.

As Dean noted in his prepared comments, we have 8 serotypes covering 30% of what is causing disease, which is unique to us. So we think that, that will have implications both in terms of catch-ups as well as potentially to be able to go for patients 50 and plus versus 65 and plus.

So if you take all of those things into account, we still see this as a very large opportunity for us. Our view is it's about an $8 billion market in '23. We anticipate it actually growing to be over $10 billion later in the decade. And with that being the pediatric segment of that is about 70%. So we're looking at 30% of that is what is the adult piece. So as we see it, this is still a growing market, a good market. And we remain very confident that V116 will both have a majority share and be a meaningful contributor.

Operator

Next, we'll go to the line of Chris Schott from JPMorgan.

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

Just a bigger-picture question on business development. The company has obviously been very active the past few years. And I'm just trying to get a sense of just kind of size and stage of assets that you consider just given the current R&D investments you're making and the asset and kind of the amount of capital you're allocating there. So I guess, specifically, are deals along the lines of an Acceleron or a Prometheus still deals that Merck would look at and prioritize? Or at this point, should you be even thinking about maybe earlier-stage assets that would be more of the focus?

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

Yes. Chris, thanks for the question. Obviously, first, I just want to reinforce the pride I have in what Dean and the team have been able to do and the meaningful progress we're making both in our internal pipeline and what we've been able to do through the business development, which is, I think, in some ways, in a weird way, underlying your question.

As we sit here today, while I feel very good about the progress we've made in the growing portfolio, the diverse and deep portfolio we have in our pipeline, we do continue to believe we need more, and we will continue to prioritize business development. And I would say that our views of deals like Prometheus, like Acceleron are still the size of deals we are very interested in, if we can find great assets. So clearly, that's an area of focus. But also continuing to do smaller deals as well, like what you saw with Harpoon.

So it's going to be a range of deals. But I think as you look in that 0 to kind of $15 billion, $1 billion to $15 billion, it continues to be where we will look for. And then obviously, we've also, I think, shown that not only are we very open to doing acquisition, but we see collaboration as an important tool as well, very similar to what we did with Daiichi Sankyo. So we're going to be looking at the full suite and including deals that fit those categories.

Operator

Next, we'll go to the line of Andrew Baum from Citi.

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

I was going to ask you about your expectations for the ACIP recommendation on revaccination of Prevnar vaccinated patients, but I suspect you may not want to share that view. So instead, maybe I could ask you about the first-line TROP2 SKB non-small cell trials that you're running in combination with KEYTRUDA. Some of the recently published academic data suggests that TROP2 internalization is a biomarker in patients who are primarily resistant to PD-1.

So it just seems like an odd population to be exploring the drug in, assuming that is real and not a fake signal. And I take completely the caveats that it's retrospective data analysis in other settings. But given that, it would seem to be more sensible to have a combination with chemo and layering on top. And can you do this given the profile of the drug in terms of bone marrow suppression?

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

Yes. So I'll just answer more broadly in relationship to TROP2 as an ADC and specifically our compound. One of the things that is extremely useful to us is its adverse effect profile, especially for lung cancer patients and relationship to lung toxicity, is readily manageable. It's a quite good profile.

In terms of your question about the paper that I think that you talked about internalization and this, I think those are interesting and important papers for us to consider. But I think one of the things that's also important for us to do is to do the clinical experiment and see what the results are in relationship. We are confident that TROP2 ADC will have an impact. TROP2 ADCs in breast cancer has had an impact. And we believe that our TROP2 ADC, especially the linker payload, will have an important impact in lung cancer.

And then the question that you have is, how do you combine it? Do you combine it with chemo? Do you combine it with PD-1? How do you think through that? I think those are questions that our clinical team thinks deeply about, but we also think deeply about what line of therapy and also what the standard of care is. And if you want to move to first line standard of care is KEYNOTE-189 with a chemo/pembro basis. So one has to think about how one would advance a TROP2 from different lines all the way to first line. So those considerations come in quite heavily.

Operator

Next, we'll go to the line of Seamus Fernandez from Guggenheim Securities.

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

Congrats on the quarter and the guidance. Can you just talk a little bit about subcutaneous KEYTRUDA, how you anticipate payers' acceptance of this new delivery modality as well as potential economic benefits to patients given the shift from Part B to Part D? I think there could be some benefits from the updated catastrophic cap being drivers there. But struggling in the face of potential biosimilars of KEYTRUDA after 2028 to see how payers would treat this. Just interested to have a little bit more color on the economic benefits, not just the benefits to the patients of subcutaneous KEYTRUDA.

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

So this is Dean. I'll take the first question, and then I'll hand it over to Rob and Caroline because the economic question and the payer is also related to the innovation that you provide. I just want to make sure that our way of thinking about something like pembro with hyaluronidase given as subcu is really there's going to be a call for that innovation.

I'll just emphasize, we constantly speak about the earlier-stage cancer. And right now, we have 9 approvals. And as I've said in relationship in the prepared remarks, of those approvals, 2 -- the only 2 that have checkpoint inhibitors that OS benefit is KEYTRUDA base, which is early lung cancer and RCC.

I actually just came from a meeting speaking to a bunch of thoracic oncologists in this, and it's quite interesting to hear how they speak for those who are thoracic oncologists, who are linked to a setting with medical oncologists, they very clearly understand why KEYNOTE-671 perioperative is a category 1.

In situations where you may have a CT surgeon outside of a major care plan or a care -- a major medical center sometimes you have CT surgeons moonlighting doing lobectomies and resection for that, the KEYNOTE-091. And constantly, what we hear from the physicians and the provider, and many of them are in provider systems of all different types, is the need to have an alternative way to get the KEYTRUDA to them, either Q3, Q6 given the regimen. So I just want to emphasize that the subcu pembro plus hyaluronidase is an innovation that is going to be demanded and is being demanded by the field.

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

Yes. Thanks, Dean. And to the questions on the economics, and I think we've commented on this a little bit in various settings. But as we think about our strategy for bringing this to the market from a commercial perspective, our view is the quality-of-life benefits this brings does demonstrate and afford us the ability to get a premium price. But we also are very cognizant that any subcu pembro will have to be considered in the context of a generic IV version.

So we will price our subcu to drive for volume and to do for conversion, which means we will be looking at prices really more in line with where you would see the generic version at a premium that history has shown is very manageable and expected and covered by payers today when you look at the different delivery for them. So in that sense, we think we will be able to manage this.

The whole question of Part B versus Part D, we'll have to see how it plays out as far as the ultimate side of administration. But if it does end up being into the Part D category, which is a reasonable chance, you are correct in that some of the new coverages that are out there in catastrophic and with a cap, also then from a patient perspective, should lower the burden they're going to face, which we also think could help with conversion.

Operator

Next, we'll go to the line of Geoff Meacham from Bank of America.

Geoffrey Christopher Meacham - *BofA Securities, Research Division - MD*

Caroline, on margins, you highlighted a benefit from KEYTRUDA and GARDASIL this year, which I think was expected. But looking forward, is the guidance this year a reasonable target until the KEYTRUDA LOE? I wasn't sure if there's other drivers going forward or whether mix could impact margins as well.

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

Thank you for the question, Geoff. So as you all know, our company has made great progress in expanding operating margin over a number of years. As we look to 2024, we expect operating margin to improve. And that's really driven by the strength of the top line and mix of revenue by the roll-off of royalties that we've noted on KEYTRUDA and GARDASIL, being disciplined in our expenses, while we do invest fully behind our expansive pipeline.

As we go beyond 2024, we still point to an operating margin of greater than 43% in 2025. But our focus as a company and as a team is to really ensure that we are fueling the pipeline, supporting the portfolio of products that we're launching to drive growth into the long term.

Operator

Next, we'll go to the line of Steve Scala from TD Cowen.

Stephen Michael Scala - *TD Cowen, Research Division - MD & Senior Research Analyst*

I believe the Merck RSV monoclonal antibody Phase II/III study is registrational and reads out this year. Is that correct? And assuming positive, how soon could Merck be on the market? And how might this product be differentiated from Beyfortus? It's just a little odd that this could be a $1 billion opportunity, not that far off, and Merck never talks about it.

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

I really appreciate the question, so I will talk about it. In relationship to the RSV monoclonal antibody, it's for the early birth. It's an antibody, it's passive immunization, and it's for the pediatric population. This is a single shot. This is not weight-based, and we believe it has a longer season in relationship to other choices. And so we think it's an important readout, and we're very excited and interested to move on this RSV monoclonal antibody.

I would also emphasize that the New England Journal of Medicine just published a series of papers, not in RSV, but also in dengue that also we're very excited about. And we're moving that forward quickly. And then more broadly from the ID vaccine, I've said previously that I'm very intrigued to see the results of our NRTTI islatravir and our other NRTTI, MK-8527. So that will also be coming out this year. We'll be able to see those. So it is the RSV. It is the dengue that was just out there, and it is the HIV data that we're going to be very interested in seeing across this year.

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

Yes. And Steve, just to maybe, from a commercial perspective, build on the question, from a launch timing perspective, our expectation is that we would be in the market in 2025. And obviously, we're working to be ready for that season in 2025.

And then from -- a differentiator for us, recall that our coverage covers what is the full prevention season for RSV, which is 5 to 6 months. We're a single fixed dose, not a weight-based administered shot. So for us, those are all very important things.

And the last thing I'd note is the site of action for us is really, we think, has low risk of development of resistance and is different than the competition. So we actually are very bullish on this. I think we don't talk about it, frankly, because we have so many other good things to talk about. It sometimes gets lost. But it doesn't mean we're not excited about this and/or dengue, which frankly, I still believe dengue is a little bit, obviously, later than this but huge for us. So those are things we're excited about. It just reinforces the breadth of the portfolio we have.

Operator

Next, we'll go to the line of Chris Shibutani from Goldman Sachs.

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

If I could ask about immunology, essentially a reentry into that realm with the Prometheus acquisition. If you could just update us on what we should be expecting to learn and also what you find interesting perhaps being to further build out on the immunology platform. Specifically, the clinicaltrials.gov has the Phase II maintenance data in UC is enrolling. Should we expect to hear from you on results there?

I did not observe something there on Crohn's disease. What's the update on that program? And then in immunology further, it appeared from the start of the year a lot of excitement about different modalities, cell therapies in particular, oral advanced treatments. Share with us some views on where you think immunology could go to take Merck to be a relevant presence in the 2030s.

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

Chris, that's a great question and an expansive question. So let me just hit in relationship to the TL1A antibody. We have our ulcerative colitis trial moving forward, and that's been listed and that's moving forward.

I think probably the really important thing for me that I look out is getting the Crohn's disease trial moving. The reason I think it's really important is I'll remind myself that TL1A is in the super TNF family. But TL1A may be different than run-of-the-mill TNF in its ability to not just dampen inflammation but affect fibrosis.

So going from ulcerative colitis to Crohn's disease, Crohn's disease has lots of strictures in this. That will be important. And it will be also important to look and follow -- I follow our data in TL1A in relationship to lung disease and scleroderma. So that's with that.

I would also emphasize that there are other assets within the partnership or acquisition that we did with Prometheus and those compounds, which had already been discussed previously, are advancing through the pipeline as well.

And then the other question that you have is, are we interested in other platforms moving forward? The answer is absolutely yes. I think you had a question in terms of cell therapy with immunology. I think there is interesting there. But as you know, we've -- when we've looked at cell therapy in relationship to cancer, especially not in heme, but in solid, we've been a little bit probably more exploratory. And right now, our view of cell therapy in immunology is one that might be more similar to our view of cell therapy in solid tumor, a little bit more exploratory.

Operator

And for our final question, we'll go to the line of Louise Chen from Cantor Fitzgerald.

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

I just wanted to ask you on your ADC platform, if you feel that what you have is enough for now or do you want to expand or add on to it. And any interest in radiopharmaceuticals?

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

Thank you very much for that question. So when we think about tissue targeting, we think of ADCs. And the answer is, I think the ADC fields will continue to develop, and I think there will be other payloads, other linkers, but also the specificity by which you do the tissue targeting in relationship to the antibody may change.

There's also clearly evidence of potential movements into peptide drug conjugates that we're interested in as well as the possibility that the payload is no longer chemotherapy-based, but other sort of compound-based. So we're interested in that.

In tissue targeting more broadly, we are interested. And so we view that as, okay, that's how we're going to move sort of toxic cell chemotherapy agents into tissue targeting sort of scheme making chemotherapy precision medicine. But we also are very interested in the IO space in relationship to tissue targeting, and that is -- our foray in that is really helped by our proposed acquisition with Harpoon that has a very interesting asset in relationship to tissue targeting and immune engagers.

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

Great. Thank you, Louise, and thank you all for the really good questions and appreciate you sticking to mostly one question. We got through a lot of questioners, so appreciate that. If you have any follow-ups, please reach out to IR. We'll be seeing you soon. Thank you.

Operator

Thank you all for participating in the Merck & Co. Q4 Sales and Earnings Conference Call. That concludes today's conference. Please disconnect at this time, and have a great rest of your day.