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OVERVIEW:

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PRESENTATION

Operator

Welcome to the Merck & Company Q3 Sales and Earnings Conference Call.

(Operator Instructions)

This call is being recorded.

(Operator Instructions)

I will now 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, Julie, and good morning, everyone. Welcome to Merck's Third 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 in 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, 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. We continue to bring forward innovation that can save and improve the lives of patients and animals around the world. We're advancing our broad pipeline and executing in support of our key growth drivers, enabling strong progress for our business and providing tangible benefits to patients. To that end, I want to acknowledge the efforts of our talented global team. Their passion and commitment to our science-led strategy are fundamental to our continued success.

Scientific innovation is truly the foundation of our strategy, and it drives everything we do. We're pushing the boundaries of science through the significant investments we are making across our deep pipeline, augmented by strategic business development. I'm pleased by the continued progress with these programs and our growing diversity across new therapeutic areas and modalities.

Along these lines, we're particularly excited by our recently announced clinical and commercial collaboration with Daiichi Sankyo for 3 potentially first-in-class antibody drug conjugates. The scientists at Daiichi Sankyo are proven innovators in this space, having developed proprietary ADC technology that has resulted in an approved product, which is being rapidly adopted for patients with certain cancers. We're privileged to begin working alongside them to advance this important science and achieve both companies' objectives of addressing the significant unmet patient need in oncology.

Based on our strong conviction in these programs and the profound benefit they may bring to patients, we believe each has multibillion-dollar commercial revenue potential for Merck on a non-risk-adjusted basis approaching the mid-2030s. We're also applying our clinical expertise to accelerate the development of other potentially transformative treatments that we've added through strategic business development, such as Sotatercept for pulmonary arterial hypertension and MK-7240 our TL1A inhibitor for ulcerative colitis and Crohn's disease. This is complemented by our strong commercial execution capabilities, which we expect to amplify the impact of these life-changing medicines and enable the creation of sustainable value for patients and shareholders over the long term.

Turning to this quarter's performance. We delivered robust growth driven by demand for our innovative portfolio. We're confident that we will close out 2023 with continued strong performance, which is reflected in the updated full year outlook that Caroline will speak to in a few minutes.

Moving to our research organization. As I mentioned, we're making remarkable progress across multiple therapeutic areas and our promising late-phase pipeline. In oncology, Dean will speak to the significant success we're having in broadly leveraging the foundational position that we've achieved with KEYTRUDA. This includes the continued advancements we're making in the treatment of early-stage cancers.

We're very excited by the recent FDA approval of a KEYTRUDA regimen for the neoadjuvant and adjuvant treatment of certain patients with resectable non-small cell lung cancer based on the KEYNOTE-671 trial results, which notably demonstrated an improvement in overall survival compared to a placebo and chemotherapy regimen.

In addition, we presented numerous important data sets at last week's European Society for Medical Oncology Meeting across a wide range of molecules, tumor types and indications. Our progress across a broad set of programs reinforces our confidence in the sustainability of our oncology leadership well into the next decade.

We're also making exciting progress in our cardiometabolic pipeline. Most significantly, the FDA accepted for proprietary review our filing for Sotatercept based on the unprecedented results of the STELLAR trial, and we look forward to the potential approval and launch in early 2024. We remain confident that Sotatercept has the potential to change the treatment paradigm for patients suffering with pulmonary arterial hypertension.

We also initiated Phase III clinical trials for our oral PCSK9 candidate, MK-0616. We believe MK-0616 has the potential to provide significant benefit to patients with elevated cholesterol and impact cardiovascular disease on a global scale. We're very pleased with our progress and what we've achieved this quarter as we continue to focus on advancing and expanding Merck's pipeline, and I want to thank Dean and his team for their unwavering commitment to addressing unmet patient needs.

In summary, we continue to move with urgency to deliver on our purpose, pursuing transformative science to save and improve lives around the world. We're executing scientifically, commercially and operationally on the significant opportunities now in front of us, while also making the disciplined investments needed to sustain strong growth well into the future. With the efforts of our global team, we've increased confidence that we will deliver value to patients, shareholders and to all of our stakeholders. 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 highlighted, we achieved very strong growth this quarter, driven by robust underlying demand across our innovative portfolio, and we remain confident in our ability to continue to deliver strong results in the near term. We are also making disciplined investments to leverage leading-edge science to save and improve lives around the world well into the future, positioning us to deliver long-term value for patients and shareholders.

Now turning to our third quarter results. Total company revenues were \$16 billion. Excluding the impact from LAGEVRIO and foreign exchange, the business delivered strong growth of 8%. The remainder of my revenue comments will be on an ex-exchange basis.

Our Human Health business sustained its strong momentum. Excluding LAGEVRIO, growth was 10%, driven by oncology and vaccines. Sales in our Animal Health business increased 2%.

Turning to the performance of our key brands. In oncology, sales of KEYTRUDA grew 17% to \$6.3 billion, driven by increased uptake from earlier-stage cancers and continued strong global demand for metastatic indications. In the U.S., KEYTRUDA growth was driven by increased utilization in both metastatic indications and earlier stage cancers, such as triple-negative breast cancer.

Uptake in earlier stages of non-small cell lung cancer remains strong, and KEYTRUDA has now achieved brand leadership in this setting, reflecting the significant impact it is having as adjuvant treatment for patients with Stage Ib to IIIa disease.

Our recently approved KEYNOTE-671 indication provides an important additional treatment options to patients and physicians by including usage in the neoadjuvant and adjuvant setting. We remain exceptionally well positioned to serve patients with non-small cell lung cancer and extend our leadership to the earlier-stage setting.

In bladder cancer, we are excited to potentially expand usage of KEYTRUDA to Cisplatin-eligible patients based on the compelling results from the KEYNOTE-A39 study. If approved, this study would more than double the eligible patient population for KEYTRUDA in first-line bladder cancer.

Outside the U.S., KEYTRUDA growth was driven by uptake in earlier stage cancers, including high-risk early-stage triple-negative breast cancer and renal cell carcinoma as well as increased demand in metastatic renal cell carcinoma and certain types of head and neck cancer. Lynparza remains the market-leading PARP inhibitor, with alliance revenue growing 6% this quarter. Lenvima alliance revenue had growth of 30%, driven by shipment timings in China, which we expect will negatively impact growth in the fourth quarter. Growth was also driven by increased demand for the treatment of certain patients with advanced renal cell carcinoma and endometrial cancer in the U.S.

Our vaccines portfolio delivered strong growth, led by GARDASIL, which increased 16% to \$2.6 billion, driven by underlying global demand, particularly in China. In the U.S., GARDASIL sales decreased due to CDC purchasing patterns. Vaccine sales also benefited from continued uptake in the pediatric indication of VAXNEUVANCE in the U.S. and its launch in key European markets.

In our Hospital Acute Care portfolio, BRIDION sales were flat as increased market share among neuromuscular blockade reversal agents in the U.S. was offset by the impact of generic entry in Europe. Sales in our Animal Health business grew 2%. Livestock sales grew 7%, reflecting price actions as well as higher demand for ruminant products. Companion animal sales declined due to a reduction in vet visits in the U.S., partially offset by pricing 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 77%, consistent with last year, as the impact from unfavorable foreign exchange was offset by product mix. Operating expenses decreased 4% to \$5.8 billion. There were no significant business development expenses in the quarter, compared with \$690 million of charges a year ago. Excluding these charges, operating expenses grew 9%. This growth reflects increased investments in support of our robust early- and late-phase pipeline, with research and development expenses increasing 17%. Other expense was \$133 million. Our tax rate was 15%. Taken together, earnings per share was \$2.13.

Before I cover the outlook for the balance of the year, I wanted to briefly touch upon the recently announced strategic collaboration with Daiichi Sankyo. This transaction follows a similar derisked and disciplined financial structure as we have employed in prior successful collaborations, and we are very excited about the opportunity to create meaningful value for patients and shareholders.

Now turning to our 2023 non-GAAP guidance, which includes the strategic collaboration with Daiichi. The continuing operational strength of our business has enabled us to raise and narrow our full year revenue guidance. We now expect revenue to be between \$59.7 billion and \$60.2 billion, an increase of approximately \$900 million at the midpoint. This range reflects strong double-digit underlying year-over-year revenue growth of 11% to 12%, excluding LAGEVRIO and an approximate 2 percentage point negative impact from foreign exchange, using mid-October rates. Our gross margin assumption is unchanged at approximately 77%.

We now estimate operating expenses to be between \$39.8 billion and \$40.4 billion. This range reflects \$17.1 billion in acquisition and upfront collaboration, research and development expenses, including \$5.5 billion for the collaboration with Daiichi as well as those associated with Prometheus, Imago, and Kelun. Our guidance does not assume additional significant potential business development transactions.

We now assume other expense of approximately \$200 million, which reflects updated foreign exchange expectations given recent dollar strengthening and higher net interest expense related to Daiichi. Our full year tax rate is expected to be between 39% and 40%, which includes an approximate 24.5 percentage point impact related to our business development activity. Our underlying tax rate is approximately 14.5% to 15.5%. We assume approximately 2.55 billion shares outstanding. Taken together, we expect EPS of \$1.33 to \$1.38. This range includes a negative impact from foreign exchange of approximately 6 percentage points versus 2022 using mid-October rates.

Recall, our prior guidance range was \$2.95 to \$3.05. Including the onetime charge of \$5.5 billion or \$1.70 per share and an estimated \$0.04 to advance the assets and financing costs from the collaboration with Daiichi, our prior guidance range would have been \$1.21 to \$1.31, with the midpoint of \$1.26.

Our current guidance midpoint of \$1.36 represents an increase resulting from the strength in our business of approximately \$0.15, partially offset by an incremental headwind from foreign exchange of approximately \$0.05.

Now turning to capital allocation, where our priorities remain unchanged. We will continue to prioritize investments in our business to drive near- and long-term growth. We are proud of the significant progress our team is making to advance and augment our pipeline, including our collaboration with Daiichi. We will continue to invest in our pipeline which contains many assets with tremendous potential to address significant unmet medical needs, positioning us for strong performance well into the future. We remain committed to our dividend and plan to increase it over time.

Business development continues to be a high priority. Our track record demonstrates our ability to identify compelling science and technologies that have the potential to advance standard of care, access such opportunities in a disciplined and capital-efficient manner, and importantly, to rapidly progress the opportunities for the benefit of the patients we serve and our shareholders. 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 continue to execute a modest level of share repurchases.

To conclude, as we finish the year, we remain very confident in the outlook of our business in the near and long term, driven by the global demand for our innovative medicines and vaccines and our exceptional pipeline. We are in a position of financial and operational strength and our continued 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, everyone. Today, I will start with our oncology programs, followed by vaccines, immunology and conclude with cardiometabolic disease.

Over the last few years, our oncology strategy has focused on leveraging the remarkable properties of KEYTRUDA to establish a diverse clinical pipeline of candidates with novel mechanisms and modalities. This is broadly based on 3 strategic pillars, immuno-oncology, precision oncology and tissue targeting.

In immuno-oncology, we continue to evaluate KEYTRUDA in the metastatic and increasingly in earlier-stage disease settings, while also investigating multiple novel immuno-oncology combinations and co-formulations. With precision oncology, we are selectively targeting pathways to inhibit cancer cell growth. And in tissue targeting, we are developing agents, such as antibody drug conjugates designed to increase cancer cell sensitivity and killing.

The latter is exemplified by our recently announced collaboration with Daiichi Sankyo. Daiichi Sankyo scientists have made pioneering contributions in advancing novel antibody drug conjugate technology with proven benefit to patients. By combining our companies' respective strength, we are well positioned to accelerate 3 clinical stage potentially first-in-class candidates with the goal of transforming the treatment paradigm.

These include patritumab deruxtecan, an investigation of fully humanized anti-HER3 ADC in Phase III. ifinatamab deruxtecan, an investigation of humanized anti-B7-H3 ADC in Phase II. And Raludotatug deruxtecan, an investigation of humanized anti-CDH6-targeted ADC in Phase I. We provided details during our investor event earlier this week, and are eager to begin working with the team. The Daiichi Sankyo collaboration complements our important ongoing alliance with Kelun-Biotech, whose talented scientists have developed their own innovative ADC platform.

At ESMO, new Phase II data for MK-2870 or SKB 264, a TROP2-targeting ADC in patients with previously treated metastatic hormone receptor positive HER2-negative breast cancer, showed encouraging antitumor activity with an objective response rate of 36.8%. This builds on existing data for MK-2870, both in triple-negative breast and non-small cell lung cancer. We are now poised to initiate larger studies, starting with non-small cell lung cancer and expand into additional tumor types.

We are also advancing clinical development of MK-1200 and ADC targeting claudin 18.2. Recognizing the proven benefit of KEYTRUDA in combination with chemotherapy in certain tumor types, we are exploring the tissue targeting concept by evaluating regimens combining ADCs and immunotherapy. At ESMO, in collaboration with Seagen and Astellas, potentially practice-changing survival data were presented from KEYNOTE-A39, EV-302, evaluating KEYTRUDA plus enfortumab vedotin as first-line treatment for patients with locally advanced or metastatic urothelial carcinoma. This regimen represents the first approval of a combination of a checkpoint inhibitor and an ADC.

Turning to immuno-oncology. Evidence continues to emerge for the benefit of KEYTRUDA in the treatment of earlier stage cancer. Positive survival data from KEYNOTE-671, evaluating KEYTRUDA in combination with platinum doublet chemotherapy as neoadjuvant therapy, followed by adjuvant KEYTRUDA in patients with resectable Stage 2, 3a or 3b non-small cell lung cancer compared to preoperative chemotherapy, were presented at ESMO, further reinforcing the benefit of routine lung cancer screening for certain populations to enable early intervention.

Based on the KEYNOTE-671 results, last week, the FDA approved this indication with a differentiated label that includes overall survival. KEYTRUDA has now been approved for 6 indications to treat patients with non-small cell lung cancer. KEYNOTE-671 represents the ACE approval for KEYTRUDA in earlier stage cancer.

Positive data from additional early-stage studies in women's cancer were also presented at ESMO. For KEYNOTE-756 in patients with estrogen-receptor positive HER2-negative breast cancer. For KEYNOTE-522 and high-risk early-stage triple-negative breast cancer. And KEYNOTE A-18 for patients with high-risk locally advanced cervical cancer. Now the FDA recently granted priority review for KEYTRUDA based upon this study, with a target action date of January 20.

We also announced KEYTRUDA significantly improved disease-free survival for the adjuvant treatment of patients with localized muscle invasive and locally advanced urothelial carcinoma based on KEYNOTE-123. And finally, in collaboration with Moderna, the Phase III trial for KEYTRUDA in combination with V940, an individualized neoantigen therapy in earlier-stage non-small cell lung cancer, has now been posted and is poised to start soon.

In Precision Oncology, our efforts continue to yield progress. WELIREG, our HIF-2 alpha inhibitor, is approved for treatment of certain cancers and patients with Von Hippel-Lindau disease, a rare cancer-prone genetic disorder. Studies evaluating WELIREG in broader populations of patients whose tumors display analogous genetic underpinnings are ongoing.

Data presented at ESMO from LITESPARK-005 evaluating WELIREG for adult patients with advanced renal cell carcinoma, following immune checkpoint and anti-angiogenic therapies, showed statistically significant and clinically meaningful improvement in progression-free survival versus the standard of care. These findings support our supplemental new drug application for WELIREG, which was granted priority review by the FDA with a target action date of January 17. Additional Phase III studies in combination with KEYTRUDA and lenvatinib in advanced and adjuvant renal cell carcinoma are proceeding.

First-time safety and preliminary efficacy data for MK-1084, our oral KRAS inhibitor, both as monotherapy in patients with solid tumors and in combination with KEYTRUDA for metastatic non-small cell lung cancer whose tumors harbored KRAS G12C mutations, were presented at ESMO. Notably, the combination arm showed a compelling objective response rate of 71%. While the data are early, we are encouraged by the potential to combine MK-1084 with KEYTRUDA.

In the hematologic space, we will begin enrolling patients in our Phase III study evaluating MK-3543 or bomedemstat, a second-line treatment for essential thrombocythemia, an area with tremendous patient need. Bomedemstat is derived from our acquisition of Imago.

Outside of the U.S., the European Union granted approval for KEYTRUDA for adjuvant treatment of patients with non-small cell lung cancer who are at high risk of recurrence, following complete resection and platinum-based chemotherapy based on KEYNOTE-091. And for KEYTRUDA, in combination with trastuzumab and chemotherapy, as first-line treatment for patients with certain gastric or gastroesophageal junction adenocarcinoma based on KEYNOTE-811.

In Japan, Lynparza, in combination with Abiraterone and Prednisone was approved for BRCA-mutated metastatic castration-resistant prostate cancer with distant metastasis based on the PROpel study.

Now to our broader pipeline. Building on the ongoing launch of VAXNEUVANCE, which Caroline mentioned, progress continues in our population-focused pneumococcal conjugate vaccine program. V116, our investigational pneumococcal conjugate vaccine specifically designed for adults, has demonstrated a robust immune response to all 21 serotypes in the STRIDE-3 and STRIDE-6 studies. Detailed findings from the STRIDE-3

study will be presented at the World Vaccine Congress West Coast in November. If approved, V116 would be the first pneumococcal conjugate vaccine specifically designed to address serotypes responsible for the majority of adult invasive pneumococcal disease in adults.

Our company has deep expertise, given our breadth and depth of knowledge, both in immuno-oncology and vaccines. We are leveraging these capabilities in immunology where the first patient is ready to be enrolled in the Phase III trial for MK-7240 in ulcerative colitis.

Turning to cardiometabolic disease programs. Last month at the European Respiratory Society International Congress, we presented data for Sotatercept, currently under review by the FDA for the treatment of adults with pulmonary arterial hypertension. In an exploratory post-hoc analysis of right heart catheterization and echocardiography data from patients in the Phase III STELLAR study, patients with PAH treated with Sotatercept for 24 weeks on top of background therapy showed a reduction in right heart size and improved right ventricular function and hemodynamic status.

In addition, we presented promising data from an analysis of the Phase III Sotera open-label extension study in PAH. The results support the potential long-term durability of the response to Sotatercept and represent the longest safety and efficacy analysis for this compound to date. Given the serious patient need in pulmonary arterial hypertension, our regulatory and clinical teams work swiftly to submit the necessary regulatory filings for Sotatercept.

The FDA has accepted the biologics license application under priority review, with a target action date of March 26. In addition, the submission to the Committee for Medicinal Products for human use in the European Union has been completed.

Also in cardiology, momentum continues in the clinical development program for MK-0616, or our PCSK9 inhibitor. We have initiated the coral reef lipid study in a broad patient population and coral reef outcomes, a randomized double-blind study evaluating the efficacy of MK-0616, with respect to major atherosclerotic cardiovascular events as well as a separate coral reef study in patients with heterozygous familial hypercholesterolemia.

Over the last 3 years, we have moved with rigor and urgency to advance the best science, while carefully coordinating our efforts internally and externally. We have and continue to leverage the foundational properties of KEYTRUDA, while adding promising candidates with novel mechanisms and modalities in oncology.

At the same time, we have expanded in our focused areas of excellence to establish a diverse pipeline of promising candidates spanning multiple additional disease areas. We understand there is still work to be done, but the tangible advances we are making underscore our purpose of creating innovative medicines and vaccines that save and improve lives. And now I turn the call back to Peter.

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

Thanks, Dean. Julie, we're ready to take questions. And as usual, we request that analysts limit themselves to a single question, please.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Our first question comes from Chris Shibutani with Goldman Sachs.

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

The comments from the capital allocation standpoint seem to indicate that you feel that you've done some critical mass, and certainly some of the deals that you've done have been very important and meaningful. You set the cardiovascular revenue goal in 2030 to \$10 billion. Do you think you've done enough there? And then to provoke relatedly, Animal Health, do you still feel that, that fits within the portfolio you've been building, but is there a reshaping that you could talk?

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

Great, Chris. This is Rob, and I'll maybe start, and Dean or Caroline can jump in if they'd like. But first and foremost, I appreciate the comments. And as we sit here today, and Dean made reference to it, we feel very good about the progress we've made over the last couple of years through the assets we brought in. You mentioned cardiometabolic, but also immunology, the progress we're making to broaden our position in oncology, and I'll get to you in a moment. But as you mentioned, the durable growth drivers we have with vaccines and Animal Health.

But specifically to the cardiometabolic area, I can tell you that today, as we sit here, and just to remind people what we had commented on in the past, we've said, based on both what we received through the acquisition of Acceleron plus other programs we've been developing internally, we expected that we could be in a position to have greater than \$10 billion of revenue potential in the mid-2030s. And I'd remind everyone that was on a nonrisk-adjusted basis.

But I would tell you, as we sit here today, given what we've seen with the remarkable data from STELLAR, the excitement that is coming and we're seeing from key opinion leaders with the potential launch of Sotatercept hopefully early next year and approval even in Europe next year, our confidence that we will achieve that \$10-plus billion is higher today than it was when we made the original comment. So we feel very good. It doesn't mean we feel like we're done, but we feel very good about the progress.

And then as you reflected on Animal Health, we continue to see the Animal Health business as an important business for us. It is a durable growth driver. As we look forward, it continues to be a business that we think will be accretive to our growth, long term. And it has strategic value to us, where we're both benefiting from the synergies that it brings to us, and that it benefits from the synergies coming from the science that we have on the Human Health side.

So as we sit here today, we remain committed that it is the strategic part of the company. But as I've often said, that's not a philosophical view that is unchangeable. It's something we're very objective about and we look at regularly. But I can tell you, as we've continued to look at it, our view has not changed.

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

I would just add one thing, Chris, in relationship to your question but not related to revenue for finance. I would just remind that we have made incredible advances in cancer, and we're known as an oncology company, but the unmet need, the unmet patient need in cardiovascular and metabolic diseases in the U.S. and in the world is quite substantial. And I don't know that we're ever going to be done with that field in the near term. So we are still very committed to do more.

Operator

Our next question comes from Mara Goldstein with Mizuho.

Mara Goldstein - Mizuho Securities USA LLC, Research Division - MD of Equity Research Department

I'm curious, the discussion around KEYTRUDA and migrating components of the revenue to earlier lines of therapy. Relative to when you first made statements about where you expect it to be from a percentage, do you think you're ahead of that at this point in time or on track to where you originally thought you'd be today?

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

Yes. The short answer, Mara is, we are ahead of our -- where we thought we would be. And just to remind everyone, we've been commenting that we expect 50% of our growth to come from movement into the earlier stages of disease in oncology as we look forward to ultimately get to a global percent with it being about 25% of our total revenues. But I can tell you, as where we sit here today, we are tracking ahead of where we expected we would be.

And obviously, not surprising when you see the phenomenal results from KEYNOTE-671, what that's going to mean in the perioperative space for people in early-stage lung cancer, building on 091, the continued strength we're seeing across adjuvant and RCC and melanoma. We're up now to 8 approvals in this space. So we're in a very good position, but maybe I'd ask Caroline if she has anything she'd like to add.

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

The only thing I'd add, Rob, is to your point, we've made tremendous progress. We think this year, we will have 20% of our KEYTRUDA business coming from the earlier stage cancer setting. And as we move forward, given the tremendous data we've had and the indications coming, we're really excited about the opportunity to further grow in lung, in potentially bladder and many other indications.

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

Yes. I just want to make a call out because we had an investor discussion this past Sunday and it really focused on the ADC and Daiichi Sankyo and Kelun. But I just want to call out that for me, KEYNOTE-671 is a watershed moment for the field. I would remind everyone that a similar watershed happened in metastatic lung cancer in 2018, KEYNOTE-189.

And 2018 is when KEYNOTE-671 was initiated. It's an earlier stage. And only after 5.5 years, after only 5.5 years in an earlier stage trial, you have clear evidence of EFS and OS benefit. And I really think this will catalyze a change in how we treat early-stage lung cancer, how we detect early lung cancer and how we screen.

If you think about treating early, those patients with Stage 2 and 3, you can reduce the mortality by 28%. I think it will catalyze people really looking at anyone going to surgery in Stage 2 and 3, not just in 3. People are going to have to think very carefully on why someone should get this regimen.

In terms of detecting early, I think it's really important. How many individuals have a chest CT or a chest X-ray with incidental findings, and there's little follow-up and day-and-age of electronic health records, it's very easy to figure out how many people have incidental nodules that never got followed up. I think that will change.

And I think in screening early, we have guidelines where the adherence is only 6% to 7%. And these guidelines were set 4, 5 years ago, where the concept was it would reduce mortality by 20%. With the data that we have, that number is no longer at 20%. It's much lower. And so I think there will be a push by the American Cancer Society, NCCN, NCI, NIH to simplify and broaden those guidelines because that is -- this is the inexorable march of I/O into earlier stage and into the most important cancer, which is lung cancer, which is the #1 cause of death for women and the #1 cause for men.

And our commitment to this field is not just 671 and 91. It is also, as we highlighted, our interest of moving INT, the individualized neoantigen therapy into earlier stage in lung cancer.

Operator

Our next question comes from Carter Gould with Barclays.

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

Great. Maybe at the risk of going back to that ADC topic, one of the key questions and sort of the back and forth have come out in the TROP2 space is just the ability to combine your TROP2 with I/O going forward. Been a lot of commentary on the myelosuppression there and to the extent that may restrict your ability to combine with I/O. Dean, I'd love to get your thoughts there and any additional commentary you can provide.

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

Yes, specifically to any ADC that we would advance in any tissue tumor type. One thinks about monotherapy, and one thinks about a clear indication and a line of sight. But one also think about how the field develops and in combinations. And those combinations can be with PD-1s, but I would also highlight it can be with chemo, it can be RAS, it can be with novel, hormonal agents, it can be with PARP, it can be with other ADCs. And you have to think from late and earlier.

In relationship that TROP2 specifically in non-small cell lung cancer, I believe that I have said in the past that one has to think about how the field has evolved. There was a watershed moment. It was KEYNOTE-189. And pembro plus chemo in a broad patient population along that indication do really well. So those of us who want to advance what I would say in ADC, a next-gen chemo, that's how I think about it, have to think about a way to combine it with PD-1 in a way that is not just effective, but substantially effective over KEYNOTE-189.

We are very interested in advancing our TROP2 ADC in relationship to that in that combination. Like all chemotherapy-based treatments, whether it's chemotherapy or whether chemotherapy on a payload with ADC, one has to think about adverse effects and combinatorial adverse effects and the ability to keep patients on the medicine.

The data that we have shown with our partner, our valued partner, Kelun, is that we think that there is room to be able to advance MK-2870 and PD-1 in a variety of tumors and that they are combinable, tolerable and will be effective. But those are the trials that we're starting to do in Phase III in the ex-China regulatory arena.

Operator

Our next question comes from Seamus Fernandez with Guggenheim.

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

So just wanted to talk about margins and some of the margin targets that you've offered, I think, historically, you called out 2024 margin target of better than 42%. Just trying to get a better sense of how we're tracking towards that target. Particularly in the context of the substantial reduction in your royalty burden, both for KEYTRUDA and GARDASIL. And if you wouldn't mind, would you perhaps disclose what that cumulative royalty burden was in the third quarter of this year, just so that we can provide some context for the upside case or at least what we should be anticipating there?

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

Seamus, thank you for the question. We've seen really strong margin expansion in our company over the last several years. And as we look forward, we expect continued margin expansion. And that margin expansion really comes from the product mix on the revenue line. It also comes from the

roll-off of royalties, as you've just noted, knowing that we have the royalty on our global KEYTRUDA sales going from 6.5% to 2.5% at the start of next year, and our royalty on GARDASIL going from 7% to 0% on our global sales, again at the start of next year, will drive significant gross margin improvement.

At the same time, we will be investing in our business. We'll be disciplined in that investment, but we're investing in the portfolio of products that we have in the market and that we will be launching as well as investing in our robust and growing pipeline.

And that obviously includes the Daiichi's collaboration, where we've noted we expect about a \$0.25 impact as a result of investing predominantly in the research and development of the wide range of programs that Dean has partially outlined as well as this financing cost. We also have made significant progress across our pipeline with many other collaborations, acquisitions and the progress we're making with our own internal assets.

So altogether, we still do point to an operating margin of greater than 43% in the year 2025. However, we will not forgo necessary investments in our business to progress our pipeline to ensure that we advance health care and drive growth, which really is our priority.

Operator

Our next question comes from Terence Flynn with Morgan Stanley.

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

I guess another one for Dean on the TROP2 landscape. I know you guys talked over the weekend about your first Phase III trial in lung cancer here. Maybe just any more context on the decision to pursue the EGFR mutant population, given what you're seeing from the landscape out there, including some of the Astra data. And then what that means for the frontline setting as you try to craft a trial in that broader population.

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

Yes. So I just want to make sure that whether we're talking about our wonderful partnership with Kelun or with Daiichi Sankyo, we sort of lay out certain indications that becomes public, but I want to be very clear that those are not the only indications that we would be interested. So that's number one.

Number two, in relationship to MK-2870 and advancing it more broadly. And it relates to the other question. There is -- we still have small numbers. But what's really interesting for us is 2870, there are differences in the construct in terms of its payload, in terms of the linker, in terms of the [DOA] for that. And one of the things that's interesting to us is, at least to date, we do not see serious ILD. And that allows us to think broadly and thoughtfully about its combinability in relationship to broader indications. So we're very interested in advancing.

In terms of 2870 and the specific first trial that's been revealed, it's -- I'll just tell you, it was driven because of the data that we have, and the data that we have we think is quite good and should be advanced. We are going to advance other ones, but the advancement in the EGFR mutant population is based on data that our partners, Kelun and us have generated, and we're very confident in advancing in that specific indication.

Operator

Our next question comes from Andrew Baum with Citi.

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

Question in relation to TIGIT and vibostolimab and your KEYVIBE-003 trial. I'm assuming that you are using a similar type clinical design and template for the stats from KEYNOTE-042, where you have a hierarchy. Given this is a PD-L1-enriched trial with the hierarchy in place, we were expecting an interim potentially at the very end of next year, beginning of the following year. Any comments on either design or timing of interims?

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

I would just say that in general principle, your observations of how we develop drugs, especially in the I/O, has been something that we're known for and the structure was laid out by by great leaders from Merck who laid the basis for that. In relationship to timing of interim analysis, we have generally not commented on interim analysis. And we let those interim analysis do what they need to do, which has come. And if they're significant, we make that publicly known. If there's significance in relationship to public disclosure, that's when we do that. But we generally do not lay out the timing of our interim analysis prior to them happening.

Operator

Our next question comes from Louise Chen with Cantor.

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

I wanted to ask you about Sotatercept, how you're preparing for that launch. What's your go-to-market strategy? And how quick do you expect uptake to be?

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

Yes, Louise, this is Rob. I'll maybe jump in, and Caroline can add if I miss anything. I would tell you that we feel well prepared. So obviously, we've been working to ensure we have supply to be able to supply the market upon launch. But as we sit here today, given what is happening in the marketplace -- so you are seeing warehousing of patients in anticipation of the launch of Sotatercept in the United States. And from feedback from key opinion leaders and what we're hearing from the market, the demand for this will be quite high. So our expectation is you will see a strong launch with this drug.

And I can tell you, we've invested and built an organization. We actually have a very focused group now in our U.S. -- within our U.S. business, whose sole job is to manage this launch. And so I think we're both prepared from a commercial perspective and from a manufacturing perspective, with the expectation, as I said, that this should go with a very strong quick uptake.

And the other thing I would highlight is, given the strength of the data, we do expect to see approval in Europe next year, which we originally thought would require a further study. So not only are we preparing in the United States, but we're also preparing in Europe as well, and we feel good about both. But Caroline, anything you would want to add?

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

No, I think you captured it, Rob. Dean, anything you'd want to?

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

Yes. I just want to emphasize Sotatercept. This is the first drug out there that really is targeting the fundamental genetic basis of the disease. It's going to be the first Activin inhibitor. But most important is, Activin is what the genetics tells you is the imbalance that occurs in pulmonary artery hypertension.

So this is really important. And I said watershed previously. I do think this is going to be a watershed moment for PAH. Rob already talked about the U.S. and EU. And the reason why that happened is because of STELLAR data was quite impressive. And that's what drove the ability to do EU.

What I would remind everyone is that we have other trials coming through. We have ZENITH, HYPERION and CADENCE. ZENITH, for example, is one that's going to look at mortality and those sort of endpoints as the primary endpoints. Should that read out in the next year or something like that relatively soon to the launch, I think whatever estimates that Caroline and Rob have talked about Sotatercept, that will only help the uptake of Sotatercept. And as Rob has mentioned, this is a field that many of the physicians -- this was a place of where I did research back in the academic days. The phone calls I'm getting is that people are warehousing patients in anticipation of that March launch.

Operator

Our next question comes from Chris Schott with JPMorgan.

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

I just had a question on GARDASIL. We've seen obviously some very impressive growth over the past few years. But looking ahead, I'm just interested in how much more opportunity for -- you see for this franchise to ramp from here. So maybe just elaborate a little bit more on what are the kind of unmet needs at this point? Where is the biggest opportunity to continue to kind of roll out the product? And just ultimately, how much larger can this franchise become over time?

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

Yes. Chris, no, I appreciate the question. So one, I would say we feel very proud of GARDASIL has -- strength of this business. And the fact that people increasingly recognize that we can fundamentally do what's the most important, which is prevent cancer, prevent cervical cancer, increasingly prevent certain head and neck cancers if we can get people fully vaccinated. So the fact that you are starting to see that progress is important.

But as we look at the business going forward, I would start by saying we remain very confident that this is a business that's going to continue to grow and that we will achieve the expectation we've communicated of over \$11 billion in revenue by 2030. So nothing has changed in how we see the business. As you know, we've made significant investments in manufacturing capacity. And from that perspective, now we're well positioned. We've brought on our 2 sites, and they're ramping now. And so we're doing quite well from that perspective.

And then as far as the opportunities that exist to potentially continue to drive even beyond what we just discussed, really, I would put in 3 buckets. And our ability to achieve that objective and then potentially exceed that objective really come down to these 3 variables.

And first and foremost, while we've had great penetration in the developed world, a huge opportunity still exists in the low and middle income markets. And I can tell you, we have a focus and an intention to drive this business into the low and middle income markets. Obviously, that's going to require us to continue to drive down our manufacturing costs, which we have plans to do. And I have confidence that we will do. And to think about lower price points, but that said, that will be a meaningful incremental revenue as we achieve that over time.

And then as you look at the established markets, there still is a large population to address. Obviously, to date, we've been driving largely through public vaccination programs outside the United States, in the United States through the nationalization program, primarily aimed at young women

-- young girls. Increasingly, the opportunity to go to broader age cohorts as we think about going now to people age 45, that ability to move into the mid-adult segment is a real opportunity in the United States.

It continues to be a driver of growth. It's increasingly going to be a growth driver in Europe, and it is currently an important part of why we're driving growth with the recent expansion we got in China, and there are more markets to come. So as we look at that, that's going to be another lever of growth.

Obviously, the difference here is this requires consumer activation. That takes commercial investment and a lot of heavy lifting. We've demonstrated we can do it like we've started to do in China and as we're starting to do in the United States. But it is going to take a lot of work and investment, and we're committed to doing that. So that's another variable that we look at.

And then lastly, this is still largely seen as a female vaccine. We only -- I think it's only 70 markets have gender-neutral approvals. And even in the markets that do have it, particularly as you look at markets like Europe, there still is a real opportunity to increasingly bring people to understand that this is not just a female cancer vaccine, it is a gender-neutral cancer vaccine. And with the growing incidence of head and neck cancers, which is primarily a male-dominated cancer, we do see real opportunity to continue to push and drive, both getting more markets to gender-neutral and in the markets where we have those approvals drive vaccination rates up. And probably one of the bigger near-term opportunities is to get gender-neutral approved in China, which is an opportunity.

So across all of those, there's opportunities and potential. It's a heavy lift. I don't want to indicate that it's going to be easy. And we're going to invest behind it. But that really will determine ultimately, our success across those variables will determine the success we see long-term with this franchise. But maybe Dean or Caroline, anything you would add?

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

Yes. I would just emphasize 2 points, one, directly related to what you said. This is a highly effective vaccine to prevent women's cancer, cervical cancer. And that is something that everyone recognizes, but the gender-neutral part is really important. And at MRL, we're advancing studies and filings in relationship to make sure that as many places that can adopt gender-neutral can be in that position to do gender-neutral.

I also want to just make one comment about cervical cancer itself. We talk about CAR T-cell in relationship to cervical cancer, but I would also emphasize that at ESMO, we had KEYNOTE A-18. I would remind people that cervical cancer is still the fourth leading cause of women cancer, and this was another trial that showed the effect of KEYTRUDA in earlier stage in combination with chemo radiation.

So that, I think, is a PDUFA date that's coming up, and that hopefully might be the ninth early stage. And I believe that PDUFA date is among like 4 that are coming up in the next 6 months in relationship to cancer. So CAR T-cell gender-neutral, but also cervical cancer being a critical driver and driving into earlier stage, those are all things that play around what we're trying to do at Merck.

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

Thanks for the question, Chris. We have time to take some additional questions and go past the hour. Julie, next question, please.

Operator

Our next question comes from Geoff Meacham with Bank of America.

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

A question for Dean or even Rob on ADCs. So you guys have obviously done a number of deals, have partnered assets. And clearly, you think this approach is strategically important for Merck. So the question is how much of an investment is Merck making in building out a broader ADC platform, in-house? I'm just thinking beyond the partner programs and especially, Dean, as you called out, the I/O paradigm is shifting earlier.

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

Yes. Thanks for that. I'll grab that one. So we've been very lucky to partner with Kelun and Daiichi Sankyo. And that advances our clinical programs at scale. We also clearly have collaborations with other ADC companies in relationship to KEYTRUDA. So we have a wall of data of understanding what we are hoping that the field might navigate towards.

And like everyone has said, there will be different antibodies, different antibody structures to be able to change how one thinks about the tissue targeting component. There will be changes in terms of the linkers. And for right now, there are probably 2 major payloads that people use, microtubule-based chemotherapy as well as Topo 1-based chemotherapy. I would just emphasize that there are only -- there are not just 2 classes of chemotherapy out there for the last 30 years, and each one has a reason why they're there.

So we have invested in an ADC platform that is separate, but we'll build off what is learned from our clinical programs both in the ones that we're doing with Daiichi Sankyo and Kelun as well as those that we're doing where we're collaborating with others in relationship with KEYTRUDA. So we have built and we continue to build that expertise within the company, and we hope to see those internal programs during its clinical head in the next couple of years.

Operator

Our next question comes from Steve Scala with TD Cowen.

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

What is VAXNEUVANCE's share in pediatrics now? And why hasn't it seen an inflection in the U.S. sales in line with Merck's prior comments that it held 30% share of the pediatric market with plans to grow from there? I mean 30% share of a \$6 billion market is a big number, and it's well ahead of where current sales are landing. So any color would be appreciated.

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

Yes. Steve, I'll maybe jump on that and then others can jump in. But so your answer is we are in that low 30% share, both in the public and private market. So that is what you're seeing in the quarter. I think the U.S. roughly was about approaching, I think, \$185 million to \$200 million of total business for the products. So we're actually seeing growth pretty much consistent with what we expect, and the share we got is pretty much what we expected. So we'll have to think through how to -- the disconnect in what you're seeing, but I can tell you, in fact, we are doing exactly what we expected we would do.

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

This is Caroline. The only thing I'd add to that would be the performance we're also seeing outside of the U.S. So while we're early in our launch outside the U.S., we have gained 50% of the tenders in which we have participated, and we're shifting shares north of that 1/3. So we're very confident in our ability to continue to drive VAXNEUVANCE and very much looking forward to augmenting our offering with V116 later next year.

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

Yes, I would just add...

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

Steve, let me just clarify one thing because I think it's important. I was just reflecting on your question. Just to clarify my comment, it's 30% is the exit share, not overall of the year. So that's an exit share as we're seeing the business grow today.

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

Yes. I wanted to just make a comment about VAXNEUVANCE in the setting of what Caroline said about V116. It's essentially with VAXNEUVANCE and V116, what we're trying to do is to drive precision medicine mindset to vaccine, giving the right vaccine with the right set of serotypes to the right age group at the right time.

And we believe that, that strategy is important for VAXNEUVANCE and to think about VAXNEUVANCE, not just on its own, but in relationship to V116. And we have work cut out to us in relationship to a potential approval from the FDA as well as we'll have to speak to the ACIP as we advance this concept of a precision medicine mindset to pneumococcal vaccination.

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 want to touch on MK-0616. So clearly prioritizing this given the advancement into multiple Phase III trials. Maybe talk to me about the importance of an oral PCSK9 given the dynamics we've seen in the injectable market with both the antibodies and other long-acting assets?

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

Okay. I will take that one. And I will give my homage to Helen Hobbs and Jonathan Cohen at the UT Southwestern Dallas Heart Study. That was really important data in relationship to showing PCSK9. And if you look at that patient population, that patient population is desperately in need of an oral potent LDL-lowering cholesterol medicine, and that's what we're trying to provide. We're trying to democratize that pathway such that people, whether they're rural, in the intercity or globally, can get this.

And so I would just emphasize the other point, which is cardiovascular disease, atherosclerotic disease is still the #1 killer in the United States and the developed countries, and lowering LDL is known to be important. We used to talk about statin-resistant or refractory, but my experience is that the level of LDL that you're going to have to drive to that increasingly, the guidelines are taking this to is, forget about whether you're refractory or resistant to statins. It will be very hard with one agent to get your LDL below 70 or below 55 in some patient populations. That patient population you want to treat, you want to have that treatment readily available with no coaching and no requirement to go into a hospital system to get it. That's what we're trying to do. And hopefully, our data will support such a move.

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

Thanks, Evan. Maybe final question, please, Julie.

Operator

Our next question comes from Mohit Bansal with Wells Fargo.

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

I just want to touch upon among EGFR mutant patients. How are you thinking about a TROP2-ADC versus HER3-ADC? Because if you look at your data or even AZ's data, it seems like TROP2 seems to be working quite well among those AGA mutations. So how are you thinking about these 2 ADCs in that same indication?

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

I think that's a great question. I would just answer that I think the TROP2-ADC data is important to look at, but I would also emphasize that the HER3-ADC program is reasonably advanced in that patient population. And so we will -- we're interested in advancing both and getting the best medicines to the patients as quickly as we can.

I do think more as a general statement that the role of biomarkers for some of these ADCs outside of EGFR will be important in relationship to tissue targeting, also in relationship more broadly for ADCs and other combinations. And so we'll have to see how that field is moving.

But essentially, the way I think about ADCs is trying to bring chemotherapy in the precision medicine approach. And with that, we're going to have to find the right patient population with the right biomarkers to give them the maximum benefit.

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

Thank you, Mohit, and thank you all for your time and attention today. Please follow up with Investor Relations if you have any additional questions. And we look forward to being in touch soon. Thank you all very much.

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