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OVERVIEW:

Company Summary

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PRESENTATION

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

Good afternoon, everybody. I'm Chris Schott at JPMorgan, and it's my pleasure to be introducing Merck today. From the company, we have Rob Davis, Chairman and CEO as well as Dean Lee, President of Merck Research Labs. So Rob and Dean, Happy New Year. And great speaking of you today. We're going to have a presentation from Rob, and then we're going to move over to a Q&A session from there.

But obviously, it's been quite a year for Merck or quite a few years for Merck. Company's built on its pipeline really nicely. It's been active in a lot of deals. So excited to hear from the progress the company has been making. So with that, turn it over to Rob.

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

Thanks. All right. Great. Happy New Year, everyone. Thanks for having us. Before we get started, I did want to just point out I will be making forward-looking statements, which obviously you can see our statement here and go to our website if you have more questions about that. But if we turn to where we are from a business perspective, I couldn't be more pleased, frankly, on where we are and how the business is performing. The slide I have up here, you can see, is really a repeat of a slide I showed a year ago, and it talked about the priorities we've been following as a company.

And I'm happy to tell you that not only are we consistently still following these priorities, but we've made significant progress across each of them. What we're doing commercially, operationally, how we're advancing the pipeline, what we've been able to do through business development, all of it positions us, importantly, for continued growth but more importantly, for sustained growth well into the next decade. And that's really where we, as a management team and as a company are focused, how do we deliver for the patients well into the next decade. And we're in a great position to do that, and that translates directly into shareholder value. So I feel very good about where we are.

But maybe just to give you some proof points to that. If you look at 2023, 2023 was another year of great execution. If you look at it from a revenue perspective, we delivered nominal growth, excluding LAGEVRIO, of 9%. And importantly, what you see is that averages out to 12% growth over the last 3 years, so consistency of growth, and that growth is coming from all of our key pillars, which is very important.

But as equally important, if not, more important is what you see in the middle column. And that's the progress we're making with our pipeline. And what you see here is that we, in 2023, initiated over 20 Phase III studies across 8 new, if you will, assets and new classes of assets, which is important.

But what that shows you is not only the increasing depth of our pipeline but the breadth, and you see that from the chart, whether you talk therapeutic area or you talk modality. We have one of the broadest and deepest pipelines we've had as a company in years. And as you look at 2024, it's only going to get better because we actually expect to start more Phase III studies in 2024 than we did in 2023.

And why that's so important is we've been a story of KEYTRUDA, of GARDASIL and of execution. We're increasingly becoming a story of growth from new product launch. And that is something we're very focused on, both from what's coming from our own pipeline but importantly from what we've been able to do from a business development perspective, whether it's Prometheus, Acceleron, and we'll talk about sotatercept in a

moment, what we did with Daiichi Sankyo. And I'm thrilled, if you look at what we've done from both Daiichi Sankyo and with Kelun, we have a leading position now in antibody drug conjugates. And we've done that through what I think is very smart deal making. And so I'm very excited about that and the breadth of the portfolio we are driving.

And what all of that really translates to is the potential for growth. But if you look at discussion of new product launches, we have 2 very important launches coming in 2024. The first one is sotatercept in PAH, and I will tell you, we see this as a foundational therapy for patients facing pulmonary arterial hypertension. That's not an insignificant statement to make. This is a devastating disease, and we have a drug that not only addresses the symptoms but we believe, based on the initial data we've seen, actually can start to look at disease modification.

And as we bring this forward and we have a PDUFA date in March of 2026, as we look at that for priority review -- actually, I should say March 26, 2024. It's something that we're very confident in our ability to deliver the launch of this drug, and we're very -- both well positioned and ready. But importantly, what we're hearing from the key opinion leaders is excitement about what this can mean for patients. And so that sets us up, we believe, for what is going to be a fast launch and one, frankly, that I continue to think, despite all the discussion of sotatercept is underappreciated. And we can probably get into that in the Q&A.

But equally important is what we're doing with V116 in pneumococcal disease. This is an area where there is still a high unmet need. And what we have is a new vaccine specifically targeted to the adult population that addresses 83% of the residual disease that causes pneumococcal disease in adults. That's about 30% higher than anyone else that's out there. We believe this is an opportunity. We believe we will take a majority share in this space, and it's building on what we have with vaccine advance and sets us up well for a continuing portfolio we have in the vaccine space.

Each of these, we see as multibillion-dollar opportunities. Each of these, we are in a position to fully go after, and I am quite confident you're going to see us not only deliver growth in the initial phase but long into the next decade.

As you look at what this means and how it translates as we think about the midterm growth, we are in a position to deliver continued strong growth based on our highly derisked portfolio of products, whether it is in oncology with KEYTRUDA as the foundation, which continues to do quite well and we expect to continue to do quite well into 2024, driven on movement, a continued movement into earlier stages of disease and into broader tumor types, with our vaccines business based on GARDASIL as a foundation.

And importantly, our Animal Health business is one where we think you're going to see it return to strong growth in 2024 and then obviously, the growing business we have in cardiometabolic based on what we have with sotatercept. So strong opportunity for revenue growth as we look out over the midterm. But importantly, we're going to deliver that growth while also delivering strong margin.

We continue to believe we're going to be at operating margins in excess of, as you can see here, 43% by 2025. And as we look at that, I think the most important thing I would want you to take away is we're delivering that margin based on the strength of the business, based on the portfolio mix, the fact that we have a meaningful step-down in royalties, and we are being very smart in how we're managing our SG&A. What we are not going to do is sacrifice any investment in our pipeline.

We will continue to fully invest in our R&D and continue to fully invest in the business development to drive the next generation of products. And I think that's very important. It doesn't take away from our belief and our ability to hit the 43%, but I want to make sure you understand that we understand investing in our business for sustainable long-term growth is the best path you can take to sustainable growth and value for the company long term, and that is where we're going to focus. And then lastly, we're going to continue to pursue business development. While I feel very good about what we've done to date, there's more to do.

There's more to do, and we see more opportunity. We're going to go after it. And most importantly, we have a balance sheet that affords us the luxury of, frankly, being able to do what we see as value creating in the business, and we will continue to pursue that.

And as you look at that, that's why, as I sit here today, I can tell you my confidence in the growth is so significant. And we'll come back to -- here, I'll come back up at the end and maybe close with some comments to give you a little sense of that. But before I do that, what I'd like to do is ask

Dean to come up and maybe dive a little bit deeper into the pipeline to give you a sense of what all we're talking about beyond just some of the few highlights I made.

So with that, Dean, I'll turn it over to you.

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

Thank You. Happy New Year's to everyone or -- and we wanted to just reemphasize what Rob said. It's -- we've made significant pipeline advancements. He's talked about the 20 Phase III and the 8 novel assets that we've moved through. But we also had greater than 25 regulatory approvals in '23 in major markets. So that's movement and the movement has breadth and depth in oncology, in vaccine, infectious disease, in general medicine. So these are important points. And probably the most important is we just had an MRL, Merck Research Laboratory, get together, and we intend to make 2024 even busier for ourselves.

What we've always said is that we needed to diversify our oncology, and we have done it, and we've done it around 3 buckets of biology: immuno-oncology, precision molecular targeting and tissue targeting. Rob talked about moving KEYTRUDA into earlier stages of cancer, especially in lung cancer. That came through. Our colleagues at Moderna just presented. We gave an update most recently about moving some precision molecular targeting agents, the CYP11A1, the PDK inhibitor and the LSD1 inhibitor into Phase III recently.

And we've always stated our interest in tissue targeting. We've had great partnerships with Daiichi Sankyo and Kelun that have been very important to us. And we've also been interested in tissue targeting not just with chemo-like payloads but with immune engagers. And as you heard today, we made a deal with Harpoon precisely for an immune engager in small cell lung cancer, a really devastating disease.

When we talk about our antibody drug conjugates, again, it's our collaborations with Kelun and Daiichi Sankyo. The HER3 ADC was submitted for -- filed. And we hope to see an approval of this in this coming year. You've heard about TROP2. We're excited B7-H3, CDH6 and the others. Most importantly is this is the past year where the concept of moving a PD-1 with an ADC was derisked not just for Merck but for the whole field in the work that we've done with Seagen in relationship of PD-1 and an ADC.

We're progressing this broad pipeline, not just in oncology. We said that we were going to also expand into other therapeutic areas. And these are some of the examples in infectious disease and vaccines, cardiometabolic. I actually want to turn your attention to neurosciences. There's a lot of interest in neuropsychiatric sort of diseases recently, and we have schizophrenia. We have Alzheimer's clinical syndrome and narcolepsy that we're advancing. And we've talked about immunology, especially in relationship to the TL1A antibody that we're advancing that I'll speak about. But I want to remind everyone, the deal for Prometheus was not just a deal about TL1A antibodies. There were other antibodies, and I've listed here CD30 ligand and another one that we're advancing in the clinic very fast. So these are moving progressively through the pipeline, and we're expanding into new therapeutic areas.

I just wanted to give an update in terms of our TL1A antibody. Again, the critical point I wanted to emphasize is we think this is going to be the first-in-class, best-in-class TL1A, and we're advancing it and our Phase IIIs have started. We believe it's anti-inflammatory and antifibrotic in ulcerative colitis. We're advancing it, thinking about it as an anti-inflammatory. In Crohn's disease, we expect that Phase III to start in 2024. And in that Crohn's disease, our mindset is this is a way that we can show that it's anti-inflammatory and antifibrotic and in scleroderma interstitial lung disease, we're going to test the concept of how effective is this as an antifibrotic.

So with that, I'm going to turn it over back to Rob to close out.

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

Thanks, Dean. Hopefully, you get a sense whether it is the breadth across all the therapeutic areas where we have opportunities, the depth given the number of programs and the fact that now we're moving from early stage with a lot of programs, as I mentioned, moving into the late stage. This is why we have such confidence in the long-term growth of this business. And what's most important, and I have it at the top of the slide, but

when we think about the impact that we can have on patients with the portfolio we're bringing forward, it's meaningful, and it will be meaningful now and well into the future. And as we've always said at Merck, if we focus on the patient and if we deliver for the patient, the value takes care of itself. And I'm confident to tell you that with this portfolio and delivering for the patients, we are well positioned to have that, in turn, create meaningful shareholder value over the long term.

And to give you some proof points. As we look out, obviously, I know the conversation continues to be about KEYTRUDA in 2028. But increasingly, we're not focused on 2028. 2020 is just another year, just another point. We're focused on 2030 to 2040. And why that is, is the confidence we have in the pipeline we developed and the value it's going to create.

And you see here -- first of all, if you remember, going back, I think it was at this conference a year ago, Chris, we mentioned for the first time that we had a portfolio of small molecules in oncology, ADCs that we believed would have the opportunity to generate greater than $10 billion. I can tell you today, as we sit here, we believe that portfolio and then when you add the 3 new ADCs we brought in through Daiichi Sankyo, if you add in the INT therapy we have now with our partnership with Moderna and if you look at several of those programs, the CYP11A1, LSD1, they're all focusing and moving into Phase III. We now are confident to tell you we believe that's going to generate greater than $20 billion as we move into the early to mid-2030s.

Now obviously, this is on a non-risk-adjusted basis, this is potential. But importantly, it's tangible in that we can point to specific assets. And also, equally importantly, we've seen no major failures in our pipeline.

If I sit back to where I was with you a year ago and look forward, every major program has moved forward. We've really had only one hiccup in the last few years, and that was islatravir. And I know Dean would tell you, we don't have time. Maybe we'll get into this into the Q&A. I would call that a dark horse. We have not given up on islatravir, and in fact, we believe that now we're starting to see some real opportunities there. So we'll see. We'll see. That's a promise to be fulfilled, but we're committed to running the experiment and seeing where it goes.

So as we sit here today, we feel very good. We also had talked about cardiometabolic disease and the fact that we saw $10 billion -- of greater than $10 billion of potential in our cardiovascular disease. That, at the time, was based largely on what we saw with sotatercept. Obviously, we have our oral PCSK9 MK-0616 and in the other assets, there was a total of 8 potential launches. As we sit here today, given the continued advancements we've seen with sotatercept, our confidence in what that drug can be, an oral PCSK9 and the continued progress we're making there.

Now with MK-6024 in NASH, we are sitting here today telling you we think that's approximately $15 billion of nonrisk-adjusted value by the time we get out into the early to mid-2030s. And then obviously, Dean spoke briefly about what we're seeing in the deal with Prometheus, but it's important to understand, in just ulcerative colitis and Crohn's alone, in each, we see multibillion-dollar opportunities with our TL1A.

So that, importantly excludes other opportunities in our pipeline, whether it's from vaccines, from neuroscience, from animal health, which we continue to believe will be a strong growing business well into the next decade, our early phase programs, everything we're doing around KEYTRUDA and thinking about how do we continue to ensure that we bring patient value from KEYTRUDA through co-formulations, through subcu delivery, through how we think about combinations and importantly, additional business development, which we plan to continue to do.

That's why, as I sit here today, my confidence that where we should be focusing is how do we bring that growth in 2030 to 2040 is where our mind is because while we still aspire to grow through KEYTRUDA -- I haven't given up on that. In fact, I would tell you, I feel a lot better about that statement today than I did a year ago -- we, at a minimum, are quite confident we will grow beyond KEYTRUDA. And if we do that, we will deliver for patients and in turn, will deliver for all of you, our shareholders.

And so with that, I'll turn it back over to Chris, and we can jump into the Q&A.

QUESTIONS AND ANSWERS

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

Great. Appreciate that. Maybe just to kick it off, Rob, you're, I guess, 2.5 years or so into your seat. A lot of change occurred at Merck, a lot of build out of the portfolio since then. I guess where -- what are you most focused on at this point given the bets you've made in the pipeline, what you've seen with commercial execution? Like what are the areas we still need to kind of address within the business?

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

Yes. So I would tell you, while I feel very good and the things that I mentioned in the prepared comments, I'm very proud of the progress we've made in the pipeline, and it continues to always outpace. Credit to Dean and our research team. Every time I believe I have an expectation, they exceed it. So I -- it makes my job easy, frankly, which I appreciate.

I feel very good about that. But we're not done. We need to continue to focus on accelerating the pipeline, delivering the assets we have. You heard us talk about the number -- greater than 20 Phase III assets that started in 2023, and we're going to start that many or more in 2024.

We have to execute, we have to execute. Dean and the team is very focused on that. So -- but we spend our time talking about how are we ready to execute those and drive those. We have to be successful with sotatercept, and we have to be successful at V116. We're very focused on those near-term launches. And if you look around both the pipeline and the launch potential of those assets, it's not only how do we think about the commercial capabilities we need, what we have to do from a clinical perspective, but it's also about the CMC work we have to do to ensure we have our manufacturing in a situation to maximize the opportunity.

I feel good. We're in a strong position across all of those elements, but we're not taking our foot off the pedal. You're going to see us -- we're going to continue -- we're going to keep focused, patient at the center. We're going to continue to accelerate pipeline, augment pipeline and prepare capabilities for the next generation.

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

And I know in the conversation, you're talking about 2030 to 2040 is kind of the focus on returning to growth. Just a little bit more perspective, though, of we're still 5 years until we get the KEYTRUDA LOE. But how are you thinking about that period of transition as we look later this decade into early next?

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

Yes. Well -- and hopefully, you got the sense from the portfolio we just walked through of -- and granted, it's a portfolio. It's potential. But the fact that we're sitting here with the number of shots on goal that I just displayed and that we've talked about, I feel good about where we are. That's why, as I said, as we look at it, we see the KEYTRUDA situation as a hill, not a cliff. And I'm confident and what we're very focused on how do we make the hill, the dip as small as possible and the return to growth as fast as possible, always shooting to see if we can grow through it.

So I think where we are right now is we need to continue to drive through what we have and add to it from business development. But given the amount of time we have sitting here 5 years forward and the progress we've made in the last 2 years, I feel very good that we're very well positioned to really be in a position of sustained growth long term.

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

And just a couple more bigger picture ones. Merck's been one of the more active companies on the business development front the last few years. So I guess my question is post the ADC collaboration with Daiichi that we saw, and I know you had a deal today, but just how are you thinking

about the size and stage of assets that you're considering as you think about the R&D investment you've already committed to and the -- where the pipeline is kind of progressing through at this point?

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

No, I appreciate the question. Obviously, I feel very good about the deals we've done. And I would say if you look at the nature of the transactions, and going to the larger size, what we did with Prometheus, what we did with Acceleron, I would say the $10 billion to $15 billion range, that's kind of the outer bound of what I would say is the sweet spot of our focus and then obviously, down to the smaller deals like the 1 we did today, $680 million but an important asset that we think has real significant potential to expand our oncology pipeline into an area of still really unmet need, which is small cell lung cancer.

So I think those types of deals across the spectrum, if you look at the therapeutic areas where we're playing now, those what you should think about. We've been very clear to say we will never do a deal just because we want to play in a therapeutic area. What we've been very consistent to say is we always will be science led and science driven. That said, when you see an opportunity, we are mindful of how it fits the portfolio and where we can both bring great science and broaden and diversify our portfolio. We're going to do that.

So that type of focus with diversification is going to continue to be what we're really aiming the troops, if you will, making sure we have a balance. One of the things I give Dean a lot of credit for, and I've said this in several occasions, if you look at the track record of execution in our clinical programs, part of that is because Dean has been a task master to say within the company, "Let's not talk about the next thing you want to do. Let's talk about what you're not going to do, so we can focus on what we have to do. Let's deliver what we have today before we commit to the next thing." And that focus is paying dividends. And I think you're seeing it in what's happening in the labs. It's also how we approach things commercially and operationally.

That said, we also know we need to be a little bit broader, and that's that balance in diversification we're trying to drive. So that will be our focal point. The strategy we followed from a business development is frankly unchanged. And I do believe we have the opportunity to continue to do more deals and to continue to augment the pipeline. The deals we will look for will be pipeline-focused deals. Obviously, if you look, we've absorbed all of the things we've done so far, and we're continuing to drive margin improvement.

So that really speaks to the strength of our margin and the portfolio mix we have, as I commented on there. But I believe we have the capacity and that margin affords us the ability to continue to invest, which we will do following the same pace and focus what we've done over the last 2 years.

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

I know you touched on this in the presentation, but just confidence in the 2025 margin targets. And as I think about BD, is that a rate limiter at all in terms of just the capacity to continue to spend?

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

Yes. So I guess what I would say is I would separate the IP R&D charges that come with business development from the ongoing run rate. So we usually will normalize those out because they're onetime events. But if you look at our underlying operating margin, achieving that percentage, getting to the greater than 43%, first and foremost, the fact that we see a significant royalty step down, as you know, happening for both GARDASIL and KEYTRUDA are important drivers. The portfolio mix as KEYTRUDA continues to grow as GARDASIL, so as you're seeing those products grow, we're seeing natural mix effect driving our numbers and we've been very disciplined across SG&A.

So my confidence in that 43% is high. But that said, I've been clear. We will not forgo an opportunity just to hit a margin target because, frankly, hitting a margin target does not create -- that does not create long-term value. Long-term value is through a sustainable revenue line, which is based on innovation and new products, and we're going to invest behind it.

We've been fortunate to be able to do both because of the strength of the business. I think we can continue to do both, but I always want to make sure because we often get a lot of questions from investors, frankly, who I think are concerned, that we will become so wed to worrying about a target that we'll make a bad long-term decision in the short term. We will not do that.

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

Okay. Great. The sotatercept launch, it's going to be a big focus of the Street this year. I know you've mentioned there's been some patient warehousing ahead of the launch. But can you just give us some color of how you envision this ramp playing out? How much investment has been made already? What are the hurdles to get reimbursement adoption, et cetera, as we just kind of think through how this plays out?

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

So maybe if I could ask Dean just to comment on kind of the regulatory situation and where we're at and then I'll give the commercial perspective.

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

So I would just emphasize, for sotatercept, we're extremely confident. We have the potential of a launch. The PDUFA is March of this year. The other point I want to make sure is, previously, after the STELLAR data was so stellar, we recognized that we could file for the EU and there is the hope that we have is that, this year, we will get approval for that. So that's really important.

In relationship to talking to scientific leaders, they are equally as enthusiastic and confident and what they describe is this is the first time a molecule has been driven to this that's at the fundamental core of the genetic basis. So they view it as a disease-modifying mechanism, which will be really important given the fact that -- the strength of the data.

But I just want to make sure that everyone understands, that's a launch with STELLAR data. We have other data, right? There is going to be ZENITH. There's going to be HYPERION. There's going to be SOTERIA. There's going to be CADENCE. That's going to tell us whether or not this works in even more ill patients, whether we can bring it in earlier line and really whether it can be expanded not just for pulmonary arterial hypertension but conditions where you have pulmonary hypertension, such as diastolic heart failure.

But in terms of the commercial outlook?

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

Yes. So if you sit here today, one, I would say, we are very much ready, and in 2 ways, I would give confidence to that. One, we've invested already to build within our U.S. operation a team. So we've actually set up a dedicated stand-alone business within the broader U.S. business, who is specifically focused on sotatercept and what we have here, primarily because this is a rare disease. It's very different than where we've been in the past, and we wanted to make sure that there was focus. And we've also augmented our internal talent by bringing in people who have experience in the rare disease space.

So I feel like we have between who we've brought in and what we have internally a knowledge base that understands what it is to launch a rare disease, and we've set up the organization to do it. As you think about this from a resource requirement, I think it's important to understand, as a rare disease, this is a very small population. There's about, roughly between the U.S., Europe, Japan, about 90,000 patients that we believe right now exist. About half of that is in the U.S., about 45,000.

Those 45,000 patients are treated across 150 specialty centers that are PAH-specific centers. So you have a very educated, focused specialist population aimed at treating these patients. About half of those 45,000 in the U.S. actually run through those centers. So your ability to get the

message out very quickly to educate and then to help partner with making sure that the patient journey is what you would like it to be is highly efficient in this space.

And so we're very focused on making sure we're ready to engage. And I feel very good that you're going to see a fast launch for the reasons that Dean said, given what we're hearing from key opinion leaders, and we've been very thoughtful in making sure we're ready. But this is a highly efficient area. So it's one where I think you can see us do quite well quite quickly.

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

And just longer term, I know you updated the CV targets. How much of that increase in the CV targets is sotatercept driven versus some of the other assets that you're adding to the mix?

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

Obviously, if you sit here today, we believe sotatercept, from a revenue potential, is bigger than if you had asked us where we were a year ago not only because of what we see in the PAH space. The fact that we're going to be launching much more quickly outside the United States based on the strength of the STELLAR data and based on what we continue to see as the potential, you truly get to disease modification and we can move into PH and into heart failure, which we think we have confidence that those are opportunities. It's there.

It's -- but we still are equally excited about PCSK9, our oral PCSK9. We continue to be confident in all of the programs underneath there. And then obviously, the one we also have added and really are starting to talk about is MK-6024 in NASH, which we think, based on the strength of the data we have there -- and by the way, for those who don't know, this is a GLP glucagon dual agonist mechanism that brings significant reduction in liver fat, I think, in the magnitude of 70%, Dean, and importantly, also carries weight loss in the 10% to 12% range. So kind of similar with what you were seeing out there.

So we're going to pursue that aggressively. And so our confidence in that $15 billion number is quite high. But it's -- I don't want you to think it's only sotatercept. Sotatercept is great, but it is all of the assets we have there.

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

Great. Maybe pivoting over to oncology. Maybe first on just KEYTRUDA. Adjuvant lung seems like next kind of big growth opportunity. Can you just frame out the potential in that setting and how you see that indication ramping? I think in the past, you highlighted there would be some education, but we saw some very, very impressive data last year. So just how do you think about that playing out?

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

I'll let Dean maybe speak (inaudible) and then I can give you the [commercial].

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

So I actually think there are some directors of cancer center, NCI cancer centers here. So I'm speaking to you, and you know who I'm speaking to. But it's a watershed moment. When you have KEYNOTE-671, which is neoadjuvant, adjuvant and you have an earlier stage lung cancer trial, to get overall survival benefit that we have after only 5 years, that's a watershed moment. And what you have in lung cancer is you have the bookends in non-small cell lung cancer. We have metastatic at KEYNOTE-189. I think we continue to tell you that it's 9 out of 10 patients.

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

8 out of 10.

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

Eight out of 10 patients. And then all of a sudden, these are the same people who are dealing with the earlier stage. So this is really important. It's not for us to say it's a watershed. It's to watch what the environment does. And the NCCN guidelines in lung cancer for earlier stage, of all the treatments with a checkpoint inhibitor, there's only one category 1 recommendation, and it's for KEYNOTE-671.

And most importantly, you see the American Cancer Society recognize, well, they have to change their lung cancer screening guidelines. So they have simplified it and broadened it. All of this happened 1 -- within 1 month of the approval of KEYNOTE-671.

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

Yes. So obviously, we highlight that because that's probably the most recent important data readout we've had in the adjuvant space. And obviously, we think it could be game changing long term in the treatment of patients with non-small cell lung cancer in combination with what we had in KEYNOTE-091, where we already had adjuvant coverage, so very important.

If you look in total across the early phase, right now, we have 8 approvals, more than anyone else. In 2023, that drove about 20% of our total revenue as a company globally. So if you think about the business, it's about 20% is in the early phase. We had previously given guidance that we would expect to get to 25% by 2025. Now based on the strength of the data and what we're seeing happening commercially, we're actually going to achieve that early. We're going to -- we believe we will end 2024 at 25% of our total. It represents, as we move out to 2025, about half of our total growth is coming from early phase.

And so as you think about it, it's very important because if we can achieve 25% in '24, it's going to continue to go north of that. And as you get out towards 2027, 2028, that, combined with -- as we think about what is the monotherapy use of KEYTRUDA and where you can combine KEYTRUDA with small molecules, that's about 50% of the patients using KEYTRUDA will be addressable with our subcu opportunity, which is not what you were asking about, but I think it's important to make the connection because, as we move into earlier lines of therapy, what we're really talking about, hopefully, is you can start to talk about chronic therapy for patients on cancer and then how do you help them have the best quality of life there.

But as we sit here today, our ability to move into the adjuvant, neoadjuvant is extremely -- is going extremely well. Excited about 671. We're also equally excited about adjuvant RCC, the only other place where we have right now overall survival. And frankly, we're the only 1 with 2 overall survivals in the adjuvant space. And some interesting studies coming down the pipe. We have over 20 studies in other adjuvant areas coming that are registration enabling, so a lot coming, but I feel very good. And as I said, we're ahead of expectations right now.

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

Excellent. Maybe talking about the INT program with Moderna. Just relative to, I guess, where we were last year when I think the Street really started to focus on this, where do we sit today in terms of derisking of the profile of the product and better understanding kind of the range of indications that you could pursue with this?

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

So when that data first came out, it was impressive. It was in melanoma, and it showed we all know that KEYTRUDA itself does quite well in adjuvant melanoma. And the improvement with INT was substantial, and it was clear. One of the concerns that someone might have in relationship to an

INT that's based on mRNA is the durability. And what you see with the press releases that come out is we're at year 3 or something like that. That durability is real.

When you treat an earlier stage and you have that effect and you have durable, that's when a patient starts thinking the word potential cure. So that, I think, is really important. And that's really been an important derisking event for us. We're focused on starting the Phase IIIs for melanoma and lung, but we're also extremely excited to explore other indications and other tumor types. And that's what we're doing with Moderna. And hopefully, that will lead to even more Phase IIIs.

But I also want to come back to we have a platform to do the earlier stage that is unique to this collaboration. And that platform is the fact that we have 8 approvals in early-stage cancer makes it very easy to layer on INT. If you do not have that base, it's very hard. So we've done a lot to derisk it with our partners, Moderna.

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

Excellent. Maybe just one last one on the cancer portfolio. Just TROP2, just level of excitement around that approach based on some of the competitor data, some of the internal data you have, where do we sit today?

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

Yes. It's what I've said previously. We think TROP2 ADCs are going to be important. We also believe that if you're going to advance a TROP2 ADC, especially in combination with KEYTRUDA, especially in lung, you have to be meaningfully better than KEYNOTE-189. And the way that one has to be better, one has to consider what is the right patient population. So we think patient selection, including biomarkers may be very important. And that combination could give us really meaningful improvement over KEYNOTE-189. That's our North Star.

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

Okay. Very helpful. Maybe in the last minute or 2 here, pushes and pulls, we think about 2024, I know you're going to be giving formal guidance, but just things we should keep in mind as we think about this year.

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

Yes. Obviously, from a pushes perspective, clearly, it's what do we have in the strength of the momentum we're driving in the business across oncology with KEYTRUDA, the fact that you're seeing us -- whether it's moving into earlier-line therapy with non-small cell lung cancer with KEYNOTE-671 on top of 091, which we think will have momentum in '24, continued movement in women's cancer, in endometrial as well as continued growth in triple-negative breast. We're very excited about as well as bladder cancer. Just those 3.

So KEYTRUDA will continue to move, continue to grow, we feel, very strongly. GARDASIL is continuing to do quite well and will continue to be a growth driver. And then hopefully, you saw we laid out, obviously, sotatercept, meaningful growth driver in the year. And while the V116 launch won't come to the back half, we think we'll start to add value as we move in the back half of the year and be an important growth driver.

So it's a combination of our in-line products with the strength of what we have from our new products is really the driver of growth. The only -- we don't have really, frankly, a lot of headwinds facing us other than the kind of what we always face. Obviously, price pressure outside the United States continues to be there. Although I will tell you, as we look forward, well, '24 will be another year of price pressure. Some of the responses we're getting from governments, whether it's in the U.K., in Japan, in Germany, where they're starting to pull back from some of their aggressive price reduction actions, recognizing that they've probably overdone it and they're starting to hurt innovation in their own markets, I think, is a little bit of a turning point. So I just raised that. It's longer term. It's still going to be a headwind in '24, but the fact that we're chipping away at that, I think, is important.

And then obviously, we have some LOEs, nothing major, but the continuation of some of the LOEs we've been facing. But those are kind of the standard fare. No unexpected boulders, if you will, that I see as any kind of headwind. So the momentum we have in -- had '23 should continue into '24. And as you saw from the slides, frankly, as we look through the end of the decade and as I said then, growth beyond that as we look into 2030 and 2040.

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

Great. I think we're just about time. Congrats on the progress on everything, and thanks for joining us.

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

Thank you very much.

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

Thank you.
