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# EDITED TRANSCRIPT

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**Stephen Michael Scala** *Cowen and Company, LLC, Research Division - MD & Senior Research Analyst*

## PRESENTATION

**Stephen Michael Scala** - *Cowen and Company, LLC, Research Division - MD & Senior Research Analyst*

Well, good afternoon, and welcome to the session with Merck at Cowen's Annual Healthcare Conference. We're very pleased to have the company back again with us this year, representing the company is Caroline Litchfield, who is the Chief Financial Officer; as well as Peter Dannenbaum, who heads the IR effort. Merck is certainly in an interesting position with good momentum driven by its top franchises, which have much growth to come. So exciting times at Merck, and we're interested in digging into those exciting times. So allow me to start out with your most important product. So Caroline, as you think about KEYTRUDA beyond the substance patent expiration in the 2028 time period, how should investors think about that? In other words, to what extent can life cycle management efforts extend sales beyond that time period?

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

So first, Steve, thank you for having Merck here, and it's my pleasure to be here representing our company. So KEYTRUDA is a really important product. It's important because of the impact that it is having on patients around the world. And it has shown significant activity across a number of different tumor types. Here in the United States, we've got 34 indications across 16 tumor types plus 2 tumor-agnostic indications, and we've seen activity in more than 30 different tumors. But even with all of that, oncology remains a significant unmet medical need, so we must continue to innovate, and we are innovating with KEYTRUDA. So the first area of innovation, I would say, is trying to get into earlier-stage disease. We're trying to support our cancer patients earlier as they get that diagnosis and move into the adjuvant -- neo-adjuvant setting. We also have a significant number of combination studies that are underway, both within Merck but also outside of Merck. So there's something like 1,200 studies at this moment in time, and that's giving Merck a unique position to understand what products may work better with KEYTRUDA to have an improved impact for patient outcomes. So we're working on a number of different strategies to improve those patient outcomes. First is combination products and where those combinations are successful looking at how we could co-formulate the products to have improved patient impact. Second is the subcutaneous formulation, as you noted. And that's really, as we move into earlier stage disease, we feel we'll be addressing a likely younger patient, and that patient will probably be on KEYTRUDA for a longer period of time. So the route of administration is really important to bring the maximum benefit to those patients. So as we see the innovation come through, we will seek to get protection for that innovation, and we will seek patent protection should we see that the innovation is novel, it's useful and it's non-obvious. So as a company, we're focused on improving the outcomes for cancer care. We're focused on the portfolio that we have, and we're confident we will see significant business beyond the KEYTRUDA LOE, which as you state Steve is in 2028 here in the United States, it's in 2030 in Europe and is in 2032 in Japan.

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**Stephen Michael Scala** - *Cowen and Company, LLC, Research Division - MD & Senior Research Analyst*

That all makes perfect sense. So clearly, the combination strategy and the subcu strategy are clear needs in the marketplace. To what extent does Merck have other strategies that are in-house but not publicly revealed. And I'm not asking you to publicly reveal them today, I'm just wondering, are there things that are in the works that we simply don't know about that could perpetuate KEYTRUDA beyond its LOE?

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

So we continue to look based on the patient impact that we will have and should there be that patient impact, Steve, we will look towards filing patent protection for the innovation that comes through. So as we've already noted, there's a number of different areas that we're looking at in co-formulation. We're looking at subcutaneous. We also have a number of different mechanisms, more than 20 that are in our labs today that we continue to investigate to maximize the impact that we'll have for patients.

**Stephen Michael Scala** - Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

Okay, okay. So let's move to another area within Merck. And that is your cardiometabolic franchise. So obviously, JANUVIA has been a huge success during its long life, but the patent expiration is coming along. So we're aware of, of course, VERQUVO sotatercept, and now more recently, the oral PCSK9, but to what extent is there more to the cardiometabolic initiative beyond those 3 products to sustain the franchise that you've built with JANUVIA.

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

So we're really excited about the cardiometabolic portfolio that is building here in Merck. And you've named a few of those assets, Steve. So first, today, we're supporting both Adempas and VERQUVO. And if I highlight VERQUVO, we see significant opportunity for patient impact as well as strong sales performance for this product in the heart failure indication we have today as well as the VICTOR study, which we think could extend that indication in the future. Sotatercept is a product that we had extreme excitement about last year when we announced the acquisition of Acceleron. And that acquisition has gone very well. We've integrated the business within Merck. And indeed, just at the end of last week, we announced that we have completed the enrollment of patients on the STELLAR study. So that's ahead of the time line that we were expecting. And now we'll work to see that study continue, but we think sotatercept will be a significant potential for the impact it will have on patients and for the impact it will have on our company. Now we also are working in pulmonary arterial hypertension in our own inhaled sGC stimulator, which again, we feel could be a significant driver of growth for our company. In the thrombosis area, we have a Factor XI compound. This is a compound that we're currently studying in end-stage renal disease. And we're really trying to see if we can stop clotting without heightening the risk of bleeding. Again, a significant unmet medical need, and if successful, could be a significant opportunity for our company. You mentioned the oral PCSK9 product, and Dean has talked about that in some of our recent earnings. We are really excited about this product the potential for increased LDL lowering. And also, we're excited about the macrocyclic peptide platform. So we think this could present a great opportunity. And then in NASH, we're active. We have a number of compounds there. And in our earlier stage development, there's a number of different modes of action that the team are working on. So in terms of the 3 products that you noted, those 3 products are just a fraction of the overall portfolio and the overall opportunity that we think we have. And we're excited to announce this morning that on April 5, we will have a cardiovascular deep-dive session. And the goal here is to share with investors the view of the scientific differentiation that our products have, the clinical pathway for those products as well as give insights to the commercial opportunity that we see.

**Stephen Michael Scala** - Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

Okay. That sounds like a great event. You mentioned 6 cardiovascular entities, which I guess I knew about them all, but I never stopped to really think how many there were. So it seems like a full portfolio, and we'll look forward to learning more on April 5. So let's move on to another important franchise that Merck has developed over time, and that is the HIV portfolio. And unfortunately, islatravir has run into a bit of an issue. So Merck, I'm sure is continuing the analysis of that situation. Are there any new news or is there any new news that you can share with on the islatravir safety analysis front?

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

So to your point, Steve, the teams are working expeditiously to review the significant body of data that we have. First, I would say and reinforce islatravir does have many important properties with its potency, its long half-life, and its strong barrier to resistance, but we're investigating the data to understand was the issue with the reduction in lymphocytes as a result of dosing? Or is it something to do with the mechanism of the drug.

So we're completing that work. We expect to complete it by about the midpoint of this year, and we'll be working with the FDA on what the appropriate path forward is. We do remain convinced on the NRTTI class. We have islatravir. We also have some other compounds in that class. So we are hopeful that we will continue to make a meaningful difference in HIV in both treatment as well as in prevention, but more to come as this year unfolds.

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**Stephen Michael Scala** - Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

Okay. So we've mentioned a number of molecules in development, both in cardiology and both in HIV, and I'm sure many other areas as well. But Merck is viewed by investors as a company that has a somewhat more limited pipeline and when you look at your published pipelines, it doesn't necessarily change that view. So what would you say to investors who assert that Merck has among the fewest products in development? What response would you say to them?

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

So we are confident in the pipeline that we have within Merck, although we continue to look to augment that pipeline with business development. We understand the need to provide more information, more insights to the investors so that you have the same confidence and insight and excitement into the pipeline that we have. So as Rob Davis has shared, our goal is to start lifting the curtain to try and provide such insights, and we're doing that with the cardiovascular event that we've just announced, and you'll see us do more of that as the months and years ahead progress.

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**Stephen Michael Scala** - Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

Okay. So the cardiology day is definitely a very important step forward. Would you think that in 2022, we will get this additional visibility? Or might that spread into subsequent years?

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

I think it will spread into subsequent years, but we will be looking to provide more communication, more clarity to the investors as this year unfolds and into next year.

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**Stephen Michael Scala** - Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

Okay. So let's pivot to another critical franchise for Merck, and that's the vaccine portfolio. So Merck has said that GARDASIL sales, at least in its view, will double by 2030 off the 2021 base, what assumptions are included in that guidance? And what factors could tilt that upward or perhaps have it come in below that doubling?

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

GARDASIL is a vaccine that we're very confident in within the company. Recently, GARDASIL has been seen as a vaccine that prevents cancer, and we're seeing that create increased demand around the world. Yet today, we have only vaccinated 9% of the world's eligible population for this important vaccine. So the journey is still in its very early stages. We are increasing the level of supply that we have to try and satisfy this global demand. In 2021, you saw us increase the level of supply to the marketplace and the growth we saw in GARDASIL, and that was really as a result of driving productivity in the current assets that we have that manufacture GARDASIL. And as we look in 2022, we expect to see another step in the productivity of those assets, and therefore, growth in GARDASIL, albeit not quite at the same rate as we saw in '21. Then in '23, we have 2 new manufacturing facilities that will be coming online, over the period '23 into '24. So that puts us in a position that we're no longer constrained in our supply to the market and can really address the opportunity that exists to protect more lives, and that opportunity is global. Here in the United States, we have the opportunity to do the catch-up of vaccinations that have been missed as a result of the pandemic. We have an opportunity to

increase the vaccination rates in the adolescent population and the young adults. We also have a newer opportunity, which is the mid adult segment. That's the people in the age group 27 to 45, that's a 70 million people population, 50% of HPV happens in that age group. So we have a chance to prevent cancers there, and we're actively going to energize that segment. Outside of the U.S., in China, is a great opportunity for us. There's 120 million females that are in our cohort eligible for the vaccine and with the ability to pay for the vaccine. And we've only just started there, and we have the opportunity, hopefully, for gender-neutral vaccination in years to come. And outside of those markets in Europe, we're looking at gender-neutral vaccinations and a great opportunity to provide growth there and protect both males as well as females from HPV-related cancers. And at the end of last year, we had Japan provide its active recommendation for the use of GARDASIL in girls aged [12] (corrected by company after the call) through 16 as well as to catch up on vaccinations missed for girls through until the age of 25. So again, a significant opportunity for us. So as we sit here today, we have a vaccine that has a 14-plus year track record that does prevent cancers. We have incremental supply coming on board. So we remain extremely confident in our ability to see long-term sustained growth and indeed double GARDASIL sales in 2030 compared with '21.

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**Stephen Michael Scala** - Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

That 9%, only 9% of the world's population being vaccinated is a pretty stunning number. So off the top of your head, do you know what the percentage is in the U.S., China and the EU, it's kind of an unfair question, but is that number top of mind?

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

So I'll give you orders of magnitude because I don't want to quote and get something wrong. U.S. would be the largest in terms of its level of vaccinations. But it doesn't sit at the 70%, 80%, 90%, right? Because we've got this new patient segment that is a tremendous opportunity. More recently in boys, which doesn't have the same level of vaccinations. So we're probably at the higher level in the more 50-ish percent mark in that area. Europe is lower than that. China, we've just started. So the opportunity in our market, Steve, here is significant. And to the point we've made we'll global -- excuse me, we'll double the sales globally the opportunity to see significant growth exists in each and every market.

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

And I'll just add, Steve, it really depends on how you cut the denominator. But in the U.S., in that 12- to 17-year-old age group, it is more like 70% to 75% for males and females, with the expanded indication as Caroline suggests that the opportunity is much bigger.

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**Stephen Michael Scala** - Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

Okay. So it seems like all the factors that you mentioned, I mean, a doubling could be conservative. I mean it's more likely to be more than that than less than that, I would imagine, given all the positive factors that you mentioned.

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

We're hopeful to protect as many lives as we can.

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**Stephen Michael Scala** - Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

This is a better question probably for someone in R&D. But I'm aware of no competitive threats on the horizon. Obviously, we knew you had a competitor early on, but that amounted to nothing. Are you aware of any competitive threats on the horizon maybe via different technologies or anything along those lines?

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

To Gardasil?

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**Stephen Michael Scala** - Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

Yes.

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

We remain focused on Gardasil and continuing to see it expand globally. We're aware of a 2-valent HPV vaccine in China at this stage.

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**Stephen Michael Scala** - Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

Okay. Let's move on to another new vaccine from Merck and that is VAXNEUVANCE. In Merck's view, can this become a blockbuster? I think investors are pretty quick to dismiss it. But in Merck's view, can it become a blockbuster?

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

So the quick answer is yes. We believe it can. So we are very much focused on the PCV market. It's a large market. It was worth \$7 billion in 2020. Approximately 30% of the market is in adults. 70% is in pediatric and the market is projected to grow and grow quite significantly to something like \$10 billion in 2025 and to \$13 billion in 2030. And so it's a large market. It's a growing market. And what we have with VAXNEUVANCE used in conjunction with PNEUMOVAX 23 is a regimen that provides the broadest protection and strong immunogenicity. So we think it's a very competitive product and will be very valuable for patients. In April this year, we have the PDUFA date for the pediatric vaccine, which, again, we think will be a very important next-generation vaccine in that segment. And we're not stopping there. We also have V116, which is a vaccine that's more targeted at adults and we believe could support approximately 80% of the residual disease for adults. And we're currently working through the Phase II data that we have. We remain confident in this program and expect to hear news from us in the near term on that program. And for pediatrics, we have V117, which is currently in Phase I, again, really focused at the residual disease for pediatrics, and more to come on that. So in aggregate, across all of the suite of vaccines that we have with VAXNEUVANCE with V116, potentially V117, we are very confident in our ability to have a competitive position in this large market.

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**Stephen Michael Scala** - Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

And does Merck see greater opportunity in the pediatric market or the adult market?

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

I think we see great opportunity in both.

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**Stephen Michael Scala** - Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

Okay. And you mentioned near-term news on V116. What might be the nature of that news? Is it data? Or what else is -- or what else it could be?

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

Yes. So we are currently running through the Phase II program. And as we go through all of that data, expect us to provide a communication on that.

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**Stephen Michael Scala** - Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

Okay, we look forward to that. So let's move to some general questions. And that is describe your business in Eastern Europe, both in terms of operations and clinical trials. Obviously, it's a very unfortunate and troubled part of the world right now. So how is Merck exposed in that region?

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

Yes. So it's a very difficult time for our colleagues that sit over in that region. And as a company, we're very much focused on their safety and their well-being and providing all the tools we can as well as trying to get our life-saving products into the market. The Ukraine and Russia represent about 1% of Merck's overall business. With that, we have an extensive global clinical trial footprint, and that footprint spans about 50 or 60, markets around the world. Russia and Ukraine collectively represent around to 6% to 7% of the clinical trial activity that we have. And at the moment, our focus is trying to make sure we don't leave any patient behind. So we continue to try and get the products to the people, both in our clinical trials as well as quite frankly, commercially who are using Merck's products. So that's our focus. At this stage, we've paused clinical trial enrollment or new sites in those 2 markets, and we'll be looking to use our global footprint to ensure we continue to execute on our clinical programs. But I'd say to close on this one, these are important markets. Our focus is on our people, our focus is on the patients that we serve and trying to do all we can to support them. And as a company, like many others, we're going through our efforts to ensure that we're donating product that is relevant at this stage for the people in market as well as the refugees that are going to other markets in the region.

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**Stephen Michael Scala** - Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

So 6% or 7% of your clinical trial activity is a decent chunk. Are those trials leaning towards one therapeutic area more than others. So, for instance, are -- is there a disproportionate representation of oncology trials or cardiovascular trials or infectious disease trials, hospital products?

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

So the reality is the countries have great scientific prowess and have been a center for Merck and indeed other companies. There's no outsized. They've been important centers for us. And as I noted, Steve, we continue to try and support our patients and not leave any patients behind there. But we remain focused on utilizing the global network to continue to execute on our clinical trial programs.

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**Stephen Michael Scala** - Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

Okay. Help us think through China. What do you foresee over the next decade? It seems an area of vast opportunity for obvious reasons, but also no shortage of challenges. So when Merck looks to expand globally as you are obviously doing now, how do you view China?

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

So China is a market that Merck pivoted to innovation some years ago. And indeed, the recent spin-off of Organon has enabled further focus on that innovation within the market. So as we look at China today, the most significant products and growth areas include JANUVIA, where today, we are the #1 oral diabetes product, and there's a significant opportunity there. It's something like more than 100 million people there are in need of diabetes care. KEYTRUDA and our oncology portfolio have a significant role to play in China. And today, we are the leading international immuno-oncology agent in the market. And we expect to see continued growth and patient impact. And GARDASIL, which I touched on a little while ago, we're very early on in our ability to protect the lives of people in China from HPV-related cancers today just indicated in females, hopefully

over time in males as well. So we see China as an important market for us and an important market to drive growth, but growth through our innovation.

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**Stephen Michael Scala** - Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

And apologies, I simply don't remember, but has Merck said what the magnitude of its China business is today in terms of dollars?

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

I think we disclosed, yes, and it's about [\$4.3 billion] (corrected by company after the call), I think, of that order in 2021, something like that.

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

It is disclosed Steve.

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**Stephen Michael Scala** - Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

Okay. Let's some -- perhaps we can move to business development. And obviously, with the imminent prospect of interest rate hikes -- how does that affect Merck's strategy relative to M&A, both relative to deal size and your ability to accept risk.

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

So business development is a really important strategic priority of our company. And the way we look at business development is, first and foremost, on the scientific merit of the target. We're looking to augment our own pipeline with the best of science that exists externally. And where in Merck's hands, we can drive greater patient impact, greater value and greater shareholder value. So that's the first criteria that we look at. And we look at targets at the whole full spectrum of the risk range from targets that are early on in their development, such as our Pandion acquisition last year through to targets that are later stage and indeed Acceleron with an asset prior to the readout of Phase III data in sotatercept, but also with the commercial asset that provides some revenue stream through the royalty stream. So we look across the entirety of the risk spectrum. We're also focused on augmenting our pipeline where we have strength. So building on the strength and the leadership position we have in oncology, building on the strength we have in cardiovascular, building on our strength of knowledge of immuno-oncology to bring in immunology assets. So we're looking to build on areas of strength, but also to provide some level of diversification. We are not looking to pursue transactions that will disrupt the engine of our company, which is R&D. We're looking for transactions that will augment our efforts within R&D. So that's very much the focus and the priority of our company. We've got a really strong balance sheet. We've got great growth ahead of us and great cash flow generation, and we will put that cash flow to good use in the business development that we do. As we look at the interest rate environment, yes, it's clear that interest rates will increase. The one reminder though is the fact that if I was to look for the last 2 decades, we still see the current interest rate environment and where the likely hikes take us as constructive to doing business development at a reasonable cost of capital.

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**Stephen Michael Scala** - Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

Okay. So we're down to only 1 minute left. So let me ask this final question. And this is a question that we're asking at the end of all sessions. But as you peer down the path a decade ahead from now, what do you think will be the biggest surprise and/or change at Merck versus today?

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

So I think, as I look towards the next decade and I take the lens of an investor, I think our investors are wondering how Merck will continue to grow over this next decade. And what I believe the biggest surprise will be is that our company navigates this decade, and we do drive growth. And we



drive that growth through innovation. Just as we have when a few years back, I think people were skeptical as to how Merck would withstand the patent loss of JANUVIA and through innovation and excellent execution we have. So I would close with we are focused as a company, we're focused on leveraging our leadership position in oncology to be a leader in oncology in '25, in '28 and into the next decade. We're focused on our growing portfolio and pipeline to really drive significant impact to patients and significant growth opportunities for our company. And that spans a number of different areas, some of which we've touched on today, some of which we haven't. And we are focused on our discovery efforts to continue to augment the pipeline further, and we'll use our strong balance sheet to augment the pipeline with business development so that Merck does deliver strong growth, strong patient impact and shareholder value through to the next decade.

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**Stephen Michael Scala** - Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

That's a very convincing answer. Let me just follow up on the following point. So you mentioned we talked about some of the things, but not others. What things did we not touch upon that are important for investors to know relative to the outlook for the next decade?

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

So I think within the pipeline, we're very excited about our opportunities in oncology, in vaccines, vaccines beyond VAXNEUVANCE and PCV generally within RSV, within dengue. We have this cardiometabolic opportunity that we've laid out. Within immunology, we haven't touched on our Pandion acquisition and our excitement around the IL-2 mutein there, and how that can have significant impact in autoimmune disease. In neurology, we've got a number of different assets there that we think could be meaningful over a number of different treatment areas. So we do feel confident, not complacent, confident in the pipeline that we have within our company and we'll continue to augment that with further business development.

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**Stephen Michael Scala** - Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

Great. That's a wonderful overview, Caroline. I appreciate your candor and thoroughness in answering all the questions. So thank you so much, and thank you as well, Peter, for allowing us to spend this time.

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

Thank you.

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

Thank you, Steve.

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