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EDITED TRANSCRIPT

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CORPORATE PARTICIPANTS

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

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

CONFERENCE CALL PARTICIPANTS

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

PRESENTATION

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

Okay. I think we're right on time. Welcome, everybody, to the Goldman Sachs Healthcare Conference. It's fantastic to see everybody in person here. We are so pleased to kick off our event today with participation of Merck's CEO, Rob Davis; President of Merck Research Labs, Dean Li. Gentlemen, thank you both for making me (inaudible) here and coming. I know that many of the investors you've been meeting with are also deeply appreciative especially for the time of a CEO to be present here for this event.

Rob, you've been at Merck for a while in the C-suite. The past year, however, has been your opportunity to have the purview of the CEO role, overall, it's a very different place. A lot has happened. Talk to us maybe some opening comments about how you feel Merck's outlook and what you feel are some of your priorities now as we sit here, so that next year when we sit here, once again, I can see how you're progressing on them, but as a CEO now for a year...

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

Sure. No, I appreciate it. Well, first and foremost, I've been so proud of the execution of the Merck team in light of everything that's going on, the fact that we've executed as strongly as we have, is really a testament to what are the -- really just the wonderful talent we have at Merck. And I feel very good about that. If you look at the performance of the company, obviously, coming off the first quarter, extremely strong first quarter, even if you remove Lagevrio, double-digit growth. And if you look at for the full year, we're guiding, excluding Lagevrio, excluding foreign currency to about 11% growth at the midpoint. So strong growth of the business.

And if you look at what's really driving that growth, it continues to be our growth drivers are all really hitting on all cylinders, starting with KEYTRUDA and what we're seeing in the Oncology space, Lynparza, Lenvima. Obviously, GARDASIL continues to just do extremely well, our Animal Health business. And then you look at assets in our hospital specialty space like BRIDION. So good growth coming from all of the key pillars of the company. And importantly, as you look at where we're going, over the next several years, looking into 2025 and beyond, those same pillars will continue to deliver very strong growth, and we will continue to be able to drive operating and margin expansion over time with the goal being in excess of 43% by 2025. So across all of the elements, the execution is happening. And if anything, as I think about the strategy, it reinforces for me that the strategy is the right strategy.

And as I look forward and you say, what are the next steps? Well, it starts with the pipeline. We are really starting to see the pipeline mature in some areas. Obviously, in the cardiovascular space, we're very excited about what we see there. Recently, we had a cardiovascular investor event. We talked about the fact that we expect to see 8 potential approvals by 2030, sales in excess of \$10 billion by the midpoint of the next decade. So a lot of opportunity there, continuing to see a lot of great opportunity in our vaccines business with the pneumococcal disease with what we see in RSV, dengue, lot of growth is going to continue to come in that space as well. And then a lot of interesting earlier stuff happening in whether you look at neuroscience and immunology is just 2 areas.

So we need, first and foremost, to make sure we're continuing to drive that pipeline, accelerate it where we can and deliver. We're going to have to continue to see those durable growth drivers deliver I mentioned. The good news is those are largely derisked assets. All we have to do is execute. And I think we've shown we have an ability to do that.

And then as we look at the business, clearly, it's about how do we make sure that we take the cash flow we're getting from the phenomenal performance we're having right now on the back of KEYTRUDA and reinvest that cash into the business through business development continues to be a priority where we're going to be appropriately aggressive in that front. And across all of that, then we look and say, while science will continue to be the core of who we are with the patient at the center of everything we do, how can we draw that science more effectively, more efficiently. We're challenging ourselves in that area and then how do we bring those inventions to the patients. So that's how we're trying to evolve the business. But pretty much, if you look at all of what I just laid out, those are pretty much the same consistent strategic pillars we've been identifying over the last year, and we're just going to continue to execute and I'm confident that if we do that, we have the foundation, we have the fundamentals to deliver strong growth and really to have a sustained business well into the next decade.

QUESTIONS AND ANSWERS

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

Touched upon many, many important areas there. So -- but let's key off on something that I think is very top of mind for investors, thematically for the sector as well. And again, you as the voice of the CEO. And maybe let's talk a little bit about business development, capital allocation strategies as this threads in very much with thinking about portfolios. You guys have done things looking at the overall structure of the company a year ago now. Organon was spun out. A lot of conversations about understanding how the company has really become such a franchise around Oncology and yet there's external factors that we're going to be hearing a lot more about in particular during this week with the FTC, et cetera.

But maybe just to talk more concretely about your overall portfolio and how you're thinking about shaping it into the future, therapeutic areas that you feel like you need to be in? Are you appropriately diversified? Is the business development a realm that you're looking broader than perhaps if we were to look at sort of see where the Oncology leads and where some of the other areas are? What is your appetite in terms of where your eye is for thinking about other therapeutic areas?

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

Yes. Well, so if you look at the portfolio we have today, I would start with an important goal, and that is we want to continue to leverage and grow in the Oncology space. We've made it very clear. Our goal is to be the leader in Oncology by 2025 and then to sustain that leadership well into the next decade. So we will continue to drive our own pipeline, continue to deepen, to broaden, extend the pipeline we have. And I do believe there continues to be real opportunities from the business development in that specific arena to add to our portfolio.

If you ask what drives us, it's very consistent. It's always the first question, where do we see the science. Where do we see the unmet need that meets the scientific opportunity aimed at that unmet need? And so that's, that focus on science always drives us. But I am mindful of the portfolio as a whole, and I do believe we can be more than an Oncology company, and we can have a balanced portfolio overall. So we look both to leverage the leadership we have in Oncology to go deeper in that space, but then to go broader into other areas.

We did that with Acceleron last year in the cardiovascular. I continue to believe cardiovascular is a space where we have opportunities to continue to grow. We're starting to invest more and more in Immunology. We did the Pandion acquisition in that space, but we've also made a lot of investments in our discovery operations aimed there as well.

And then neuroscience, if you look from a discovery perspective, we've done a lot of early stage deals in the discovery space. We have a few mid-stage opportunities in our development arm in the neuroscience space, but I think there's opportunities to continue to expand in that area. And then obviously, cardiometabolic is also an area where we're focused. So it is really about looking at the science, looking at the portfolio and then where can we find the strategies aligned around the opportunity. It's going to take us where we want to go. But that gives you at least the high levels of the way we think about it. And I don't know, Dean, if you want to add to that.

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

Yes, I would just emphasize 2 things. One is, our ambition is to use our strong position in Oncology and leverage that. We have 1,300 combination trials. We have 120 or so at an early stage. We have around 100 or so that are registrational. And that keeps a focus on Oncology. But I also -- I was in a different meeting where I said that, that information is actually really important for non-Oncology, and I'll just emphasize our interest in Acceleron is related to the TGF-beta BMP family. We had made an acquisition, and we had pushed programs in that TGF-beta family in Oncology, and that made us understand that pathway. And that helped us decide that we're going to go after Acceleron.

The other program, I think at ASCO, we revealed to the ASCO community that there have been some stumbles in relationship to cytokines in IO, especially IL-2. We believe that there is a way to make biased interleukin 2s. And so we're advancing that for cancer. But fundamentally, in those studies to do that, we had run into how you could bias it for Immunology. And in our internal programs, we saw the readout and we knew that we should get Pandion. So I just want to emphasize that the 2 major deals that we had were in non-Oncology last year, but I want to be very clear that our understanding of that pathway and how to manipulate it came from our work in Oncology.

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

Okay. No, I think that threads through a lot of common themes. Focusing in with what you have now and folks are very concerned about, well, aware of the 2028 KEYTRUDA loss of exclusivity. Embedded within your current strategy with your assets, there's a lot of work that's being done, scientifically driven, looking at novel combinations, also looking at many of the strategies which could fit in with a commercial interface subcutaneous formulations, et cetera. I think we have some studies that are going to have data readouts in the 2024 to '25 time period, kind of right in that arc of the journey until we get to 2028. Can you talk to us about how the outcomes of those studies are influencing the way you're thinking about things, anticipating the potential need to pivot, how dependent upon the outcomes -- positive outcomes from those efforts? Do you feel your vantage point is right now?

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

So I would just say that the outcomes will change what we do, but the outcome doesn't change how aggressive we are in relationship to what we need to do. So the first issue is that you talk in terms of Oncology and how we think about it. We continue to expand into tumor types that we've never been in. We also expand going from late to early. That early stage is going to demand innovations from the greater community given the fact that people don't want to go every 3 weeks for an adjuvant therapy. They don't want to go to an infusion center.

The second sort of thing is we talk about [deepen] with combination. We deepen with combinations with non-IO agents, Lenvima, LYNPARZA, RAS inhibitors, others, but we also are combining them with other IO agents like TIGIT, LAG-3, CTLA-4. All of those give us an opportunity to co-formulate and that creates an environment where one can think about loss of exclusivity differently than 2028.

And so the final thing is that we are doing lots of things in relationship to extending the reach of KEYTRUDA and not just KEYTRUDA, LENVIMA, LYNPARZA, for that future. But I'll just give -- basic I was asked this question, do you like dosing changes? Do you like frequency of coming in? Do you like devices? Do you like formulation? And I sat there and I said, why should I choose? We want to do all of those because that's important for the patient population.

The final thing I would just say is when you look at adjuvant, there's enormous innovation that's going to be required to fill that market or that need. Whenever you see KEYTRUDA plus an oral medicine, the same thing is true, does that patient really need to go to infusion center? And the final thing is, as you combine KEYTRUDA with many infusion medicines, you ask yourself, do I really want to infuse KEYTRUDA for 45 minutes when I could give it over 2 minutes. And I think all of those are meaningful innovations that help providers and patients access important medicines.

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

Okay. That's helpful. I just want to tick through a couple of more of the business development focus questions or I'd be remiss, and I'll get punished afterwards by folks. Size of potential business development deal? Your CFO, Caroline, has [shamelessly] said that the company would be willing to take a 1 notch downgrade. Is that still an accurate characterization? And where are you in terms of thinking about prospective size of potential deals?

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

Yes. Well, I would start with -- if you look at the balance sheet we have, the capital structure we have, capital structure will not be the rate limiter in what we pursue. We have the balance sheet and the firepower to go after everything that would be of interest to us. We've been very clear to say that our priority is to invest for sustainable growth in the business long term, and that will be science-based investments. If we see the right opportunity to do that and we need to leverage the balance sheet to be able to go after those assets, we're willing to do it, including if it means a downgrade.

But I also would point out that we will have the strength of EBITDA, the strength of cash flow that we should be able to delever coming off of that fairly quickly. So that's the way I'm looking at it. And then from the size of the deal, it's less about the dollar size. It's more about is it an area of interesting science? Do we see an asset or assets that we think brings something unique that when we combine it with our capability and aim at an unmet need that there is something that we can drive sustainable long-term growth for the business? And if we see that and it aligns with the strategy, and we think there's value creation, we're going to go for it and be appropriately aggressive in doing so and leverage the balance sheet to do it as needed.

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

And if we were to zoom up a little bit in terms of the larger environment and think about potential external constraints, let's talk a little bit about the Federal Trade Commission, working group that they're talking about addressing issues related to pharma competition as a result of consolidation or deal activity. Given KEYTRUDA and its dominance and your presence in Oncology, how does this factor into your thinking about how you're making assessments about potential deals and what you're seeing currently literally this week, I think we're going to be having some discussions that will become more public.

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

Well, the first thing I would say is KEYTRUDA is a great drug, but I actually -- I don't think we can look at KEYTRUDA as dominant in Oncology. You have to look at tumor by tumor, at stage of disease, at line of therapy. Oncology is not monolithic. It is very specific. And in specific areas, specific tumor types, specific stages of disease, specific lines of therapy, KEYTRUDA does quite well, but there are several areas where it doesn't. So I don't think you can look at it as the space of Oncology. I think you have to look at it in a much more nuanced way than that. And obviously, as we look at what we see from the FTC, there clearly is a focus, but I continue to believe there is a path for good deals that are pro innovation, that are going to bring and solve a problem for a patient. There's going to be good justification to continue to drive those forward. It might be more complex in how do you navigate the evolving landscape, but it does not change on where we would look and how we would try to capitalize on what we see as pro innovation aimed at really delivering for patients.

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

Got it. And then another issue to address final on the business development front is the mindset of the folks that you may be sitting around the table or across the table from. We're seeing a really challenging environment for small, mid-cap biotech. Science is advancing tremendously, but certainly amongst the smaller companies in the public spheres, it's been very difficult. And the debate inevitably becomes whether or not the willingness to reach across that table and shake hands, the bid-ask spread. Has that mindset adjusted in any way?

I think during the first quarter call, you had commented that you had not necessarily seen some of that shift. Tick tock, we're further along. Where are things at now?

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

I would tell you that as of now, the world has not meaningfully shifted from where we were. We continue to not see a meaningful change yet. We're going to have to see what happens obviously, as the market continues to be down and for a sustained period of time. And as cash becomes tighter for a lot of these companies, I do think it could evolve, but we're not seeing it. I think there's enough cash still in the system for a lot of the companies that they have time to kind of wait. So we'll have to see how it plays out over the rest of the year.

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

Got it. Okay. In terms of things that can and do get talked about and possibly could change makes me want to shift over to the topic, which again is appropriate for you as the CEO of drug pricing and legislation. We're about 4, 5 months away from the next midterm elections. I think if you think about conversations we've been having with investors, the whole potential for legislative possibility on the drug pricing front has become a little bit more top of mind, particularly from commentary from recent congressional members as well as the Biden administration. Can you talk about maybe there's been a suggestion of willingness to revisit some elements of build back better, which does weave together potential inclusion of Medicare negotiation elements. Your thoughts?

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

Yes. Well, obviously, the timing is tight between now and the midterms. So whether or not given what is going to be a complex negotiation, the Democrats are able to get enough of a coalition together to move something forward is not yet clear. So whether or not something comes over a finish line, it's not clear to me yet. But importantly, as we look at it, we do believe eventually you are going to see some reform in The United States. I don't know if that's going to happen in the near term or long term. And as we look at our business and look at the parameters of the features of what were included in build back better, assuming that is the framework that ultimately is adopted, we actually think that it's manageable within our business and something that as we have talked about, what is our long-term growth potential. We've already contemplated it in those expectations, and we continue to expect strong growth in the face of that so we'll have to see what happens in the short term, but I more look at it and say, do I see it as a fundamental threat. I don't.

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

Got it. No, that's very helpful. Then lastly, with the portfolio. Your Animal Health business, if you look across the landscape of what your peers have been doing in terms of identifying ways to optimize perhaps capital allocation decisions, thinking about what is the appropriate structure now -- you're post Organon. You've commented previously that you see value with a combination. What are your latest thoughts there? And can you be a little bit more specific in terms of where you see perhaps some of those synergies that some folks may not necessarily appreciate in a world that could have...

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

Well, one, this is something we revisit on a regular basis. We are always asking what is the optimal portfolio. But I always ask the question thinking for the long term and what is going to put Merck in the best position to be a sustainable, growing and vibrant company well into the future as opposed to what do I see as potentially short-term opportunities. And in that spirit, we continue to believe that we are the best long-term holder of that asset, and it comes for several reasons. Some of it is I look at first and ask a question, are we able to invest fully to make that business successful?

And if you look at the amount of money we have been able to invest in capacity expansion, in business development, a lot of the strong growth you're seeing now in our business, which is, frankly, continues to be well above the market, is coming from the capital we've been willing and able to deploy. So we are fully investing in that business. We're investing to win, and we have the capital to do it. Then I ask, are there synergies that I believe allow us to work together better than if we were 2 independent companies. And I continue to believe there are, from an R&D perspective, from a manufacturing perspective. Obviously, they are a leader in vaccines for animals. On the human health side, we're a leader in vaccines for humans, a lot of overlap in our ability to look for shared learnings there. A lot of what's driving the growth in that business are coming in the vaccine space and in the companion animal space, and most of that growth is being driven off of the, if you will, the human health catalog of opportunities we're seeing from an R&D side -- on the human health side.

So I do think there's meaningful synergies from an R&D perspective. There are similar stories from a manufacturing perspective and the growth of Animal Health is an innovation story, and it is that innovation that we are getting the synergies for that are driving it. So I think it's driving growth for them. And in turn, what does that give us? It gives us an annuity-like revenue stream. It's accretive to our growth. It's accretive from a cash flow perspective, and it's a business that gives us a nice diversification from a lot of what is the risk you see on the human health side. So for all those reasons, I continue to think we're the best owner, but that's something we're always looking at. And if any of those factors change, we obviously would reconsider and maybe make a different decision.

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

Got it. Another aspect of the overall business that's been a franchise. And Dean, perhaps to you, (inaudible) the vaccines business, maybe pre-pandemic, close to a decade ago, people would have thought (inaudible) a lot of infrastructure requirements, manufacturing, Jesus, the government as a payer, why would you want that? Dynamics have changed. And yet I often have conversations where investors perhaps don't appreciate sort of the extent of the contribution and the value embedded within the vaccines business. What's your sense for what might be underappreciated still about the vaccines business?

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

Well, let me just give some concrete examples. You take a vaccine like GARDASIL, a minority of people out there who are eligible to get vaccinated aren't vaccinated. This is a vaccination that oftentimes we talk about Oncology of cancer vaccine. This is the cancer vaccine. This is the cancer vaccine. You are dropping the rate of cancer by 90%. I mean, that's incredible. And so that vaccine where we're a leader, we've invested a tremendous amount in relationship to increasing the capacity for that. So that's a major growth driver that's stable and is going to change the outlook of cancer in the world. You look at relationship to pneumococcal disease, that's a huge important disease. And we've decided to take a different approach than other people in relationship of we're trying to drive our V114 program. Right now, it's under review by the FDA. And then shortly after that, we expect to have an ACIP discussion in relationship to that. For V114 VAXNEUVANCE, it's there for adult but really driving it for pediatrics.

But one of the issues for us is that the serotypes that are important for pediatric population is very different than that for the adult, and we're going after that in a sort of -- the simplest way to think about it is people talk about personalized medicine. This is us thinking about personalized vaccines. And so we think those vaccines are really important. And it starts with they will have a major impact on human health. And then the other sort of issue is, I think they're great businesses. But Rob, did you want to make any comment from a commercial standpoint, kind of the vaccine business?

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

No, I think you hit most of the areas clearly. We continue to believe GARDASIL is underappreciated for all the reasons being said, VAXNEUVANCE. So I think if you look at the totality of what we will be in the pediatric space, which is still 70% of really the opportunity relative to adult. But the overall portfolio of VAXNEUVANCE is underappreciated and what is hitting on at the last point here is V116 and potentially then V117, but I can speak to V116 because that's more near term. I also think that's very underappreciated. So I do think our vaccine business is going to be a growth driver for this company. We're investing in it, and we have other programs, RSV, dengue, and then other earlier-stage programs across all of the various modalities. We're really playing in all the different modalities and believe that there isn't any 1 solution. It's going to take the totality of all the different approaches. And I think we're very well positioned for success long term.

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

Got it. Okay. With 10 minutes to go, let's do some pipeline quick it, so I'm going to be trying to be a little bit reminiscing about specific answers. So thank you for hosting the event at ASCO. That was a great overview, specifically with KEYTRUDA in the adjuvant setting, lung. Thinking about what kind of overall survival data will be needed in that PD-L1 high expresser population? What do you think is going to be needed to be seen by the FDA? You've previously made some commentary about this. You have the results in the all-comers population, but is a static result, is it favorable trend, particularly in that population expressor? What are we going to need to see?

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

Yes. In relationship to any adjuvant therapy, in any cancer, I would say that EFS, event-free survival or DFS is really an important marker, and that is the registrational. I think that in relationship to OS, I think in general, they want a trend. But fundamentally, it's different than metastatic where you can see the OS very quickly. In adjuvant or earlier stages, it takes longer. So I think that event-free survival is really important.

In relationship to the KEYNOTE-091, I would just emphasize, this is a trial that has a dual endpoint. That means if we hit on anyone, it's actually successful. So it's an [OR] statement. And essentially, whether you look at -- regardless of your PD-L1 expression, 1/3 is greater than 50, 1/3 is around 1 through 49 and 1/3 is less than one. Throughout that whole spectrum, we have event-free survivals that are clinically meaningful and statistically robust. So we think that's important for the FDA to consider. And clearly, there will be a discussion about the type of data that they will want to see, but I don't know that any adjuvant needs to hit an OS, but I think you're going to have to have a trend towards that.

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

Got it. No, that's helpful. Let's talk TIGIT. ASCO, Roche update. I want to direct the questions around implications and read across to your own program and how that makes you think about it. Let's talk about squamous cell first, implications of the results that we heard. You're designing in your approach, how should we think about any read across?

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

Right. The first thing I would just say is, our concept has always been it will take multiple different IO agents in relationship to pembro to really be important to develop. And so in relationship with TIGIT, we are mainly focused on TIGIT with pembro in the lung cancer space. Clearly, the readout from Roche is something that we take into account, and it may alter the tactics of how we do things, but not in relationship with strategy. We have trials both in non-small cell lung cancer and in small cell lung cancer. Our molecule is different than theirs, and both of our molecules are different than other people.

The other sort of issue is it's not just the molecule, it's how you can develop it in relationship to clinical development. We have, in many situations, the option to look at the full range of PD-L1 expression that could be important. We don't have to look at just greater than 50. And so we will see, as the data develops, we keep our tabs on other companies in relationship to how they develop, whether it be their CTLA-4, their LAG-3 or their TIGIT. But we're comfortable in the position where we are in relationship to finding out the answers whether TIGIT can add something meaningful to pembro in relationship to lung cancer.

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

Got it. And then in non-small cell lung cancer, if you could just make sure to clarify, KEYVIBE-003 enrollment. Comment upon how that's going. I'm not sure whether my team and I have been interpreting whether or not some of the time lines for that may have been pushed back slightly for a year?

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

Yes. I think some of it relates to time line, but some of it relates to us recalibrating how many patients we want and what sort of subgroup analysis that we have. So I wouldn't read too much in relationship to that. As we see external data, it changes how we think about where we should play our statistical plans.

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

Got it. Okay. Let's shift over to cardiovascular, where you hosted that event. Our team has been quite bullish in terms of the Acceleron acquisition and the opportunity for sotatercept. The Street really gets creeped up by 6-minute walk distance. That seems to be one of these squishy on infallible factors, which tends to have a difficult translation into the actual real-world clinicians. All of us talk to the key opinion leaders, and we know what the regulatory barriers were there. What gives you confidence in the studies that you essentially have been inheriting about the outcomes for those?

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

So just to sort of lay out, there's 6-minute walk, there's time to clinical worsening and then there's what I would call hospitalization, those sort of -- and they become harder and harder endpoints in relationship to that. I would say that very few PAH medicines, and I'm probably going to be a little bit extreme here, so I'm going to have to test myself, can't work all the way through. So that's number one. We are very bullish about sotatercept. So we have all 3 trials going.

In relationship to 6-minute walk, 6-minute walk isn't important. It is a registrational endpoint by the FDA. We have a Phase II where there was clear data and the fundamental issue for us is how do we broaden it -- how do we increase the number of patients but really make sure that we don't have that much deviation. And so that's why one of the issues with our acquisition of Acceleron is they come with a lot of know-how. They have a lot of know-how in relationship to the centers they work with. So essentially, we look at the Phase III as how do we scale up the Phase II, but not put variability in that.

And so keeping the people engaged both at the sites as well as Acceleron talent was critical for us. And so that, I think, is how we're navigating the Phase III trials. But we're very excited to watch that and then we're very excited to continue with time to clinical worsening and then even harder endpoints. And all of those trials have enormous enthusiasm and you see that we're recruiting faster than either of us expected.

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

Right. I think the clinicians are clearly enthusiastic. We know regulators can be quite sober. And so let's just say, hypothetically, in the event that 6-minute walk business is not positive. And yet if the secondary endpoints are quite compellingly positive, do you see a regulatory path forward?

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

I think that's something that we would have to talk to the regulators, but it would also -- if we saw that, it would also make us comfortable where we are in terms of time to clinical worsening and other readouts as well.

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

Okay. Time lines for some of those Phase III readouts, in my mind, I think about end of 2022, possibly into '23. What's the latest?

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

Yes, I mean, so we actually announced that we actually recruited faster than we expected. And so we're hoping to see that data this year and potentially, depending on that data, begin to talk to regulators early next year.

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

Got it. Okay. And then with the oral PCSK9 was also introduced during the cardiovascular meeting there, talk about progress and how we should be thinking about positioning there. That's a category where, obviously, the mechanism has had convincing biology, challenges on the commercial front.

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

Yes. So that biology is the most -- I'm going to be a little bit hyperbolic. It is the most underused mechanism above the medicine. We know that, that mechanism can drive your LDL down. And we know that LDL is such a great biomarker. It's probably the best biomarker you have in medicine in relationship to when you see to drive that down, you know what's going to happen in terms of mortality and all of this. So we think that's really important.

When you look at it, it's been hard to access. And so our concept is potentially opposite of other people's concept, which is how do we make this an oral drug that someone can deliver to you immediately. How do we make this look no different than a statin but really be even more potent than a statin and also be something that can be made and distributed with broad access without coaching and a price point that is reasonable for a branded small molecule.

And we believe that we have begun to accomplish that, and we're driving that into the Phase II. And we'll see what the results for the Phase II, but I think this will be a very important medicine that can tremendously change the trajectory of cardiovascular mortality, not just in this country, not just in the developed countries but also the developing countries, which are going to see a major spike in this disease.

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

Our risk going into a little bit of overtime to ask 2 quick questions on items that have been pushed a little bit to the back shelf. One is islatravir, the other is on molnupiravir and just developing next generation. On islatravir, it's been about 3-plus months or so, should we anticipate getting any further update or insight into some of the safety-related challenges?

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

Right. So just stepping back, we have 2 Phase III trials with islatravir and doravirine that were spectacular. We also have a signal and relationship to reduce white blood cell count. And so we have been in conversations with ourselves in doing the experiments that can begin to explain that. We think we have a good line of sight as to how to explain it and how to move both islatravir, not just islatravir but other compounds in that class, and we're in discussions with the FDA as to how to navigate that and providing them the data to see -- to think about that.

And we've done that with a focus on treatment, in combination treatment, so we've also had those discussions with internal compounds that we would combine and also with our partners that we have partnerships with as well. So we believe that we will be learning more from the FDA and a path forward.

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

Great. And then an unfair question with 30 seconds left, thinking about COVID, antiviral therapeutics, you've had molnupiravir. How keen are you to lean into continued investment in development of next-generation antivirals for COVID?

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

The short answer is we continue to, one, think there's a lot of opportunity with molnupiravir and what that can be, given the fact that it has breadth of activity well beyond just COVID-19, and we are continuing to invest beyond that into other antivirals as well. So we do see that as an area for us to continue to focus.

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

We thank you for your commitment to all of those efforts. Thank you, gentlemen, both for participating today.

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

Great. Thank you.

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