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MRK.N - Merck & Co Inc at JPMorgan Healthcare Conference

EVENT DATE/TIME: JANUARY 13, 2026 / 12:30AM GMT

OVERVIEW:

Company Summary

LSEG DATA & ANALYTICS

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PRESENTATION

Christopher Schott - *JPMorgan Chase & Co - Analyst*

Good afternoon, everybody. I'm Chris Schott at JPMorgan. It's my pleasure to be introducing Merck today.

From the company, we have CEO, Rob Davis; as well as Dean Li, President of Merck Research Labs. Rob and Dean will say a lot to go through. Happy New Year. Looking forward to the presentation.

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Thank you. Thanks, Chris. Appreciate it.

All right. Good afternoon, everybody. I appreciate you spending some time with us this afternoon.

Before I get started, just real quickly, I'd remind you that we do have forward-looking statements being made. I'd point you to our language on our website, if you'd like more information about that.

If you look at where we are as Merck, I'm pleased to say we are in a moment where we're really starting to see our transformation underway. We've been executing on our strategy. I can tell you, we're in a position now where I think we are well positioned for success.

Whether it's advancing our diverse and expansive late-stage pipeline, we now have 80 Phase 3 studies underway. We'll talk a little bit about some of those in a moment. We're commercially succeeding in launching the first wave of the next 20 growth drivers we have of the company. We're augmenting that through business development.

The success and progress we've had, to date, now puts us in a position where we see visibility to more than $70 billion of commercial opportunity, as we look out to the mid-2030s. Importantly, over the next two years, we're going to meaningfully, from a clinical perspective, de-risk that opportunity, which we'll talk about.

As we sit here today, my confidence is high. It continues to grow. We're really in a position to be set up for the next wave of success, as we look at Merck, going forward.

But before we look to longer term, maybe just take a moment and focus on 2025, where we have had many accomplishments. I'll look both from a clinical and regulatory perspective. But, maybe, starting first with significant approvals.

Obviously, we're excited that, in the third quarter, we got approval of QLEX, which is our subcutaneous form of KEYTRUDA, an administration under the skin that we can do in as little as one minute. Very important innovation for patients.

In ENFLONSIA, which is our infant RSV vaccine, it's the only vaccine that you can basically administer, regardless of weight, in a single dose, something we're very excited about.

In our Animal Health business, where we don't talk as much, we're actually also seeing a wave of new product introductions, one of which we're very excited about, NUMELVI, which we just recently had approved in Europe.

We will get approval early in 2026 in the United States for a next-generation JAK inhibitor for atopic dermatitis for animals. This is a huge market in the animal health space, one we are very excited about with the next-generation product we're bringing; and one that we will continue to focus on, as we move forward.

We also are delivering key positive data read-outs. I'd focus you on enlicitide. During 2025, we read out three clinical studies for enlicitide. This is our oral PCSK9, a drug we're very excited about. Given the fact that this is an oral pill, simple to take, we're going to make it simple to access at affordable prices. We really have the opportunity to democratize care for patients dealing with the need to lower LDL-C. It's something that we're very focused on as an opportunity, not only in the United States but globally.

In the infectious disease space, we have important data read-outs in both HIV PrEP, as well as multiple read-outs in treatment with islatravir, which is really becoming, we believe, the next anchor medicine in HIV. I'm happy to say we're actually going to have this April, hopefully, the first approval with islatravir/doravirine in our once-daily treatment coming in April. So that will be the first of many to come.

We also are seeing important late-phase clinical trial initiations. I would highlight just a few of them for you, starting with sac-TMT. You might know this is our TROP2 antibody drug conjugate. We now have this antibody drug conjugate in 16 Phase 3 studies; 11 of which have the potential to be first-in-class. This is going to be a very important area, as we look forward.

In immunology with tulisokibart, we have an important Phase 2b study underway now, looking at different opportunities beyond where we started in ulcerative colitis and Crohn's. We now have six studies; four that are in Phase 2, two that are in Phase 3.

In ophthalmology, we have important studies underway now with MK-3000, as well as MK-8748. I'll get more into that in a little bit. We can jump to it on stage. But, importantly, we're about ready to start anytime -- I think it's imminent, Dean -- a new Phase 3 study for MK-8748, which would be a meaningful acceleration of that asset when we did the EyeBio deal.

In addition to what we're doing from a clinical perspective, we are also delivering successful new launches. We have a growing first wave of products, which are starting to contribute to the growth of the company.

You can see those with WINREVAIR for pulmonary arterial hypertension; CAPVAXIVE, which is our PCV vaccine; ENFLONSIA for RSV. As I mentioned, we had QLEX, which we launched in the third quarter. Recently, we just closed and added OHTUVAYRE through the acquisition of Verona, which we brought in and we'll see the benefits of as we move into the fourth quarter, which is an important new drug in the area for patients with COPD. This is, in and of itself, a multibillion dollar opportunity we've added.

So as we sit here today, we feel very good that we're starting to deliver proof points for our ability to commercially execute on the more than 20 growth drivers we have. This is just a small sampling of those. We'll get into more of them in a moment.

Importantly, we're starting to see a much more diverse and broad pipeline to drive that growth with these growth drivers, as we look forward.

We've been doing business development to augment the strong pipeline we have internally. With Verona, I just mentioned with OHTUVAYRE, the first-in-class PDE3, PDE4, for treatment of patients facing COPD. This is the first new maintenance inhaled treatment in over 20 years in this space. It's off to a very strong start. We're very excited about this opportunity.

Recently, we just closed on Cidara, which is -- you, probably, maybe know it as CD388. That's the way it was referred to under Cidara. We now call it MK-1406. But this is a potential first-in-class, once-per-season, strain-agnostic antiviral in an important space to help high-risk patients facing the serious consequences of flu.

We have the deal we did with Hengrui for their oral, small molecule Lp(a). We are already looking at how can we combine this with enlicitide as a potential combination therapy for patients facing cardiovascular disease.

This all builds on the business development we've already been doing since 2021. We've now invested over $60 billion since 2021 in business development. You see the list of companies here.

But, importantly, we're not done. We have more to do. I think we've shown a track record where we will move with discipline and we will move with intention where we see scientific conviction behind an opportunity that aligns with value. We're going to continue to do that in the exact same way we've been doing it, to date.

As you look at all of this, what this starts to pull together is the success we've had since 2021 in focusing on building out our pipeline. I'm happy to say it's now becoming a reality. We have the most diverse pipeline, in terms of both therapeutic areas and modalities.

Legally, I have to say in recent history but I would tell you it's probably at any time in Merck's history.

Importantly, based on what we're seeing, we now have visibility, as I mentioned, to commercial opportunities, based on that success through new growth drivers, that will be more than double what KEYTRUDA will be at its peak sales, based on consensus estimates in 2028.

Importantly, that $70 billion is $20 billion more than where we were this time last year due to what we've added through business development and our increasing confidence in some of our internal assets.

I would point out that while we talk about $70 billion by mid-2030s, we now believe we're going to achieve $50 billion by the early 2030s.

The progress is significant. Our confidence is high. Probably, the most important point -- and I'll come to it in just a moment -- we're going to have the opportunity to materially de-risk a big portion of this over the next two years.

If you look at what makes up this $70 billion, we often get asked: What are the drivers? There are really 10 programs -- 10 key programs -- that make up 70% of this $70 billion. If you look at them, all of them have blockbuster potential. We see them as multibillion-dollar opportunities.

Nearly all of them are first-in-class molecules. Four of the 10 are either already launched or have positive Phase 3 data. The rest will have important Phase 3 read-outs over the next 12 to 18 months. Two of them have received the Commissioner's National Prioritization Voucher. That goes for enlicitide and our sac-TMT offering. So we have the opportunity to not only deliver a pipeline but to continue to accelerate our ability to bring that forward. That's why we have the confidence I'm talking about.

If you look forward, in addition to the products we talked about, which were either launched or about to launch with enlicitide on the base, by the end of 2026, we will be in a position that we will have de-risked clinically $35 billion of the $70 billion through positive Phase 3 read-outs we would expect to see.

We will cover substantially all of the $70 billion by the time we get to the end of 2027 through what we have with sac-TMT, MK-1406, and our I-DXd.

So as we sit here today, we feel very good about what we have. There's always more to do. But I'm really proud of the team. I'm proud of Dean and our commercial colleagues, our manufacturing colleagues. They have delivered. They continue to deliver. I have every confidence we will continue to do so.

As you look forward into 2026 through the remainder of this year, we have some really important data read-outs. We have islatravir in combination with lenacapavir in a Phase 3 study focused on once-weekly oral for the treatment of people with HIV. This has the potential to be the first weekly oral.

With MK-3000, we have a new mechanism of action, the first new mechanism of action in this space in 20 years, aimed at diabetic macular edema. We see that coming forward with a Phase 3 in September of 2026.

Importantly -- this is well ahead of when we did the deal -- we've significantly accelerated this program. I already mentioned to you that we also accelerated MK-8748. It's why we have such confidence in our ability to have a meaningful impact in the ophthalmology space.

And then, we have tulisokibart, where we have the first of many studies coming but this one is the Phase 3 in ulcerative colitis, which will read out in August of 2026.

As you look forward to 2027, for sac-TMT, I mentioned we have 16 Phase 3s; 11 that are potentially first-in-class. We have multiple Phase 3 read-outs coming in 2027. I mentioned one of those will have the CNPV Voucher.

For MK-1406, which is previously what we called the CD388 -- this is the long-acting antiviral we got with Cidara -- we expect to be in a situation to have the Phase 3 read-out there with the primary completion date of January of 2027.

And then, for I-DXd, which is our B7-H3 antibody drug conjugate, this is actually being studied across multiple different tumor types but we'll have the first Phase 3 read-out in a very important space in small cell lung cancer coming during the year; and then, we'll see more coming after that. Small cell lung cancer continues to be an area where there's really a true unmet need. We could have one of the first real meaningful opportunities to drive innovation in that space.

So as we sit here today, I feel very good about the progress we've made. We have more to do. But as we sit here today, we're executing on our strategy.

We have, I mentioned, over 20 growth drivers. The first wave already here among us. We have a catalyst-rich period over the next 12 to 18 months.

Importantly, we're delivering on our purpose. We're delivering for patients. We're delivering for unmet needs. Ultimately, if we do that, we're delivering for our company and for you, our shareholders.

I couldn't be more confident as I sit here today. It's why we continue to talk about KEYTRUDA as more the LOE, as more of a hill than a cliff. I'm quite confident that we will be in a position, at a minimum, to go through a very shallow period, post the LOE, returning in a few years to growth.

But we aspire for more. We aspire to grow through it. My confidence we'll be able to achieve that is high.

We have more to do. We're not there yet. But with the actions we've already taken, the progress we've made, and the execution we've demonstrated, I'm confident we eventually will be there. That's my hope, as we look forward to the future.

With that, maybe I'll stop. We can jump in for Q&A. Thank you.

QUESTIONS AND ANSWERS

Christopher Schott - *JPMorgan Chase & Co - Analyst*

Maybe, just to kick off the question with that hill, not a cliff comment, I think you've described the KEYTRUDA LOE is something that's very manageable. You've obviously continually been building out this pipeline.

Where we sit today, how confident are you that you can manage through this 2029 through early 2030 period without a meaningful degradation in the company's earnings?

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Based on what I just showed you, we're highly confident. The fact that we now have that $70 billion and that we're going to be able to be in a situation by the time we get to the end of 2027 to have clinically de-risked almost all of that is very important.

I should point out -- and I didn't say it in the prepared remarks -- that does not include animal health. Our Animal Health business, right now, is one we think will double, more than double, from 2024 through the mid-2030s on a story very similar. It's about a wave of new product innovation coming in that space.

It doesn't include our early Phase 1 pipeline. We have a large number of important Phase 1, late Phase 1 products, or Phase 1 programs that will be reading out starting this year. It's going to accelerate, as we go into '27. Many of those could potentially have impact in this window of time. You'll see more of that as those move into Phase 2. We'll start to talk more about those.

And then, also, it precludes further business development.

So when I look at all of those elements, my confidence that we will see it be a shallow fall, followed by growth, in a few years is quite high.

I would point out: We modeled it on a risk-adjusted basis. That's assuming we achieve standard industry probabilities of technical success. If you actually look at what we've done over the last three to five years, we've actually done much better than that.

So if you can assume we are more successful, that is on the upside from what we're communicating.

Christopher Schott - *JPMorgan Chase & Co - Analyst*

Excellent. On the $70 billion target, I know it's stepped up $20 billion over the last year. How much of that is external? How much of that's internal? Any directional color you can provide?

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Yes. It's roughly -- if you look at the change we made, it's about half from the external opportunities we see and about half from internal.

Christopher Schott - *JPMorgan Chase & Co - Analyst*

Right. As we go through the next year or two, in terms of de-risking, what are the most important events you'd point to that help de-risk that $70 billion charge?

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Well, I would go back to the six programs I showed coming. I think those are going to -- those are really -- if you think about it, of those 10 key programs, we focused on 10 key products, which will make up 70% of the $70 billion.

By the time you get to the end of '27, they all will have been meaningfully de-risked. So you can pick which one. It's hard to pick which is your favorite. You don't want to tell your children which one you love the best. I love them all equally.

Christopher Schott - *JPMorgan Chase & Co - Analyst*

On business development, obviously, 2025 was a very busy year for the company. There's been some headlines heading into this year.

Can you, just, take a step back, with the $70 billion that you now feel you have in-house, what's the appetite for further deals? What's the parameters you're looking at, as you consider putting additional capital to work ?

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

I appreciate the question. Now, if you look at where we are -- and I tried to address it a little bit in the prepared remarks -- we have been very disciplined.

Since Dean and I took over in 2021, we followed a very consistent pattern. It always begins with, what is the science? It always comes down to, is the conviction of my scientific teams there behind the opportunity? What is the unmet need that we're addressing?

If there is high conviction and excitement among my scientists, there's an unmet need we can address and I see it aligning with our strategy. And overall, we see a path to create value.

I think we're showing we're willing to move fairly quickly and decisively.

We've done it ahead of data. We've done it after data. It all comes down to that conviction. And so that is the model we've been following. It will continue to be the model we've been following.

The areas of focus continue to be the same: oncology; cardiometabolic, now cardiopulmonary -- you can look at both of those spaces; immunology. And then, beyond that, it's more around areas of, probably, opportunistic focus. But really, those three tend to be the sweet spot of what we're looking at.

From a phase of development, we're open from Phase 1 through to Phase 3. Obviously, as we move closer to the LOE, we've been more focused in the later stages. You've seen that the deals we've been doing have been either Phase 2; Phase 3; or, in some cases, commercialized assets. We'll continue to focus that.

As I think about the periods of time, there's, now, through 2028, there's 28 through 2032, 2035, if you will; and then, 2035 and beyond.

Everything we do looks at how do we impact each of those periods of time. We don't look at trying to drive revenue for any one window. It's how can I bring science that brings commercial opportunity; but then, it's complementary and builds a us on to our sustainable base for long-term growth.

If you look from a dollar perspective, we've been in that. Looking in that up to $15 billion range has been where we've been looking. But we've been very clear: We're willing to go larger than that but we only will do so following the exact same logic and discipline. If we see an opportunity that brings the science where we see value, we'll move. We have the capacity, I think, to do pretty much anything we would want to do. But we will be disciplined.

In the end, while I feel very good about where we are, I still aspire to grow through KEYTRUDA. That's starting to become within potentially our reach. We need to keep executing. We need to stay focused.

And so we want to do more. We're going to continue to be disciplined. I don't feel that we have to do something. But we're going to do it if it's a smart thing to do, it's the right thing to do.

That's been where we have been. That's where we'll continue to operate.

Christopher Schott - *JPMorgan Chase & Co - Analyst*

Just remind us on capacity; where the company is today; where you'd be comfortable taking leverage?

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Yeah. I would say we're multi-tens of billions of dollars. Is that the way -- I got to look at my CFO. I would spend more, she won't let me. It's just the way it goes. But in the multi tens of billions.

I would look at it differently and say, we are not limited from a balance sheet. It's more, where do we see strategic opportunity?

Christopher Schott - *JPMorgan Chase & Co - Analyst*

Okay. Excellent. Maybe pivoting to some specific products, oncology. TROP2 seems like a very interesting one. One that, to me, feels very underappreciated by investors.

Can you just talk about your aspirations for your program? I know you've got a huge Phase 3 set of studies running at this point. When you dig into those studies, which ones are the ones you're most excited about?

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

Yeah. Our vision of sac-TMT or our TROP2 ADC is that it will be a workhorse ADC. We have 16 Phase 3s. We say 11 of them are in indications that other people haven't moved in. Many of them are, for example, in GI.

But I would also emphasize that we have a great collaboration with Kelun. They've shown China data in where some people say the TROP2s are crowded, which is lung and breast. That data looks compelling and differentiated.

So we're going to places that no one is there or will be first, 11 out of 16. But in the places where it's tight, one can look at the data from Kelun and potentially extrapolate to us and say, that's a differentiator.

You ask yourself, why is it differentiated? It's one thing to say TROP2 in the antibody but ADCs are linkers and payloads. Some are too loose; some are too tight. Maybe ours is just right.

Christopher Schott - *JPMorgan Chase & Co - Analyst*

I like that one. In terms of the timelines of these reading out, is it possible we see more data in '26 from some of these programs?

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

I think there's PCD dates in '27. But this is oncology. It's event. There's always chances for interim analysis earlier than that.

We're also excited by the fact that the administration also recognizes the possibility of this being an important asset and giving us CNPV so that if we do have data turnover, our ability to get it to patients even faster is there.

Christopher Schott - *JPMorgan Chase & Co - Analyst*

Great. Of the -- I think you said 11 of these are novel -- correct me if I'm wrong -- which are the ones there that you're most excited about?

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

I would say, endometrial; many of the ones in the GI space. It's a place where it's -- we have the potential of being the first-mover advantage.

But I should also say that in "the crowded space" like lung and breast, we have seen pretty differentiated data from Kelun. And so if that flips over, that can get me very excited as well.

Christopher Schott - *JPMorgan Chase & Co - Analyst*

So this isn't just about the novel (multiple speakers) --?

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

Right. Right. Yeah.

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Yeah. It might be worth just also commenting on: We recently went from 15 to 16 because we initiated new study in combination with QLEX. As we think about what we're going to have is our next -- as our life cycle planning for how do we continue to bring value for patients longer term, we are already looking at how can you combine with QLEX as an opportunity that brings advantage to patients; brings combinations with better outcomes and, also is one that we think we feel very good about.

Christopher Schott - *JPMorgan Chase & Co - Analyst*

Actually, on QLEX, maybe just an update of how that roll out -- as (multiple speakers) --?

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Yeah. Yeah. As I said, we received approval at the end -- I think it was October -- end of Q3 of last year. It's early. Obviously, we're still just through the fourth quarter.

I would say we're on track. But, importantly, our confidence that we can achieve that 30% to 40% adoption in the next 18 to 24 months continues to be quite high.

As we've pointed out in the past, for the first six months, while we're waiting for the final J-code, it will be a little bit slower. But then, we do expect to ramp to that 30% to 40% in the United States.

As you know, this is primarily where we see the highest rates of adoption coming. It will be in monotherapy or in combinations with oral agents like LYNPARZA, like WELIREG, as an example.

But we do -- while we see those as the areas where we see most adoption -- and I should stress that would also include where we have many of the early-stage indications. We now have 11 early-stage indications. What, five with overall survival.

But it also -- we do think we'll have adoption into the space in patients who are on IV. We just think it will be less in that space.

Christopher Schott - *JPMorgan Chase & Co - Analyst*

You're only just thinking in terms of what a tail could look like on KEYTRUDA when we can consider that 30% or 40% opportunity?

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Yeah. If you look at where we are, our goal is in 18 to 24 months to have 30% to 40% adopted. That would put us out about the period of time, depending on what happens with the LOE, to be in a situation that we have that at the time that we lose exclusivity.

Our intention is to price, to ensure, we can maintain share and maximize that tail as long as possible. So we're looking much more at the value under the curve, as opposed to trying to do something where you take a short window of time to optimize value and then, have it fall off a cliff, if you will.

We've not given specific guidance for how we see that. But I do think it will be a meaningful tail that we can maintain through time.

Christopher Schott - *JPMorgan Chase & Co - Analyst*

Great. Just going to one of your acquired assets from last year, Cidara, can you just talk a little bit about how you see this fitting into the flu landscape and how big of an opportunity this could become for Merck?

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Yeah. Maybe Dean can start on the clinical side. I can speak to the commercial piece.

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

Yeah. I really like this asset. It's essentially an antiviral that we know works. It's conjugated, not as an ADC but conjugated to an Fc so that, all of a sudden, you can give it one time and you can protect someone for the whole season.

As everyone knows, those people who are immunocompromised or those people who are, let's say, on KEYTRUDA or on tulisokibart or sotatercept or OHTUVAYRE, they need extra protection than the normal vaccine can give you.

So it just fits perfectly with the story in our pipeline and the patients that we want to treat.

One of the other things that I think is important is, it's one time that you give it. It's strain-agnostic. It's going to cover you for the whole season.

But I think the other thing that -- I don't know if you call it a tailwind or whatever. But with the pressure on vaccination, I cannot foresee flu vaccination increasing in this country over the next three years. I would imagine that if we're hopeful it stays the same, there's a chance that it comes down.

And so I think this product is really important but it's also really important in a timely manner, as well.

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Yeah. Maybe just to give you a sense from a commercial opportunity, I think, obviously, we're all living this, right now, with what is one of the worst flu seasons we've seen.

What you often forget is, if you're immunocompromised, if you otherwise have comorbidities that puts you at high risk, if you're over 65, this is a serious situation. 70% to 80% of hospitalizations are with people over 65. 90% of deaths from flu are in that over-65 category.

So while we have the vaccines -- and I would tell you, we believe probably 70% to 80% of that high-risk population or immunocompromised population are being vaccinated -- the vaccines, while effective, are not -- let's face it, they're not as effective as you would like. We actually show much more effectiveness with the antiviral than just with the vaccine.

And so the opportunity to protect that population is important. We're talking about 110 million people. 85 million who are high risk or immunocompromised. 25 million in that over-65 age range. So just going after that population, which is where we're starting, is a huge opportunity.

Obviously, our ability to potentially expand beyond that we're looking at for many reasons that Dean was highlighting. But that alone is a significant opportunity. We're going to go there first.

But we're looking at this as a greater-than $5 billion opportunity for us, as we look forward. I think this could be one of those assets that still surprise us to the upside.

Christopher Schott - *JPMorgan Chase & Co - Analyst*

And then, potential for an interim analysis here, just given the flu season that we're seeing?

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

Yeah. It's been completed for the Northern Hemisphere. We are going to open it up to the Southern Hemisphere. So those of you who are sitting next to someone from the Northeast, right now, if you want to be in the trial, you need to go to the Southern Hemisphere.

But there will be times for interim analysis. We won't quite announce that. But there is a possibility that we'll see an interim analysis.

But, right now, we are going to open in the Southern Hemisphere. We need those patients. We need a broad patient population to be able to have as robust of a label as possible.

Christopher Schott - *JPMorgan Chase & Co - Analyst*

Okay. Pivoting over to the oral PCSK9, can you talk a little bit about just timelines here; how we should think about this; and then, as we approach the launch, how you think about patient segments that could adopt this one quickly?

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Why don't you go ahead, Dean?

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

Yeah. You've seen some of the data at American Heart Association. I think the data -- the way that we've said it is, we want to make the most potent LDL-cholesterol-lowering pill ever made and that we wanted to have a pill that essentially looked like the antibodies. I think the data at AHA -- two of the three studies were shown. A third one will also be shown later on this year.

We basically have a biologic in a pill. When you look at the clinical data, it's 97% compliance. If you look at the adverse effects, the adverse effect looks no different than placebo.

So this is something that we could really democratize the PCSK9. Our intention is to file. And then, we are, also, like sac-TMT; has the opportunity to do with the CNPV.

That's a relatively new program. And so we're working with the government. And so that timeline means that we probably have the opportunity to potentially launch maybe early next year but maybe even this year.

We're excited by that.

The last thing I would just say is, there was also data presented at American Heart Association that's really important. So many of us here have an LDL of 90 and 100 and our doctor said it's just fine. But there was data shown that if you take an antibody to PCSK9 and you lower that LDL from 90 to 100 to 45, I think they had an improvement in cardiovascular outcomes of 20%, 25%. This emphasizes why it's important to democratize PCSK9.

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

You might comment on -- that we act in exactly the same way as (multiple speakers) --?

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

Yeah. This molecule is truly interfering with PCSK9 in a very similar epitope as where those antibodies. So this is truly an antibody in a pill.

Christopher Schott - *JPMorgan Chase & Co - Analyst*

Ask about just -- you talked about a multibillion-dollar opportunity here. Should we expect a gradual ramp like we saw with REPATHA? Or just given some of the dynamics of how the injectable markets played out, could this be a little different?

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Well, I would say I think we will see a faster ramp than REPATHA. What will drive, though, what ramp we see is really -- we're looking at, really, three factors that we're focused on.

Obviously, it starts with our ability to educate and activate patients and physicians. I would say this is an area where it's been a little bit sticky, if you will. You haven't seen much change. And so we're going to have to educate people and get them willing to think differently about layering therapies in a way that maybe they haven't thought about, both as the physicians, as well as the patients. So doing that education and activation will be important.

One of the things we think that can help drive that desire is if we can get the guidelines changed. We've done a lot of work. I know others in the space are doing work in this space. Dean can speak to it.

But with all the data that came out through the VESALIUS study through what we're doing and others, I think there's a renewed discussion about what should be how you think about managing your cholesterol and what is good enough but what actually can you do to be even better, especially if you're a high-risk.

So we're going to continue to push for those guideline modifications. If we can achieve that, which I actually have pretty good confidence, we will, I think that's going to be an important step.

And then, the third element of it is, we've talked about we're going to affordably price this to drive access. That still will require the payers, the insurance companies, to adopt this. We think they will. But we're going to have to do work.

So those three levers will determine the speed of the ramp. But maybe just -- so the long-term opportunity, by the way, is meaningful. But how fast it happens will depend on that.

But maybe just to size this real quickly: If you look about it, today, there's 80 million people across US, Europe, and Japan who are on lipid-lowering therapies and not at goal.

In the United States, it's 30 million. That's both primary and secondary prevention. It's roughly -- it's not exactly but it's close enough -- half-primary prevention, half-secondary. So our intention is to go first for the secondary prevention market. And then, from there, over time, broaden into the primary prevention market.

So we see an opportunity, both initially to go with a layered approach on this to try to do the lipid-lowering therapy. But, over time, we have a broadening strategy; not to mention then we have a combination strategy.

If you go on clintrials.gov (sic - clinicaltrials.gov), we already have underway a combination study in combination with rosuvastatin -- so a single pill -- both the PCSK9 and the statin. As I mentioned, while we haven't started the studies, we are looking at kicking off with our LP(a) small molecule, a combination of our PCSK9 with that.

So Dean talks about you got to be first or best and then, you got to think about what's next. We have a life cycle management strategy here to make this a meaningful long-term opportunity beyond that first wave.

Christopher Schott - *JPMorgan Chase & Co - Analyst*

Maybe last one on the pipeline for me. You highlighted immunology, ophthalmology, HIV, in terms of important read-outs over the next year or two. Can you just talk about the strength of Merck's pipeline in these settings? How do you think about Merck competing in some of these spaces, where there maybe is a bit more entrenched competition?

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Yeah. Well, I firmly believe -- and Dr. Perlmutter used to always say when he was at Merck -- great products make great franchises; great franchises don't make great products. I think the key of what that -- really, the message of that is it starts with, if you have a product that is truly differentiated, that is the most important aspect.

Part of the confidence across everything we've laid out, we think we have that, especially in immunology and what we have with tulisokibart with our TL1A.

So across immunology and ophthalmology, I think we are there. That's the most important piece.

But beyond that, we've spent a lot of time focusing on how do we make sure we build out, both in terms of dollars of investment -- you remember, we did the multiyear optimization, where we were looking to take out $3 billion of spend. That was not because we wanted to lower our spend. In fact, we're going to be accelerating our spend but redirecting that $3 billion into these programs.

So we are very focused to make sure we invest behind them fully, which we're doing; and that we have the right capabilities. We spent all of last year going bottoms-up and then, top-down, outside-in, to look at this, with myself and the strategy team doing the top-down, outside-in; and then, looking at what we would build, based on the way the peers have operated; and then comparing that to the plans the teams were building.

That's informed where we saw we needed investments and capabilities. We're already addressing those gaps. We've brought in a lot of external talent where we needed to augment.

So I actually feel very good that we're positioned to succeed across these commercially.

Christopher Schott - *JPMorgan Chase & Co - Analyst*

Great. Maybe time for one last question here. Just on GARDASIL. I know this is a big area of focus for the last one-and-a-half years or so.

Latest update, in terms of how you're thinking about trajectory of that one, given what you're seeing, ex-US, some of the recent CDC changes, et cetera?

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Well, I would start by saying GARDASIL continues to be a very important product, first and foremost, for patients. It is truly an anticancer vaccine. It's a tragedy that everyone is not vaccinated because it can prevent cervical cancer. It can prevent many head and neck cancers; other cancers. I start there.

But putting aside the patient aspect, if you think about it from a business perspective, it remains important for the company. But as we've already said in the past, it is no longer a key growth driver for the company.

As we came into the year, where we had communicated previously -- is we expected modest growth with this. Obviously, the things that has changed, as we recently heard from the CDC, that are now putting out a recommendation to move to a single dose in the United States -- I can talk about that in just a second. But we'll have to deal with that.

But as you look, in total, at this, as we think about 2026, I would say we see it as a stable product. We're going to continue to invest for the growth. Any growth that's there is modest. We need to see how this single dose plays out.

As it relates to that, specifically, if you look at the market in the United States, for the first nine months, just to size this, in the first nine months, we've sold $2.2 billion of GARDASIL in the US. Two-thirds of that is in the pediatric adolescent space. That's really the only piece we're talking about. That's where the CDC change is going to single dose effect; not the adult population, one-third.

So that $2.2 billion, if I annualize that, for simple math, let's just say $2.7 billion -- that's not a guidance number, by the way; it just divides easily by 3. You should look at it and you say, of that, then you can think of $1.8 billion being the total for that adolescence.

Today, average completion rates are only 1.6 doses. In worst case, it will go to 1. We don't actually think it goes to 1 because, importantly, what the FDA and the CDC maintain is they maintain shared decision making with your physicians.

All of the insurance coverage, both from a commercial and from the government, have been maintained. So if you want the 2 dose, per the label, you can get it. It will be reimbursed. We believe pediatricians largely will continue to prescribe and recommend that.

So we're going somewhere from 1.6 to something between 1, maybe 1.2, 1.3. Needless to say, it is not significant for us in 2026.

It's manageable, overall. I'm more concerned about it from a health policy perspective than I am, frankly, as a financial matter for the company.

Christopher Schott - *JPMorgan Chase & Co - Analyst*

Well, I think we're out of time. Congrats on all of (multiple speakers) --.

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Thank you very much. Thank you, all.
